vTv Therapeutics Inc.
Form 10-K
February 26, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001-37524

vTv Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	47-3916571
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4170 Mendenhall Oaks Pkwy	
High Point, NC	27265
(Address of principal executive offices)	(Zip Code)

(336) 841-0300

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each Class	Name of each exchange on which registered
Class A Common Stock (Par Value $0.01)	NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes No

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The aggregate market value of the registrant's Common Stock held by non-affiliates on June 30, 2018 (based on the closing sale price as reported on the NASDAQ) was $10,955,991.

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 26, 2019.

Class of Stock	Shares Outstanding
Class A common stock, par value $0.01 per share	22,792,716
Class B common stock, par value $0.01 per share	23,094,221

vTv THERAPEUTICS INC. AND SUBSIDIARIES

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FOR THE FISCAL YEAR ENDED December 31, 2018

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

As used in this Annual Report on Form 10-K, the "Company", the "Registrant", "we" or "us" refer to vTv Therapeutics Inc., "vTv LLC" refers to vTv Therapeutics LLC. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes that appear elsewhere in this report. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, assumptions and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this report under "Part I—Item 1A, Risk Factors." Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies and operations, financing plans, potential growth opportunities, potential market opportunities, potential results of our drug development efforts or trials, and the effects of competition. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or similar expressions and t of those terms. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's plans, estimates, assumptions and beliefs only as of the date of this report. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I

ITEM 1. 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 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"). We have initiated start-up activities for an adaptive Phase 2/3 trial to evaluate azeliragon as a potential treatment of mild-AD in patients with type 2 diabetes. Our type 2 diabetes drug candidates are TTP399, an orally administered, liver-selective glucokinase activator ("GKA"), which successfully completed a Phase 2b clinical trial in type 2 diabetes (the "AGATA Study"), and TTP273, an orally administered, non-peptide agonist that targets the glucagon-like peptide-1 receptor ("GLP-1r"), which successfully completed a Phase 2 clinical trial in type 2 diabetes (the "LOGRA Study"). We are currently investigating TTP399 as a treatment for type 1 diabetes in an adaptive Phase 2 study in partnership with JDRF International ("JDRF"). In addition, we are furthering the development of our peroxisome proliferation activated receptor delta ("PPAR- ") agonist and phosphodiesterase type 4 ("PDE4") programs through partnerships with pharmaceutical partners via licensing arrangements. Finally, we continue to advance our NRF2 pathway program via research agreements with academic and industry collaborators.

Our Pipeline

The following table summarizes our current leading drug candidates and their respective stages of development:

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:

- Initiated start-up activities for an adaptive Phase 2/3 clinical trial for azeliragon as a potential treatment of mild Alzheimer's disease in patients with type 2 diabetes. Subsequent post-hoc subgroup analyses of our phase 3 STEADFAST Study identified a population that experienced positive benefit. Based on these results, we have initiated start-up activities for an adaptive Phase 2/3 trial to evaluate azeliragon as a potential treatment of mild-AD in patients with type 2 diabetes. We are currently finalizing a protocol for the study, negotiating with clinical research organizations to support study conduct activities for the trial and beginning the site selection process. We expect to initiate patient enrollment in this study in mid-2019. We plan to continue to develop azeliragon, through internal efforts, with additional funding, or through partnerships with other life science entities.
- Continue to execute the ongoing phase 2 study of TTP399 for type 1 diabetes. We are currently enrolling patients in the simplici-T1 Study, an adaptive Phase 2 clinical trial of TTP399, assessing the pharmacokinetics, pharmacodynamics, safety and tolerability of TTP399 in adult patients with type 1 diabetes. We have completed enrollment of the part 1 learning phase and expect to report results for this portion of the study in June 2019. We have begun the start-up activities for the part 2 confirming phase and expect to report results for this portion of the study in the latter part of the first quarter of 2020.
- Seek additional strategic collaborations and additional funding to support the continued development and commercialization of our diabetes programs. We will continue to seek additional strategic collaborations with other pharmaceutical companies and additional funding to support the continued development of TTP399 and TTP273 for type 2 diabetes and related diabetic complications. We have entered into certain collaboration agreements to further the development of these diabetes compounds. In connection with these collaboration agreements, we are required to sponsor certain clinical trials to further the development of TTP399 and TTP273. Refer to "Business – License and Research Agreements" for additional details.

- Continue to monitor and support existing partnerships for pipeline programs. Our partners for our GLP-1r, PPAR- , and PDE4 programs continue to advance these programs in the licensed territories. We continue to support and monitor these partnerships.

Our Alzheimer's Program – Azeliragon

Alzheimer's Disease and the Role of RAGE in its Onset

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. Amyloid Beta ("A ") plaques, neurofibrillary tangles of tau protein, and neuroinflammation in the brain are believed to be the main causes of the disease, leading to loss of neuronal connectivity in the brain.

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 ligands that are implicated in multiple factors of AD, including A 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 non-clinical in-vitro and in-vivo models studied by third parties that show RAGE is overexpressed in brain tissue. Taken together, we believe that the scientific literature provides substantial support for RAGE inhibition as a validated and promising therapeutic approach in the treatment of AD.

Advanced glycation endproducts ("AGEs") also accumulate in tissues of people with type 2 diabetes. When the concentration of RAGE ligands (e.g., AGEs) increases, more RAGE expression is induced. AGEs play a major role in the worsening of complications of type 2 diabetes, such as retinopathy, neuropathy and nephropathy. Furthermore, AGE accumulation parallels the development of cognitive impairment and dementia in individuals with type 2 diabetes.

Current Treatments of Alzheimer's Disease and Their Limitations

Currently, there are only two classes of approved therapies for the treatment 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 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 synthesis or clearance from the brain, the phosphorylation of tau protein, chronic inflammation, vascular dysfunction, metabolic dysregulation and neurotoxicity.

Our Solution: Azeliragon

Azeliragon is an orally administered, small molecule investigational drug candidate with a novel mechanism of action of inhibiting RAGE. 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 currently approved treatments are focused on symptom relief, we believe that azeliragon represents a potential new approach for the treatment of AD. In addition, we believe that in order to successfully treat and combat the physiological progression of AD, an effective treatment must act on multiple causes of the disease. Azeliragon is designed to inhibit RAGE, which affects the multiple factors of AD, including A transport into the brain, the phosphorylation of tau, chronic inflammation, vascular dysfunction, metabolic dysregulation and neurotoxicity. To date, we have conducted eight Phase 1, three Phase 2 and two Phase 3 clinical trials of azeliragon. Both Parts A and B of our Phase 3 STEADFAST Study of azeliragon in people with mild Alzheimer's disease failed to meet either of the co-primary efficacy endpoints.

Phase 3 STEADFAST Study

We initiated the STEADFAST Study in April 2015 pursuant to a Special Protocol Assessment ("SPA") with the FDA. The study was conducted in the United States and certain English-speaking foreign countries under a single protocol and was designed to enroll 800 mild AD patients in total, divided equally across two independent 400-patient sub-studies, in which each subject received either a 5 mg/day dose of azeliragon or placebo, randomized on a one-to-one basis, added to the standard of care. Though we announced in 2018 that neither the A-Study nor the B-Study met its clinical endpoints, a post-hoc subgroup analysis of 24 patients from the A-Study of the STEADFAST Study with type 2 diabetes (defined by glycosylated hemoglobin (HbA_{1c}) of greater than or equal to 6.5% at baseline; HbA_{1c} greater than 7.7% was an exclusion criterion at screening) and a clinical diagnosis of Alzheimer's disease showed benefit to azeliragon. The azeliragon-treated group in the A-Study (n=17) demonstrated a 6.1 point benefit on ADAS-cog relative to the placebo group (n=7), which was nominally statistically significant ($p = 0.018$) after 18 months of treatment. The azeliragon-treated group in the A-Study (n=17) demonstrated a 1.7 point benefit on CDR-sb relative to the placebo group (n=7) (p=.05) after 18 months of treatment.

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Based on these results, we have initiated start up activities for an adaptive Phase 2/3 trial to evaluate azeliragon as a potential treatment of mild-AD in patients with type 2 diabetes. We are currently finalizing a protocol for the study, negotiating with clinical research organizations to support study conduct activities for the trial and beginning the site selection process. We expect to initiate patient enrollment in this study in mid-2019.

Azeliragon was previously awarded Fast Track designation by the FDA and, relying upon the program's Fast Track Designation status, we have pursued discussions with the FDA and EMA to propose a pathway for further clinical development in support of regulatory approval of azeliragon. In July 2018, we submitted a full briefing book to the FDA in support of our request for a Type C meeting seeking development guidance for azeliragon. In September 2018, we received a written response from the FDA to our Type C meeting request. In the response, the FDA advised that the efficacy of azeliragon should be demonstrated in at least two adequate and well-controlled trials, unless under the exceptional circumstances in which a single trial might suffice as set forth in the FDA's guidance document entitled "Providing Clinical Effectiveness for Human Drug and Biological Products". We met with the Scientific Advice Working Party ("SAWP") of the EMA in October 2018, to discuss future development requirements in support of approval of azeliragon in the European Union. In response, the SAWP advised on the circumstances in which a single trial might suffice. For a single pivotal trial to be acceptable, the results would need to be particularly compelling with respect to internal and external validity, clinical relevance, statistical significance, data quality and internal consistency. The SAWP acknowledged preliminary data concerning overexpression of RAGE in the A- and B-studies and subgroups analyses, based on patients with evidence of high circulating levels of RAGE ligands such as HbA_{1c} and Amyloid beta, provide support for the hypothesis that patients with increased concentrations of RAGE ligands have beneficial effects of azeliragon.

Adverse Events (Phase 3 Mild AD Patients)

Among the most frequent adverse events ("AEs") occurring in >2% of subjects who received the 5 mg/day of azeliragon in Phase 3 were urinary tract infection ("UTI") (10.2%), depression (4.8%), upper respiratory tract infection (4.5%), dizziness (4.1%), weight decreased (3.9%), nausea (3.2%), cough (2.9%), insomnia (2.5%), syncope (2.5%) constipation (2.3%) and musculoskeletal pain (2.3%). A comparison to placebo subjects is provided in the table below:

Treatment emergent adverse events occurring in >2% of azeliragon treated subjects and numerically more frequent than placebo

	Azeliragon	Placebo
Preferred Term	N = 441	N = 434
	n (%)	n (%)
Urinary tract infection	45 (10.2%)	35 (8.1%)
Depression	21 (4.8%)	20 (4.6%)
Upper respiratory tract infection	20 (4.5%)	16 (3.7%)
Dizziness	18 (4.1%)	15 (3.5%)
Weight decreased	17 (3.9%)	13 (3.0%)

Nausea	14 (3.2%)	10 (2.3%)
Cough	13 (2.9%)	9 (2.1%)
Insomnia	11 (2.5%)	7 (1.6%)
Syncope	11 (2.5%)	9 (2.1%)
Constipation	10 (2.3%)	8 (1.8%)
Musculoskeletal pain	10 (2.3%)	5 (1.2%)

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

Diabetes Overview

A person suffering from diabetes does not produce or properly use insulin (a hormone that enables people to get energy from food).

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 has and 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.

Type 1 diabetes is an autoimmune disease in which a person's pancreas stops producing insulin. Type 1 diabetes results when the body's immune system attacks and destroys the insulin-producing cells in the pancreas called beta cells. While its causes are not yet entirely understood, scientists believe that both genetic factors and environmental triggers are involved. The onset of type 1 diabetes is not believed to be affected by diet or lifestyle.

Current Treatments for Diabetes and Their Limitations

Diabetic patients have difficulty achieving and maintaining consistent glycemic control, defined as $HbA_{1c} < 7\%$ as recommended by the American Diabetes Association. 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.

The current treatment paradigm for type 2 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 type 2 diabetes, including injectable drugs and oral anti-diabetic drugs ("OADs"). Existing injectable therapies for type 2 diabetes 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. We believe the continued and significant unmet medical need for diabetes treatments is demonstrated by the continued to development of new potential therapies such as Novo Nordisk A/S's oral semaglutide and Lexicon's SGLT-1/SGLT-2 inhibitor.

While multiple oral drugs are approved for the management of high blood glucose (hyperglycemia) in type 2 diabetes, insulin injection is the only treatment option approved in the United States for type 1 diabetes. There is an unmet medical need to provide people with type 1 diabetes additional treatment options that can help them to achieve tighter blood glucose levels and reduce insulin doses without increasing the risk of hypoglycemia (blood glucose levels

below normal) or ketoacidosis.

We expect our diabetes investigational drug candidates, if approved, 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, cost, convenience and no training requirements. For patients with type 2 diabetes, the goal of these therapies is to delay the progression to insulin dependence. Despite the availability of multiple oral therapies and the introduction of new oral therapies (DPP-4 and SGLT-2 inhibitors) with novel mechanisms for the treatment of type 2 diabetes, which are used both as monotherapy and in combination with other agents, there remains a lack of differentiation and inadequate efficacy. While injectable GLP-1r agonists are generally considered to have superior efficacy compared with approved 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 for an oral drug that mimics the superiority of GLP-1r agonists and reduces the incidence of hypoglycemia.

Our Solutions: Glucokinase Activator and GLP-1r Agonist

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, safety, and convenience. We have chosen two different approaches for the treatment of diabetes: activation of glucokinase (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. In addition, there is a significant unmet medical need for treatments of type 1 diabetes with agents other than insulin injection. TTP399 could also fill this unmet need by reducing the extent of reliance on insulin.

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 -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 -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.

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 of efficacy. These liabilities have been correlated to hyperstimulation of the -cells in a glucose independent manner and/or the accumulation of lipids in the liver, consistent with the disruption of GK and the glucokinase regulatory protein ("GKRP") interaction by these GKAs. Thus, liver-selective compounds that do not activate GK in pancreatic -cells or affect the GK-GKRP interaction in the liver are expected to demonstrate a superior profile in comparison to previously identified GKAs.

GK activation is also attractive as a potential therapy for the treatment of type 1 diabetes, with a mechanism of action entirely distinct from currently marketed OADs. GK activation has been demonstrated in animal models of type 1 diabetes to reduce HbA_{1c} and to be well tolerated.

TTP399

TTP399 is an orally administered, small molecule, liver-selective GKA in development as a new potential OAD for the treatment of type 1 and type 2 diabetes with a novel mechanism of action: liver-selective activation of GK that

seeks to provide intensive glycemic control without inducing significant hypoglycemia. If approved for type 2 diabetes, we believe TTP399 would compete primarily with other OADs, including DPP-4 and SGLT-2 inhibitors. Our trials for TTP399 suggest that our approach to GK activation has the potential to avoid the 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 normalize HbA_{1c} levels without having contraindication for renal impairment and with little risk of pancreatitis. Based on data from Phase 1 and 2 trials to date, we believe that TTP399, if approved, has the potential to be a first-in-class OAD due to its liver-selectivity and novel mechanism of action. We have completed nine Phase 1 and two Phase 2 clinical trials of TTP399. In our Phase 1 and 2 clinical trials, TTP399 was well tolerated with negligible incidence of hypoglycemia.

Ongoing Phase 2 simplici-T1 Study

In November 2017, we initiated the simplici-T1 Study, an adaptive Phase 1b/2 clinical trial of TTP399, assessing the pharmacokinetics, pharmacodynamics, safety and tolerability of TTP399 in adult patients with type 1 diabetes (“T1D”). The study is designed to evaluate whether TTP399 is well tolerated when administered as an add-on to insulin therapy and can improve daily glucose

profiles and HbA_{1c} in people living with T1D. We have completed enrollment of the part 1 learning phase and expect to report results for this portion of the study in June 2019. We have begun the start-up activities for the part 2 confirming phase and expect to report results for this portion of the study in the latter part of the first quarter of 2020. The study is being conducted in partnership with JDRF.

Completed Phase 2b AGATA Study

In August 2016, we completed a Phase 2b clinical trial of TTP399, the AGATA Study, which was a six-month trial to demonstrate proof-of-concept that the benefits from TTP399 could be sustained over time. The AGATA Study was 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 190 subjects with type 2 diabetes on a stable dose of metformin. Patients had a baseline HbA_{1c} of 7.0 - 9.5%. The AGATA Study included 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 was the change from baseline in HbA_{1c} at six months. A key secondary endpoint was change in weight.

In the AGATA Study, TTP399 demonstrated achievement of the primary endpoint of statistically significant change from baseline in HbA_{1c} at six months of daily administration of 800 mg of TTP399. The reduction in HbA_{1c} was dose-dependent and sustained throughout the duration of the study. TTP399 was also found to be well-tolerated and no adverse events of severe hypoglycemia or hyperlipidemia were reported in the TTP399-treated group.

In January 2019, a paper was published in Science Translational Medicine showcasing the discovery and development of TTP399. It reviews the scientific rationale underpinning the development of TTP399 and its progression from preclinical to clinical development concluding with the positive results of the AGATA Study.

We are continuing to explore options, including various fundraising strategies, for further development of TTP399 for type 2 diabetes and diabetic complications either alone or in collaboration with a partner.

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 exendin-4 (Byetta) and liraglutide (Victoza). Subcutaneous administration of these peptides lowers blood glucose, decreases HbA_{1c} levels and reduces weight. However, the injectable method of administration has limited their use. This injectable class of peptides is also 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 efficacy in clinical trials to date.

TTP273

TTP273 is a potential first-in-class, orally administered, small molecule, non-peptide GLP-1r agonist. We believe an orally administered GLP-1r agonist that mimics the metabolic effects of GLP-1r peptides 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.

We have completed two Phase 1 clinical trials and one Phase 2 clinical trial of TTP273. Additionally, we have completed nine Phase 1 clinical trials and one Phase 2 clinical trial of TTP054, which was a predecessor orally administered GLP-1r agonist. In our Phase 1 and Phase 2 clinical trials, TTP273 has been well tolerated with negligible incidences of nausea and vomiting. Based on the results of our completed Phase 1 and 2 clinical trials of TTP273, we believe TTP273 to have the potential to provide both competitive efficacy and superior tolerability versus peptide GLP-1r analogues.

Completed Phase 2 LOGRA Study

Our completed Phase 2 LOGRA study of TTP273 was a 12-week study conducted in 30 centers in the United States in 174 patients with type 2 diabetes on stable doses of metformin. In the LOGRA study, the patients were randomized to receive either placebo or TTP273 at doses of 150 mg once or twice daily. Patients in the once and twice daily treatment arms had mean placebo-subtracted HbA_{1c} differences of -0.86 percent and -0.71 percent, respectively. HbA_{1c} increased by 0.15 percent in patients randomized to placebo. Although the study was not powered to demonstrate weight loss, trends were observed with patients losing on average 0.9 kg and 0.6 kg in the once and twice daily arms, respectively. An increase in weight of 0.05 kg was observed in the placebo group. TTP273 was well tolerated with no incidence of vomiting in the TTP273-treated groups and an incidence of nausea lower than that in the placebo group: 7.3% in the Placebo arm, 3.4% in QPM arm and 5.0% in the BID arm.

Huadong License Agreement

Following the successful LOGRA Study of TTP273, on December 21, 2017, we entered into a License Agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (“Huadong”) (the “Huadong License Agreement”), under which Huadong obtained a license to develop and commercialize the GLP-1r program in China and other Pacific Rim territories. Refer to “Business – License and Research Agreements – Huadong License Agreement” for additional details.

Additional Pipeline Opportunities

We are also developing a portfolio of additional investigational drug candidates for the treatment of inflammatory disorders. Such candidates include: (1) a novel PDE4 inhibitor (HPP737) with a low potential for emesis which may allow an expanded therapeutics scope than currently marketed products in Psoriasis and Atopic Dermatitis. HPP737 has been licensed to Newsoara Biopharma Co., Ltd., (“Newsoara”) for development in China, Hong Kong, Macau, Taiwan and other pacific rim countries. Refer to “Business – License and Research Agreements – Newsoara License Agreement” for additional details; and (2) a BACH1/NRF2 modulator (HPP971), which we continue to develop via research collaborations. These additional candidates have been through varying stages of preclinical and Phase 1 testing and we have submitted investigational new drug applications (“INDs”) for certain of them to the FDA.

While our primary focus is on the development of azeliragon, TTP399 and TTP273, we plan to continue to evaluate opportunities for furthering the development of these other compounds in our pipeline. Such development may be done internally or through partnering relationships.

We entered into a License Agreement with Reneo Pharmaceuticals, Inc. ("Reneo"), under which we granted Reneo an exclusive, worldwide, sublicensable license to develop and commercialize our peroxisome proliferation activated receptor delta (PPAR-) agonist program, including the compound HPP593. Refer to "Business – License and Research Agreements – Reneo License Agreement" for additional details.

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 issued patents in 20 countries and territories, including the U.S, Europe, Japan, Canada, Australia, and China, directed to azeliragon as a composition of matter. The issued U.S. patent covering azeliragon as a composition of matter will expire no earlier than 2024 but may expire as late as 2029, if we obtain and apply the maximum possible extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). 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 azeliragon also includes patent families in multiple jurisdictions covering polymorphs, salt forms, metabolites, degradation products and a synthetic precursor of azeliragon, methods of treatment using select dosage regimens of azeliragon, and methods of treating select patient populations. These additional patent families have expiration dates ranging from 2028 through potentially 2039. The issued U.S. patent covering the polymorph of azeliragon used in clinical development will expire no earlier than 2028 but may expire as late as 2033, if we obtain and apply the maximum possible extension under the Hatch-Waxman Act can only be applied to a single patent following approval. The issued U.S. patent covering a method of treating patients with mild Alzheimer's disease by administering about 5 mg per day of azeliragon expires in 2034.

The IP portfolio for TTP399 includes issued patents in over 35 countries and territories, including the U.S., Europe, Japan, Canada, Australia, and China, directed to TTP399 as a composition of matter. The issued U.S. patent covering TTP399 as a composition of matter will expire no earlier than 2025 but may expire as late as 2030, assuming we obtain and apply the maximum possible extension under the Hatch-Waxman Act following approval. 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 TTP399 also includes patent families in multiple jurisdictions covering combinations of TTP399 with metformin, DPP-4 inhibitors, GLP-1r agonists, or insulin, patent families covering two different solid formulations of TTP399, and a patent family covering methods of treating type 1 diabetics using TTP399 in combination with insulin. These additional patent families have expiration dates ranging from 2031 through potentially 2039.

The IP portfolio for the GLP-1r program includes issued patents in over 35 countries and regions, including the U.S., Europe, Japan, Canada, Australia, and China, directed to TTP273 as a composition of matter. The issued U.S. patent covering TTP273 as a composition of matter will expire no earlier than 2030, and may expire as late as 2035, if we obtain and apply the maximum possible extension under the Hatch-Waxman Act following approval. 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. The IP portfolio for TTP399 also includes patent families in multiple jurisdictions covering combinations of TTP273 and metformin, synthetic precursors to TTP273, and dosage regimens of TTP273. These additional patent families have expiration dates ranging from 2032 through potentially 2039.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. 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 and Research Agreements

Reneo License Agreement

On December 21, 2017, we entered into a License Agreement with Reneo Pharmaceuticals, Inc. ("Reneo") (the "Reneo License Agreement"), under which Reneo obtained an exclusive, worldwide, sublicensable license to develop and commercialize our peroxisome proliferation activated receptor delta (PPAR-) agonist program, including the compound HPP593, for therapeutic, prophylactic or diagnostic application in humans.

Under the terms of the Reneo License Agreement, Reneo paid us an initial license fee of $3.0 million. We are eligible to receive additional potential development, regulatory and sales-based milestone payments totaling up to $94.5 million. In addition, Reneo is obligated to pay us royalty payments at mid-single to low-double digit rates, based on tiers of annual net sales of licensed products. Such royalties will be payable on a licensed product-by-licensed product and country-by-country basis until the latest of expiration of the licensed patents covering a licensed product in a country, expiration of data exclusivity rights for a licensed product in a country or a specified number of years after the first commercial sale of a licensed product in a country. In addition, we have received common stock and certain participation rights representing a minority interest in Reneo's outstanding equity.

Under the terms of the Reneo License Agreement, Reneo will be responsible for the worldwide development and commercialization of the licensed products, at its cost, and is required to use commercially reasonable efforts with respect to such development and commercialization efforts.

The Reneo License Agreement, unless terminated earlier, will continue until expiration of all royalty obligations of Reneo to us. Either party may terminate the Reneo License Agreement for the other party's uncured material breach. Reneo may terminate the Reneo License Agreement at will upon prior written notice. Upon expiration (but not earlier termination) of the Reneo License Agreement, the licenses granted to Reneo will survive on a royalty-free basis in perpetuity.

Huadong License

On December 21, 2017, we entered into a License Agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("Huadong") (the "Huadong License Agreement"), under which Huadong obtained an exclusive and sublicensable license to develop and commercialize our glucagon-like peptide-1 receptor agonist ("GLP-1r") program, including the compound TTP273, for therapeutic uses in humans or animals, in China and certain other Pacific Rim countries, including Australia and South Korea (collectively, the "Huadong License Territory"). Additionally, under the Huadong License Agreement, we obtained a non-exclusive, sublicensable, royalty-free license to develop and commercialize certain Huadong patent rights and know-how related to our GLP-1r program for therapeutic uses in humans or animals outside of the Huadong License Territory.

Under the terms of the Huadong License Agreement, Huadong has paid us an initial license fee of $8.0 million, and we are eligible to receive potential development and regulatory milestone payments totaling up to $25.0 million, with an additional potential regulatory milestone of $20.0 million if Huadong receives regulatory approval for a central nervous system indication. In addition, we are eligible for an additional $50.0 million in potential sales-based milestones, as well as royalty payments ranging from low-single to low-double digit rates, based on tiered sales of licensed products.

Under the Huadong License Agreement, we are also responsible for conducting a Phase 2 multi-region clinical trial (the "Phase 2 MRCT") including sites in both the United States and the Huadong License Territory for the purpose of assessing the safety and efficacy of TTP273 in patients with type 2 diabetes. The Phase 2 MRCT will be designed to satisfy the requirements of the China Food and Drug Administration necessary in order for Huadong to begin a Phase 3 clinical trial in China. We will also be responsible for contributing up to $3.0 million in connection with the Phase 2 MRCT.

Huadong will be responsible for the development and commercialization of the licensed products in the Huadong License Territory, at its cost, and is required to use commercially reasonable efforts with respect to its development efforts. Further, Huadong is required to use commercially reasonable efforts to develop and commercialize at least one GLP-1r compound in China.

The Huadong License Agreement, unless terminated earlier, will continue on a product-by-product and country-by-country basis until expiration of the royalty obligations Huadong 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 eight years after the first commercial sale of such product in such country. Either party may terminate the Huadong License Agreement for the other party's uncured material breach. Huadong may terminate the Huadong License Agreement at will upon prior written notice, subject to certain timing restrictions related to the Phase 2 MRCT.

Newsoara License Agreement

On May 31, 2018, we entered into a license agreement with Newsoara (the "Newsoara License Agreement"), under which Newsoara obtained an exclusive and sublicensable license to develop and commercialize our phosphodiesterase type 4 inhibitors ("PDE4") program, including the compound HPP737, in China and other Pacific Rim countries (collectively, the "Newsoara License Territory"). Additionally, under the Newsoara License Agreement, we obtained a non-exclusive, sublicensable, royalty-free license to develop and commercialize certain Newsoara patent rights and know-how related to our PDE4 program for therapeutic uses in humans outside of the Newsoara License Territory.

Under the terms of the Newsoara License Agreement, Newsoara paid us an upfront cash payment of $2.0 million. We are eligible to receive additional potential development, regulatory and sales-based milestone payments totaling up to $63.0 million. In addition, Newsoara is obligated to pay us royalty payments at high-single to low-double digit rates, based on tiers of annual net sales of licensed products. Such royalties will be payable on a licensed product-by-licensed product and country-by-country basis until the latest of expiration of the licensed patents covering a licensed product in a country, expiration of data exclusivity rights for a licensed product in a country or a specified number of years after the first commercial sale of a licensed product in a country.

Under the terms of the Newsoara License Agreement, Newsoara will be responsible for the development and commercialization of the licensed products in the Newsoara License Territory, at its cost, and is required to use commercially reasonable efforts with respect to such development and commercialization efforts.

The Newsoara License Agreement, unless terminated earlier, will continue until expiration of all royalty obligations of Newsoara to us. Either party may terminate the Newsoara License Agreement for the other party's uncured material breach. Newsoara may terminate the Newsoara License Agreement at will upon prior written notice. Upon expiration (but not earlier termination) of the Newsoara License Agreement the licenses granted to Newsoara will survive on a royalty-free basis in perpetuity.

JDRF Agreement

In August 2017, we entered into a research, development and commercialization agreement with JDRF International ("JDRF") (the "JDRF Agreement") to support the funding of the simplici-T1 Study, an adaptive Phase 1b/2 study to explore the effects of TTP399, in type 1 diabetes. We have completed enrollment of the part 1 learning phase and expect to report results for this portion of the study in June 2019. We have begun the start-up activities for the part 2 confirming phase and expect to report results for this portion of the study in the latter part of the first quarter of 2020. According to the terms of the JDRF Agreement, JDRF will provide research funding of up to $3.0 million based on the achievement of research and development milestones, with the total funding provided by JDRF not to exceed approximately one-half of the total cost of the project. Additionally, we have the obligation to make certain milestone payments to JDRF upon the commercialization, licensing, sale or transfer of TTP399 as a treatment for type 1 diabetes.

Novo Nordisk

In February 2007, we entered into an Agreement Concerning Glucokinase Activator Project with Novo Nordisk A/S (the "Novo License Agreement") 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. Under the terms of the Novo License Agreement, we have additional potential developmental and regulatory milestone payments totaling up to $115.0 million for approval of a product. We are also obligated for an additional $75.0 million in potential sales-based milestones, as well as royalty payments, at mid-single digit royalty rates, based on tiered sales of commercialized

licensed products.

Columbia University

In May 2015, we entered into a New Exclusive License Agreement (the "Columbia License Agreement") with The Trustees of Columbia University in the City of New York ("Columbia") whereby we obtained a worldwide, exclusive license, with the right to grant sublicenses under certain Columbia RAGE-related patent rights to discover, develop, manufacture, use, sell, have sold, import, have made, offer to sell, rent, or lease RAGE-inhibiting small molecules, including azeliragon. We also obtained a worldwide right to use certain RAGE-related research information and material. Under the terms of the Columbia License Agreement, we are required to pay an annual fee of $0.1 million, a potential milestone payment of $0.8 million and royalty payments at low-single digit royalty rates based on the net sales of licensed products. We notified Columbia of our intent to terminate this agreement in December 2018.

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, price and reimbursement, and availability of comparable alternative therapies.

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 limited approved treatments for AD in the United States and 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 we are successful in our development of azeliragon as a treatment of probable Alzheimer's dementia in patients with type 2 diabetes, it would be used as a treatment of this narrower patient group rather than as a treatment of AD in all patients. Further, if it is approved, its mechanism of action may be complementary to existing standard of care, as well as that of drug candidates with differentiated mechanisms currently in development for AD, including anti-A monoclonal antibodies, BACE inhibitors, tau aggregation inhibitors and monoamine oxidase-b inhibitors. This will allow the opportunity for co-administration with these other drug candidates if they are successfully developed. We are not aware of any other clinical-stage RAGE inhibitor investigational products being developed for the treatment of AD.

Potential Competing Products – Type 2 Diabetes

If approved, we expect that our type 2 diabetes investigational 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 pioglitizone, 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: Yabao Pharmaceutical Co, Inc., Pegbio Co. Ltd., 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., Heptares Therapeutics Ltd., Novo Nordisk, Eli Lilly, Pfizer, and Oramed Pharmaceuticals Inc., are among the companies evaluating oral GLP-1r agonists in clinical or preclinical studies.

In type 1 diabetes, oral non-insulin agents that are currently being developed that may compete with TTP399 include SGLT-1/2 inhibitors, such as sotagliflozin, being developed by Sanofi/Lexicon and SGLT-2 inhibitors such as AstraZeneca's dapagliflozin and Eli Lilly/ Boehringer Ingelheim's empagliflozin.

We believe that our investigational 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, existing treatments come off patent, and more 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.

Collaboration Revenue and Customers

The majority of our collaboration revenue for the years ended December 31, 2018, 2017 and 2016 is related to our licenses of certain compounds in the pre-clinical stage or clinical stage, including the Huadong License Agreement, the Reneo License Agreement, the Newsoara License Agreement and the Calithera License Agreement. Revenue recognized in these periods relates to initial consideration received in the form of upfront payments and equity interests coupled with research activities performed by our personnel. While we are continuing to seek partnership opportunities for our assets, we continue to focus on the development of azeliragon, TTP273 and TTP399 in the US.

Government Regulation and Product Approvals

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacture, pricing, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of biopharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Approval and Regulation of Drugs in the United States

In the United States, drug products are regulated under the Federal Food, Drug and Cosmetic Act (“FDCA”), and applicable implementing regulations and guidance. The failure of an applicant to comply with the applicable regulatory requirements at any time during the product development process, including non-clinical testing, clinical testing, the approval process or post-approval process, may result in delays to the conduct of a study, regulatory review and approval and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA’s refusal to allow an applicant to proceed with clinical trials, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines and civil or criminal investigations and penalties brought by the FDA or Department of Justice (“DOJ”), or other government entities, including state agencies.

An applicant seeking approval to market and distribute a new drug in the United States generally must satisfactorily complete each of the following steps before the product candidate will be licensed by the FDA:

- preclinical testing including laboratory tests, animal studies and formulation studies, which must be performed in accordance with the FDA’s good laboratory practice (“GLP”), regulations and standards;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (“IRB”), representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with current good clinical practices (“GCP”);

- preparation and submission to the FDA of a new drug application ("NDA"), for a drug product which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labelling for one or more proposed indication(s);
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third parties, at which the product candidate or components thereof are manufactured to assess compliance with current good manufacturing practices ("cGMP"), requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GCP and the

integrity of clinical data in support of the NDA;
- payment of user fees and securing FDA approval of the NDA to allow marketing of the new drug product; and
- compliance with any post-approval requirements, including the potential requirement to implement a risk evaluation and mitigation strategy ("REMS") and the potential requirement to conduct any post-approval studies required by the FDA.

Preclinical Studies

Before an applicant begins testing a product candidate with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as other studies to evaluate, among other things, the toxicity of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. Such authorization must be secured prior to interstate shipment and administration of any product candidate that is not the subject of an approved NDA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, must be submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, on April 28, 2008, the FDA amended its regulations governing the acceptance of foreign clinical studies not conducted under an investigational new drug application as support for an IND or a new drug application. The final rule provides that such studies must be conducted in accordance with good clinical practice ("GCP"), including review and approval by an independent ethics committee ("IEC"), and informed consent from subjects. The GCP requirements in the final rule encompass both ethical and data integrity standards for clinical studies. The FDA's

regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee ("DSMB"). This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of

development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about clinical trials must be submitted within specific timeframes to the National Institutes of Health ("NIH"), for public dissemination on its ClinicalTrials.gov website.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of a qualified investigator in accordance with GCP requirements which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written clinical trial protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may also be required after approval.

Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or in patients. During Phase 1 clinical trials, information about the investigational drug product's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials. Phase 2 clinical trials are well controlled, closely monitored and conducted in a limited patient population.

Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 clinical trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a drug: such Phase 3 studies are referred to as "pivotal."

In some cases, the FDA may approve an NDA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of a larger number of patients in the intended treatment group and to further document a clinical benefit in the case of drugs approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2

and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, 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 are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Special Protocol Assessment

The special protocol assessment ("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. Agreement by the FDA to the SPA does not guarantee that the results of a study conducted in accordance with the agreement will be successful or that other issues that arise may not impede approval of the investigational product.

Review and Approval of an NDA

In order to obtain approval to market a drug product in the United States, a marketing application must be submitted to the FDA that provides sufficient data establishing the safety, purity and potency of the proposed drug product for its intended indication. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the drug product to the satisfaction of the FDA.

The NDA is a vehicle through which applicants formally propose that the FDA approve a new product for marketing and sale in the United States for one or more indications. Every new drug product candidate must be the subject of an approved NDA before it may be commercialized in the United States. Under federal law, the submission of most NDAs is subject to an application user fee, which for federal fiscal year 2019 is $2,588,478 for an application requiring clinical data. The sponsor of an approved NDA is also subject to an annual program fee, which for fiscal year 2019 is $309,915. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

Following submission of an NDA, the FDA conducts a preliminary review of the application generally within 60 calendar days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept the application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also 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. The FDA has agreed to specified performance goals in the review process of NDAs. Under that agreement, 90% of applications seeking approval of New Molecular Entities ("NMEs"), are meant to be reviewed within ten months from the date on which the FDA accepts the application for filing, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the filing date. For applications seeking approval of products that are not NMEs, the ten-month and six-month review periods run from the date that the FDA receives the application. The review process and the Prescription Drug User Fee Act goal date may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an

outstanding deficiency identified by the FDA following the original submission.

Before approving an application, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including component manufacturing, finished product manufacturing and control testing laboratories. 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. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Under the FDA Reauthorization Act of 2017, the FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain applications, including applications for products in shortage or those for which approval is dependent on remediation of conditions identified in the inspection report.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events and whether the product is a new molecular entity.

The FDA may refer an application for a novel product to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Special Expedited Review and Approval Programs

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation, priority review designation, regenerative advanced therapy designation and accelerated approval.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. We have obtained Fast Track designation for azeliragon for the treatment of dementia of the Alzheimer's type. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case by case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

With passage of the 21st Century Cures Act (the "Cures Act"), in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Finally, the FDA may grant accelerated approval to a product for a serious or life threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and 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. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional

post approval confirmatory studies to verify and describe the product's clinical benefit.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a new product, it may limit the approved indications for use of the product. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA may have imposed as part of the approval process. The sponsor will be required to report, among other things, certain adverse reactions and manufacturing problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors 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 ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. 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 revisions to the approved labeling to add

new safety information; imposition of post-market studies or clinical trials to assess 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 applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, health care professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, and its implementing regulations, as well as the Drug Supply Chain Security Act ("DSCA"), which regulate the distribution and tracing of prescription drug samples at the federal level, and set minimum standards for the regulation of distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA ("Hatch-Waxman Act"), Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA"), to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug ("RLD").

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA indicates whether the generic product is

"therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Act, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity ("NCE"), is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

The FDA must establish a priority review track for certain generic drugs, requiring the FDA to review a drug application within eight (8) months for a drug that has three (3) or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA's drug shortage list. The new legislation also authorizes FDA to expedite review of ''competitor generic therapies'' or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

• the required patent information has not been filed;

• the listed patent has expired;

• the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or

• the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other health care laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable federal and state health care laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing •or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services ("CMS"), within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity 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 and regulations, such as state anti-kickback and false claims laws, which may apply to health care items or services that are reimbursed by non-government third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Finally, based on the conduct of some of our clinical trials overseas, we are also subject to the Foreign Corrupt Practices Act that prohibits payments to foreign public officials relating to official acts. In addition to its prohibition on bribery of foreign government officials, the Act requires companies to maintain accurate records and have vigorous internal controls. The DOJ and SEC have made FCPA enforcement a high priority. In addition, other anti-corruption laws such as the UK Bribery Act are even broader than the FCPA in that they apply to bribes offered to any person, not just government officials. There are significant criminal and civil penalties and fines that attach to violations of the FCPA.

Pharmaceutical Insurance Coverage and Health Care Reform

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated health care costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of health care costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and biologics and other medical products, government control and other changes to the health care system in the United States. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") was enacted, which includes measures that have significantly changed health care financing by both governmental and private insurers. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drug agents or biologic agents, which is apportioned among these entities according to their market share in certain government health care programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to 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;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;
- 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;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements under the federal Physician Payments Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board, which, if and when impaneled, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs; and
- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and will stay in effect through 2024 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

These healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price for any approved product and/or the level of reimbursement physicians receive for administering any approved product. Reductions in reimbursement levels may negatively impact the prices or the frequency with which products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures was passed by the U.S. Senate.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health

insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction (CSR) payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain.

More recently, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and may become subject to additional foreign regulations pertaining to 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.

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union ("EU") (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the United Kingdom from the EU will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the United Kingdom provides a notice of withdrawal pursuant to the EU Treaty. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

Employees

As of December 31, 2018, we had 52 employees, of which at least 20 hold graduate degrees (including 15 doctorate degrees) and 31 are engaged in full-time research and development activities.

On December 11, 2018, we initiated a corporate restructuring to align with a strategic decision to continue the development of our drug candidates using external resources rather than internal resources (the "Restructuring"). The Restructuring will allow us to reduce costs while continuing to conduct clinical trials, to support existing partnerships that are advancing development of additional assets, and to pursue new licensing and partnership opportunities. The Restructuring includes a reduction in our workforce affecting approximately 65% of our employees, as of December 31, 2018.

None of our employees are represented by a labor union, and we consider our employee relations to be good.

Our Corporate Information

We were incorporated under the laws of the State of Delaware in 2015. Our principal executive offices are located at 4170 Mendenhall Oaks Pkwy, High Point, NC 27265, and our telephone number is (336) 841-0300. We also maintain a corporate website, www.vtvtherapeutics.com, where stockholders and other interested persons may review, without charge, among other things, corporate

governance materials and certain SEC filings, which are generally available on the same business day as the filing date with the SEC on the SEC's website http://www.sec.gov. The contents of our website are not made a part of this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

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 $8.7 million, $16.1 million and $16.4 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had a total accumulated deficit of approximately $233.9 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 continue to incur significant additional expenses as we continue the development of azeliragon, 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 Discovery, 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 several 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
- obtaining favorable formulary placement with government and third party payors that allows for favorable reimbursement;
- 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 development and commercialization of azeliragon and our other drug candidates, and there is a substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital for these purposes, 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 to continue to incur significant research and development expenses in connection with our ongoing activities, particularly as we undertake additional clinical trials of azeliragon and our other drug candidates and continue to work on our other research programs. Our current capital will not be sufficient for us to complete the development of our drug candidates. As such, we will need to raise additional capital to fund continuing drug development including to finance the adaptive Phase 2/3 trial of azeliragon for the treatment of mild-AD in patients with type 2 diabetes, the future development of our other drug candidates, the portion of the clinical trial costs imposed upon us by the Huadong License Agreement and the JDRF Agreement for TTP273 and TTP399, respectively, and prior to the commercialization of any of our drug candidates. We are seeking possible additional partnering opportunities for our GKA, GLP-1r and other drug candidates which we believe may provide additional cash for use in our operations and the continuation of the clinical trials for our drug candidates. We are also evaluating several financing strategies to fund the proposed clinical trial of azeliragon for the treatment of mild-AD in patients with type 2 diabetes, including direct equity investments and future public offerings of our common stock. The timing and availability of such financing are not yet known.

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 other than the funds available to us under the letter agreement between vTv and MacAndrews & Forbes Group LLC ("M&F Group"), a related party and an affiliate of MacAndrews & Forbes Incorporated (together with its affiliates "MacAndrews") dated as of December 11, 2018 (the "December Letter Agreement"), for its commitment to invest up to $10.0 million over a one-year period, of which $4.0 million is still available to us as of February 14, 2019. We also will need to raise substantial additional capital in the future to conduct further clinical trials of azeliragon, TTP399, and TTP273 and to continue 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 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. 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 recurring losses, accumulated deficit and our current levels of cash and cash equivalents raise substantial doubt about our ability to continue as a going concern as of the date of this report. If we are unable to continue as a going

concern, we may have to liquidate our assets and it is likely that investors will lose all or a significant part of their investments. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all, and such additional funding may cause substantial dilution to our existing investors. Further, 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.

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

- the progress, costs, results and timing of our adaptive Phase 2/3 trial to evaluate azeliragon as a potential treatment of mild-AD in patients with type 2 diabetes;
- 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 M&F TTP Holdings Two LLC in the future under the Tax Receivable Agreement.

Raising additional capital may cause dilution to our stockholders, 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 other than those available to us under the December Letter Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the interest of our 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.

We have entered into the December Letter Agreement with M&F Group, the terms of which are more fully described in “Management’s Discussion and Analysis of Financial Conditions and Results of Operations – Liquidity and Capital Resources” in Item 7 of this Annual Report on Form 10-K. Any shares of our Class A common stock that are sold pursuant to the December Letter Agreement will dilute the interest of our stockholders. In addition, in connection with the December Letter Agreement and previous similar letter agreements, we also issued to M&F Group warrants to purchase 1,057,455 shares of our Class A common stock. Sales of Class A common stock under the December Letter Agreement or the related warrants may result in substantial dilution to existing investors.

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.

Our significant amount of debt could adversely affect our business, operating results and financial condition and prevent us from fulfilling our debt-related obligations.

We have a significant amount of debt. As of December 31, 2018, the total principal amount of our debt was $14.9 million, all of which was incurred under the venture loan and security agreement (the “Loan Agreement”) with Horizon Technology Finance Corporation and Silicon Valley Bank Loan Agreement.

As a result of the termination of the STEADFAST Study, we granted the Lenders a first priority security interest in all of our intellectual property, subject to certain limited exceptions. We have agreed not to pledge or otherwise encumber our intellectual property assets, subject to certain exceptions. The level and nature of our indebtedness could, among other things:

- make it difficult for us to obtain any necessary financing in the future;
- limit our flexibility in planning for or reacting to changes in our business;

- reduce funds available for use in our operations and other strategic initiatives;
- impair our ability to incur additional debt because of restrictive covenants or the liens on our assets that secure our current debt;
- hinder our ability to raise equity capital, because in the event of a liquidation of our business, debt holders receive a priority before equity holders;
- make us more vulnerable in the event of a downturn in our business; and
- place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources.

We may also incur significantly more debt in the future, which will increase each of the risks described above related to our indebtedness.

Restrictions and covenants in the Loan Agreement limit our ability to take certain actions and impose consequences in the event of failure to comply.

The Loan Agreement contains a number of significant restrictions and covenants that limit our ability (subject in each case to limited exceptions) to, among other things,

- convey, sell, lease, transfer or otherwise dispose of certain of our assets;
- maintain a minimum cash balance of $2.5 million in a deposit account pledged to secure the Loan Agreement and subject to an account control agreement;
- engage in any business other than the businesses we currently engage in or reasonably related thereto;
- liquidate or dissolve;
- make certain management changes;
- undergo certain change of control events;
- create, incur, assume or be liable with respect to certain indebtedness;
- grant certain liens;
- pay dividends and make certain other restricted payments;
- make certain investments; and
- enter into any material transactions with any affiliates, with certain exceptions.

These covenants affect our operating flexibility by, among other things, restricting our ability to incur expenses and indebtedness that could otherwise be used to fund the costs of executing our business strategy and to grow our business, as well as to fund general corporate purposes. Our ability to comply with these covenants may be affected by events beyond our control and we may not be able to meet these covenants. A breach under the Loan Agreement would permit our lenders to accelerate amounts outstanding thereunder. We may not have sufficient funds at the time of any such breach to repay, in full or in part, the borrowings under the Loan Agreement.

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 Discovery, Development and Regulatory Approval of Our Drug Candidates

We may not be able to continue the development of, obtain regulatory approval for, or successfully commercialize azeliragon.

We have expended considerable resources and efforts on the development of azeliragon. In April 2018, we announced that results from Part A of our Phase 3 STEADFAST Study did not meet either co-primary efficacy endpoint as required by the SPA with the FDA. Following the April 2018 announcement, we discontinued clinical trials involving azeliragon, including Part B and open label extension.

At the time of the closure of Part B, a substantial number of participants completed 12 months of treatment under the study protocol. Based on the subpopulation data analyses from Part A and the prior azeliragon trials, we prepared and submitted a revised SAP to the FDA for Part B that pre-specified a target population for the primary study analysis at 12 months. In June 2018, we announced that the results from Part B did not meet either co-primary efficacy endpoint.

Relying upon the program's Fast Track Designation status and study results to date, we have pursued discussions with the FDA and European Medicines Agency ("EMA") to propose a pathway for further clinical development in support of regulatory approval of azeliragon. On July 31, 2018, we submitted a full briefing book to the FDA in support of our request for a Type C meeting seeking development guidance for azeliragon. On September 17, 2018, we received a written response from the FDA to our Type C meeting request. In the response, the FDA advised that the efficacy of azeliragon should be demonstrated in at least two adequate and well-controlled trials, unless under the exceptional circumstances in which a single trial might suffice as set forth in the FDA's guidance document entitled "Providing Clinical Effectiveness for Human Drug and Biological Products".

The failure of Parts A and B of the STEADFAST Study to meet their co-primary endpoints is expected to delay the potential commercialization of azeliragon and may make such commercialization more difficult or impossible. We will need to commence and complete additional clinical trials that satisfy the specified primary endpoint criteria, manage clinical and manufacturing activities, obtain necessary regulatory approvals from the FDA or other comparable regulatory authorities, and, if approved, successfully market and commercialize azeliragon. There is no guarantee that we will be able to successfully complete these steps. As an organization, we have never completed a successful Phase 3 clinical trial or submitted a New Drug Application before, and we may be unsuccessful in doing so for azeliragon.

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, our Phase 3 STEADFAST Study in mild AD patients failed to meet its co-primary endpoints in either sub-study, and the B-Study was discontinued early due to the results of the A-Study. However, subsequent post-hoc subgroup analyses conducted using information from the STEADFAST Study found that a subgroup of azeliragon-treated patients with type 2 diabetes showed benefit to azeliragon. Based on these results, we have initiated start-up activities for an adaptive Phase 2/3 trial to evaluate azeliragon as a potential treatment of mild-AD in patients with type 2 diabetes. See further discussion under "Business—Our Alzheimer's Program—Azeliragon—Phase 3 STEADFAST Study." While we plan to explore developing azeliragon for the treatment of patients of this subgroup, there can be no assurance that the results a future trial, if any, would be successful or consistent with our previous findings. 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 our future clinical trials of azeliragon or our other drug candidates 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 materially harmed.

Fast Track designation for one or more of our product candidates may not actually lead to a faster development or regulatory review or approval process.

If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. The FDA granted Fast Track designation to azeliragon. Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it

believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

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 and adversely affect our business.

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. For example, our Phase 3 STEADFAST Study in mild AD patients failed to meet its co-primary endpoints in either sub-study, and the B-Study was discontinued early due to results of the A-Study. Our clinical development programs for azeliragon and 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. This is particularly true in the area of treatments for Alzheimer’s disease, where pharmaceutical development has been particularly challenging. 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 (“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 our 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 as well as personnel changes at the FDA. 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 REMS, measures that may, for instance, place restrictions on the distribution of new 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;
- 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. 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.

The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.

We currently have no drugs approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our drug candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Success in early-stage clinical trials does not mean that future larger registration clinical trials will be successful because drug candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through early-stage clinical trials. Drug candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Additionally, the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials, and interim results of a clinical trial are not necessarily indicative of final results.

The FDA or non-U.S. regulatory authorities may disagree with our and/or our clinical trial investigators' interpretation of data from clinical trials in determining if serious adverse or unacceptable side effects are drug-related.

We, and our clinical trial investigators, currently determine if serious adverse or unacceptable side effects are drug-related. The FDA or non-U.S. regulatory authorities may disagree with our or our clinical trial investigators' interpretation of data from clinical trials and the conclusion by us or our clinical trial investigators that a serious adverse effect or unacceptable side effect was not drug-related. The FDA or non-U.S. regulatory authorities may require more information, including additional preclinical or clinical data to support approval, which may cause us to incur additional expenses, delay or prevent the approval of one of our drug candidates, and/or delay or cause us to change our commercialization plans, or we may decide to abandon the development or commercialization of the drug candidate altogether.

Changes in law could have a negative impact on the approval of our drug candidates.

The FDA has established regulations, guidelines and policies to govern the drug development and approval process, as have foreign regulatory authorities. Any change in regulatory requirements resulting from the adoption of new legislation, regulations or policies may require us to amend existing clinical trial protocols or add new clinical trials to comply with these changes. Such amendments to existing protocols or clinical trial applications or the need for new ones, may significantly and adversely affect the cost, timing and completion of the clinical trials for our drug candidates. In addition, the FDA's policies may change and additional government regulations may be issued that could prevent, limit or delay regulatory approval of our drug candidates, or impose more stringent product labeling and post-marketing testing and other requirements. If we are slow or unable to adapt to any such changes, our business, prospects and ability to achieve or sustain profitability would be adversely affected.

Under the CURES Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.

In December 2016, the 21st Century Cures Act ("Cures Act"), was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. 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 and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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 do not know whether current or future clinical trials of azeliragon or our other drug candidates will begin on time or at all or will be completed on schedule or at all. The commencement, enrollment and completion of our 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 ("IRB"), approval to conduct a clinical trial;
- 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 recruit and 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 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 ("CMOs"), that we use to comply with current Good Manufacturing Practices ("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 submitted an NDA before and may be unable to do so for azeliragon and other drug candidates we are developing.

The submission of a successful NDA is a complicated process. As a team, we 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 clinical trials in a way that leads to an NDA submission and approval of any of our drug candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of the drug candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials would prevent or delay commercialization of the 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 any of our drug candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials 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.

If any of our 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 any future trials successfully, obtain market approval for and successfully commercialize our drug candidates, as well as our ability to develop and market those 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 patients with type 2 diabetes is limited to post-hoc sub-group analyses generated in our STEADFAST Study and a single Phase 2b study. These results may not be replicated in future clinical trials of azeliragon, 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.

We have conducted, and may in the future conduct, clinical trials for certain of our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We conducted a portion of the STEADFAST Study outside the United States. Also, we are required to conduct a portion of the Phase 2 MRCT outside the United States pursuant to the Huadong License Agreement. We may in the future choose to conduct additional clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any of our clinical trials that we determine to conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt the development of a product candidate.

In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations; and
- diminished protection of intellectual property in some countries, particularly in Asia.

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

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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 not be successful.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our drug candidates, we may not be successful in commercializing our drug candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of pharmaceutical drugs. To achieve commercial success for any approved drug for which sales and marketing is not the responsibility of any strategic collaborator that we may have in the future, we must either develop a sales and marketing organization or outsource these functions to other third parties. In the future, we may choose to build a sales and marketing infrastructure to market our drug candidates, if and when they are approved, or enter into collaborations with respect to the sale and marketing of our drug candidate.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any commercial launch of a drug candidate. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our drugs on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive drug lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

Entering into arrangements with third parties to perform sales and marketing services may result in lower revenues from the sale of drug or the profitability of these revenues to us than if we were to market and sell any drugs that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our drug candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drugs effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates.

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.

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. Azeliragon, is being developed for use in the treatment of probable Alzheimer's dementia in patients with type 2 diabetes. If approved for this indication, new competitors may emerge and azeliragon may face competition from several therapies currently in clinical development for AD that address different mechanisms of action than azeliragon and may serve as treatments for a broader population group than azeliragon.

Potential competitors with products in late stage clinical development are Biogen Inc, with its drug candidate aducanumab and Roche with its drug candidate gantenerumab.

Our drug candidates TTP399 and TTP273, compounds for treating type 2 diabetes, would compete with both marketed non-insulin anti-diabetic medications and 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, SGLT-2 inhibitors, such as dapagliflozin and canagliflozin, and GLP-1 agonists, such as liraglutide and exenatide.

Companies with GKAs in clinical development that may compete with TTP399 include Hua Medicine Ltd., Yabao Pharmaceutical Co, Inc., Pegbio Co. Ltd. and Teijin Pharma Limited. Oral GLP-1 agonists in clinical development that may compete with TTP273 include oral semaglutide being developed by Novo Nordisk A/S and ORMD-0901 being developed by Oramed.

In type 1 diabetes, oral non-insulin agents that are currently being developed that may compete with TTP399 include SGLT-1/2 inhibitors, such as sotagliflozin, being developed by Sanofi/Lexicon and SGLT-2 inhibitors such as AstraZeneca's dapagliflozin and Eli Lilly/ Boehringer Ingelheim's empagliflozin.

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 (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 any of our 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.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of our other drug candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs.

Moreover, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent drug labeling and post-marketing testing and other requirements.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any drugs that we may develop.

We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our drug candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any drugs that we may develop.

We currently hold clinical trial liability insurance coverage, but that coverage may not be adequate to cover any and all liabilities that we may incur. We would need to increase our insurance coverage when we begin the commercialization of our drug candidates, if ever. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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 Food, Drug and Cosmetic Act ("FDCA") is the statute that provides the FDA with authority to oversee the safety and approval of pharmaceutical products. The FDCA vests authority with FDA to conduct inspections sponsors conducting pharmaceutical development, such as vTv, to protect the rights, safety and welfare of clinical trial subjects, ensure the accuracy and reliability of clinical trial data, and verify compliance with FDA regulations. The FDCA sets forth the standards for approval of new and generic drugs, as well as setting forth the prohibition on marketing investigational products that have not been approved by the FDA as safe and effective. The government (FDA and SEC) use the FDCA to ensure that companies do not mislead the medical, patient or investor communities about investigational products prior to their approval. To that end, the FDCA prohibits "off-label promotion" of any investigational or approved product for any uses, doses or populations, except that set forth in the full prescribing information approved by the FDA. While physicians can prescribe a product for any dose, purpose or population in their medical judgment, manufacturers can only market products for their FDA-approved dose, purpose and population. There are significant civil and criminal penalties that attach to violations of the FDCA, including strict liability misdemeanors for responsible corporate officers, even if such officers were not involved in or aware of the underlying wrongdoing;
- 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 Foreign Corrupt Practices Act that prohibits payments to foreign public officials relating to official acts. In addition to its prohibition on bribery of foreign government officials, the Act requires companies to maintain accurate records and have vigorous internal controls. The DOJ and SEC have made FCPA enforcement a high priority. In addition, other anti-corruption laws such as the UK Bribery Act are even broader than the FCPA in that they apply to bribes offered to any person, not just government officials. There are significant criminal and civil penalties and fines that attach to violations of the FCPA;
- 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;

- 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 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 azeliragon 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;
- 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.

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;
- 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.

Any collaborative partners we enter into agreements with in the future may 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 (“CROs”) and clinical trial sites to ensure the proper and timely conduct of certain of our clinical trials. While we have agreements governing their activities, and continue to monitor their compliance with those agreements as well as federal standards and regulations, we 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 (“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 although we monitor their activities related to our trials, we are not able to control whether or not they devote sufficient time and resources to our clinical trials. 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 our drug candidates. We also do not have long-term supply agreements with any of our suppliers. If for any reason we are unable to obtain drug substance or drug product from the manufacturers we select, we would have to seek to obtain these from other manufacturers. 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 our drug candidates or, if we obtain regulatory approval for our 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, although we monitor our suppliers and their compliance with our contractual terms and federal laws and regulations, we do not control 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 source 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 other confidential and proprietary information; 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 regulatory exclusivity, 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 December 31, 2018, we were the owner of record of 63 issued U.S. patents and at least 320 issued non-U.S. patents, as well as the licensee of at least 3 issued U.S. patents and at least 33 issued non-U.S. patents. As of December 31, 2018, we were actively pursuing 23 U.S. patent applications, of which eight are provisional and 15 are non-provisional and at least 87 non-U.S. patent applications in twelve or more jurisdictions as the owner of record.

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 licensees, 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 patent 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. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties. Therefore, such patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. 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 United States Patent and Trademark Office ("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. 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 laws 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.

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 Inter Partes Review ("IPR") proceedings before the USPTO or 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 been granted or may grant or 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.

IPR, 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, the length of our patent exclusivity will be shorter which may harm our business materially.

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 (“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, the U.S. patent providing composition of matter protection for azeliragon is scheduled to expire in 2024, but if we obtain the maximum possible extension in the United States, a period of patent extension for the approved azeliragon product could extend as late as 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 may 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 may need to increase our product development, scientific and administrative headcount to manage these programs. If we commercialize our products, we may need to expand our staff further, particularly in sales and marketing. See "—Risks Relating to the Commercialization of Our Drug Candidates." We do not presently 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, or successfully partner with a third party organization that will oversee those efforts; 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. In addition, our recent corporate restructurings may have impacted employee morale and may lead to higher rates of voluntary attrition compared to prior years. We are highly dependent on the development, regulatory, commercialization and business development expertise of our executive officers and key employees. 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 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 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 legal, compliance or 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, pre-market promotion, 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 new comprehensive compliance policies, and revised our code of conduct, but it is not always possible to identify and deter employee or non-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 have here to date focused primarily on the regulatory approval of azeliragon. As a result, we may have foregone or delayed the pursuit of opportunities with other drug candidates or for other indications that could later prove to have had greater commercial potential. Our future 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 any drug candidates or products we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or delay 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 or delay in our ability 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 any products we develop. We currently carry clinical trial liability insurance in the amount of $10.0 million 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 for any drug product, we intend to expand our insurance coverage to include the sale of that product, 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 $6.0 million per occurrence, with an annual aggregate limit of $7.0 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 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 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 or be offered at a more competitive price. 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.

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.

We may be subject to foreign exchange fluctuations.

Our functional and reporting currency is the United States dollar. A portion of our expenditures are in foreign currencies, most notably in Canadian dollars, and therefore we are subject to foreign currency fluctuations, which may, from time to time, impact our financial position and results.

Risks Related to our Common Stock

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

MacAndrews holds, directly or indirectly, 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;
- determine the composition of the committees on our Board of Directors;
- 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 our Class A common stock to decline.

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

Half of our directors are 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 provides that none of MacAndrews, any of our non-employee directors who are employees, affiliates or consultants of MacAndrews or its affiliates (other than us or our subsidiaries) or any of their respective affiliates 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 its 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, our Loan Agreement includes restrictive covenants which prevent us from paying dividends to our stockholders. 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 result in substantial losses for our stockholders.

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 and receipt of data from the 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. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased their shares.

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An active trading market for our Class A common stock may not be sustained.

Our shares of Class A common stock began trading on The NASDAQ Global Market on July 30, 2015 and its listing was transferred to The NASDAQ Capital Market on October 30, 2018. Given the limited trading history of our Class A common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our Class A common stock and thereby affect the ability of our stockholders to sell their shares.

Our stock price may decline and we may not be able to maintain compliance with NASDAQ listing requirements.

Our Class A common stock is listed on The NASDAQ Capital Market, which imposes certain minimum continued listing requirements. If compliance with these requirements is not maintained, NASDAQ may make a determination to delist our Class A common stock.

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.

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.

As of December 31, 2018, MacAndrews and its affiliates hold 23,084,267 non-voting common units of vTv LLC ("vTv Units") and the same number of shares of vTv Therapeutics Inc. Class B common stock as well as an aggregate of 13,232,785 shares of our Class A common stock. As a result, MacAndrews and its affiliates hold shares representing approximately 83.6% of the combined voting power of our outstanding common stock. Pursuant to the terms of the Exchange Agreement among the Company, vTv LLC and the holders of vTv Units party thereto (the "Exchange Agreement"), vTv Units (along with the corresponding number of shares of our Class B common stock) will be exchangeable 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 upon an exchange of vTv 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 have entered into the December Letter Agreement with M&F Group and previously entered into other similar letter agreements with MacAndrews. Under the December Letter Agreement, we have the right to sell to M&F Group shares of our Class A common stock at set prices, and M&F Group has the right (exercisable up to three times) to require us to sell to it shares of Class A common stock at the same prices. An aggregate of $10.0 million worth of Class A common stock may be sold under the December Letter Agreement (whether at our or M&F Group's option), with $4.0 million remaining to be sold as of February 14, 2019. In addition, in connection with the December Letter Agreement and previous letter agreements, we also issued M&F Group warrants to purchase shares of our Class A

common stock at set prices. The warrants are exercisable for seven years from their issuance. Sales of shares of Class A common stock to M&F Group under the December Letter Agreement or pursuant to the exercise of the related warrants (or resales by M&F Group of such shares) could negatively affect our stock price, as could the anticipation of such sales or resales.

On August 13, 2015, we filed a registration statement under the Securities Act registering 3,250,000 shares of our Class A common stock reserved for issuance under our 2015 Plan. As part of our Loan Agreement, we issued warrants to purchase 190,586 shares of our Class A common stock to our lenders.

On February 27, 2018, we filed a shelf registration statement on Form S-3 through which we may offer and sell from time to time shares of our Class A common stock with an aggregate initial offering price of up to $250,000,000. However, in no event will we sell Class A common stock under this registration statement with a value exceeding more than one-third of the “public float” (the market value of our Class A common stock and any other equity securities that we may issue in the future that are held by non-affiliates) in any 12-calendar month period so long as our public float remains below $75 million.

Further, we have entered into an investor rights agreement with an affiliate of MacAndrews providing certain governance and registration rights.

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, the exercise of outstanding warrants or pursuant to the Loan Agreement or the December Letter Agreement, 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, including under the December Letter Agreement and warrants issued to M&F Group, and such sales could result in substantial dilution to existing investors.

In addition, under the Loan Agreement the Lenders have the right to purchase shares of our Class A common stock from us, at a discounted price, with a value up to $1.0 million in the event that we conduct a public offering in which we receive cash proceeds of at least $10.0 million. If we sell Class A common stock, convertible securities or other equity securities, the percentage ownership of our stockholders will be diluted. In addition, new investors could gain rights superior to our existing stockholders.

We are an “emerging growth company,” and are taking 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 (the “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 from the date of our initial public offering, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 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. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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 are 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, 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.

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 are exempt from certain corporate governance requirements since we are 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 controls more than 50% of our combined voting power. As a result, we are considered a "controlled company" for the purposes of NASDAQ rules and corporate governance standards, and therefore are permitted 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 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 do 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.

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 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;
- authorized but unissued shares of common stock and preferred stock that will be available for future issuance;
- the ability of our Board of Directors to increase the size of the Board of Directors and fill vacancies without a stockholder vote;
- provisions that have the same effect as a modified version of Section 203 of the Delaware General Corporation Law, an antitakeover law (as further described below); 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 contains provisions that have the same effect as Section 203 of the Delaware General Corporation Law, except that they provide that MacAndrews and its various 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.

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 M&F TTP Holdings Two LLC ("M&F") for certain tax benefits we may claim. In certain circumstances, payments under the Tax Receivable Agreement may be accelerated and/or significantly exceed the actual tax benefits we realize.

The only asset of the Company is its interest in vTv LLC. Class B common stock, together with the corresponding number of vTv Units, may be exchanged for shares of our Class A common stock, or for cash, at our option (as the managing member of vTv LLC). These exchanges of Class B common stock, together with the corresponding number of vTv LLC Units, may result in increases in the tax basis of the assets of vTv 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 have entered into a Tax Receivable Agreement with vTv Therapeutics Holdings (an entity which was dissolved in October 2015, but to which M&F became a successor) that will provide for the payment by us to M&F (or certain of 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 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 M&F could be substantial.

M&F 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 M&F 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 M&F for a number of years following the initial time of such payment. As a result, in certain circumstances we could make payments to M&F 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 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 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 the Company is its interest in vTv LLC, and accordingly it will depend on distributions from vTv LLC to pay taxes and expenses, including payments under the Tax Receivable Agreement. vTv LLC's ability to make such distributions may be subject to various limitations and restrictions.

The Company is a holding company, has no material assets other than its ownership of vTv Units and has no independent means of generating revenue or cash flow. vTv LLC is treated as a partnership for U.S. federal income tax purposes and, as such, is not 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 LLC. Under the terms of vTv LLC's Amended and Restated LLC Agreement, vTv 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 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 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 LLC is then a party, including the Loan Agreement or any other potential debt agreements, or any applicable law, or that would have the effect of rendering vTv LLC insolvent. If vTv 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 M&F and certain of its successors and assigns that will not benefit Class A common stockholders to the same extent as it will benefit M&F.

Our organizational structure, including the fact that M&F owns more than 50% of the voting power of our outstanding voting stock and owns part of its economic interest in our business through vTv LLC, confers certain benefits upon M&F that will not benefit the holders of our Class A common stock to the same extent as it will benefit M&F. For example, the Tax Receivable Agreement will provide for the payment by us to M&F (or certain of 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 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 M&F may in some circumstances conflict with our interests and the interests of our other stockholders. For example, M&F 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 M&F's tax or other considerations, which may differ from the considerations of us or our other stockholders. To the extent that M&F is dissolved or liquidated, MacAndrews and/or its affiliates will succeed to the rights and obligations of M&F under the Tax Receivable Agreement, and the same considerations described above apply to any such successor parties.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters and lab facilities are located in High Point, North Carolina, where we lease 32,776 square feet of mixed laboratory and office space in the Mendenhall Oaks office park. The lease agreement for this space continues through December 2019.

As a result of the Restructuring, we do not expect to require in-house laboratory space in future periods, and our expected need for office space has decreased. Since our current facility lease expires in December 2019, we expect to seek to negotiate new leases or look for alternate space for our operations. We believe that appropriate alternative space is readily available and expect that our facility costs will decrease as a result of the change.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our Class A common stock is listed on the NASDAQ Capital Market under the symbol "VTVT".

Dividend Policy

No cash dividends have ever been declared or paid on the common equity to date by the Company. Our ability to pay dividends is restricted by our Loan Agreement. See "Management's Discussion and Analysis of Financial Conditions and Results of Operations – Liquidity and Capital Resources" in Item 7 of this Annual Report on Form 10-K.

Holders

As of February 25, 2019, there were approximately 21 holders of record of our Class A common stock and 7 holders of record of our Class B common stock. Because almost all of the shares of our Class A common stock are held by brokers, nominees and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2018. The only awards that have been granted under the plan below are in the form of option and restricted stock unit awards related to our Class A common stock:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders			
2015 Omnibus Equity Incentive Plan	1,790,836	$ 8.57	1,459,164
Equity compensation plans not approved by			

security holders		
Total	1,790,836	1,459,164

Issuer Purchases of Equity Securities

There have been no repurchases of the Company's common stock during the fourth fiscal quarter of fiscal 2018.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read together with the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the notes to those financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the years ended December 31, 2018, 2017 and 2016 and balance sheet data as of December 31, 2018 and 2017 set forth below have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the year ended December 31, 2014 and the selected balance sheet data as of December 31, 2015 and 2014 set forth below has been derived from the audited financial statements for such year not included in this Annual Report on Form 10-K. The historical periods presented here are not necessarily indicative of future results.

	Year Ended December 31,				
(dollars in thousands, except for per share data)	2018	2017	2016	2015	2014
Statement of operations data:					
Revenue	$12,434	$291	$634	$519	$1,549
Research and development	23,035	39,640	45,748	29,584	18,729
General and administrative	9,223	11,333	9,906	9,077	11,717
Total operating expenses	32,258	50,973	55,654	38,661	30,446
Loss from operations	(19,824)	(50,682)	(55,020)	(38,142)	(28,897)
Other expense, net	(3,821)	(3,165)	(333)	(2,965)	(7,204)
Income tax provision	200	800	—	—	—
Net loss attributable to noncontrolling interest	(15,934)	(38,503)	(39,001)	(13,609)	—
Net loss attributable to vTv Therapeutics Inc.	(7,911)	(16,144)	(16,352)	(27,498)	(36,101)
Net loss attributable to vTv Therapeutics Inc. common shareholders	(8,650)	(16,144)	(16,352)	(27,498)	
Net loss per share, basic and diluted [1]	$(0.69)	$(1.67)	$(1.71)	$(3.32)	
Weighted average number of shares outstanding, basic and diluted	12,449,236	9,693,254	9,545,527	8,276,520	

Balance sheet data:	2018	2017	2016	2015	2014
Cash and cash equivalents	$1,683	$11,758	$51,505	$88,003	$1,384
Working capital	(15,364)	(6,567)	40,683	81,460	(5,253)
Total assets	8,559	27,917	54,495	91,532	12,951
Current liabilities	18,837	26,929	11,434	7,726	6,864
Long-term debt, net of current portion	6,330	15,316	11,058	—	29,420
Deferred revenue, net of current portion	1,067	4,497	—	—	—
Other liabilities, net of current portion	2,696	782	433	245	37,387
Redeemable convertible preferred units	—	—	—	—	438,086
Redeemable noncontrolling interest	62,482	131,440	122,515	161,531	—
Total stockholders'/members' deficit	(82,853)	(151,047)	(90,945)	(77,970)	(498,806)

(1) Loss per share is not presented for the year ended December 31, 2014 as the Company did not have any economic interests prior to the date of the IPO and Reorganization Transactions through which it was given ownership in vTv LLC. Losses prior to the IPO and Reorganization Transactions would have been allocated to the original members of TTP and HPP. Loss per share for the year ended December 31, 2015 includes the 2015 losses recognized both

prior and subsequent to the IPO and Reorganization Transactions. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations” for additional information regarding the IPO and Refinancing Transactions.

ITEM 7. 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 consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains 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 in Part I, Item 1A, “Risk Factors” in this Annual Report on Form 10-K. See the sections entitled “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements.”

Company 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 mild Alzheimer's disease ("AD") and diabetes. Our drug candidate, azeliragon (TTP488), is an orally administered, small molecule antagonist targeting the receptor for advanced glycation endproducts ("RAGE"), for which we have initiated start-up activities for an adaptive Phase 2/3 trial to evaluate azeliragon as a potential treatment of mild-AD in patients with type 2 diabetes. We are currently finalizing a protocol for the study, negotiating with clinical research organizations to support study conduct activities for the trial and beginning the site selection process. We expect to initiate patient enrollment in this study in mid-2019.

Our type 2 diabetes drug candidates include TTP399, an orally administered, liver-selective glucokinase activator ("GKA"), for which we successfully completed a Phase 2b clinical trial in type 2 diabetes (the "AGATA Study"), and TTP273, an orally administered, non-peptide agonist that targets the glucagon-like peptide-1 receptor ("GLP-1r"), for which we successfully completed a Phase 2 clinical trial in type 2 diabetes (the "LOGRA Study").

We are also developing TTP399 for type 1 diabetes. In August 2017, we entered into a research, development and commercialization agreement with JDRF International ("JDRF") (the "JDRF Agreement") to support the funding of the simplici-T1 Study, an adaptive Phase 1b/2 study to explore the effects of TTP399 in type 1 diabetics. We have completed enrollment of the part 1 learning phase and expect to report results for this portion of the study in June 2019. We have begun the start-up activities for the part 2 confirming phase and expect to report results for this portion of the study in the latter part of the first quarter of 2020. According to the terms of the JDRF Agreement, JDRF will provide research funding of up to $3.0 million based on the achievement of research and development milestones, with the total funding provided by JDRF not to exceed approximately one-half of the total cost of the project. Additionally, we have the obligation to make certain milestone payments to JDRF upon the commercialization, licensing, sale or transfer of TTP399 as a treatment for type 1 diabetes.

We have also entered into partnerships with other pharmaceutical companies to continue the development of our GLP-1r, PDE4, and PPAR- programs. In December 2017, we entered into a License Agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("Huadong") (the "Huadong License Agreement"), under which Huadong obtained an exclusive and sublicensable license to develop and commercialize our glucagon-like peptide-1 receptor agonist ("GLP-1r") program, including the compound TTP273, in China and certain other Pacific Rim countries, including Australia and South Korea. We also entered into a License Agreement with Reneo Pharmaceuticals, Inc. ("Reneo") (the "Reneo License Agreement") in December 2017, under which Reneo obtained an exclusive, worldwide, sublicensable license to develop and commercialize our peroxisome proliferation activated receptor delta agonist program, including the compound HPP593. Finally, in May 2018, we entered into a License Agrement with Newsoara Biopharma Co., Ltd., ("Newsoara") (the "Newsoara License Agreement"), under which Newsoara obtained an exclusive and sublicensable license to develop and commercialize our phosphodiesterase type 4 inhibitors ("PDE4") program, including the compound HPP737, in China and other Pacific Rim countries. For more information regarding the JDRF Agreement, the Huadong License Agreement, Reneo License Agreement and the Newsoara License Agreement, see Part 1 – Item 1 – "Business – Intellectual Property – License and Research Agreements" of this Annual Report.

In addition to the above, we continue to advance the nonclinical development of our NRF2 pathway program through industry and academic collaborations.

vTv Therapeutics Inc. (the "Company", the "Registrant", "we" or "us") is a holding company, and its principal asset is a controlling equity interest in vTv Therapeutics LLC ("vTv LLC"), the Company's principal operating subsidiary. The Company has determined that vTv LLC is a variable-interest entity ("VIE") for accounting purposes and that vTv Therapeutics Inc. is the primary beneficiary of vTv LLC because (through its managing member interest in vTv LLC and the fact that the senior management of vTv Therapeutics Inc. is also the senior management of vTv LLC) it has

the power to direct all of the activities of vTv LLC, which include those that most significantly impact vTv LLC's economic performance. vTv Therapeutics Inc. has therefore consolidated vTv LLC's results under the VIE accounting model in its Consolidated Financial Statements.

To date, we have devoted substantially all of our resources to our research and development efforts relating to our investigational 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, 2018, we (including our predecessor companies) have funded our operations primarily through:

- a series of private placements of preferred equity from 1999 through 2006 totaling $109.3 million;
- the receipt of $23.4 million from completed research collaborations with Novo Nordisk, A/S Merck and Boehringher 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 TTP and HPP, our predecessors;
- borrowings of $46.6 million from April 2014 through June 2015 from entities affiliated with MacAndrews;
- the completion of the IPO in August 2015, which raised proceeds of $104.4 million from the sale of our Class A common stock, par value $0.01 per share (the "Class A Common Stock"), net of offering costs;
- borrowings totaling $20.0 million from a venture loan and security agreement (the "Loan Agreement") with Horizon Technology Finance Corporation and Silicon Valley Bank (together, the "Lenders") in October 2016 and March 2017; and
- letter agreements (the "Prior Letter Agreements") with M&F Group in December 2017 and July 2018, under which we had the right to sell to M&F Group shares of our Class A common stock at a price equal to $4.38 and $1.33 per share, respectively, and M&F Group had the right (exercisable up to three times) to require us to sell to it shares of Class A common stock at the same price (subject to an aggregate maximum of $10.0 million worth of Class A common stock that may be sold under each Letter Agreement, whether at our option or M&F Group's); and
- and December 2018, under which, we had the right to sell to M&F Group shares of our Class A common stock at a price equal to $1.84 per share, respectively, and M&F Group has the right (exercisable up to three times) to require us to sell to it shares of Class A common stock at the same price (subject to an aggregate maximum of $10.0 million worth of Class A common stock that may be sold under each Letter Agreement, whether at our option or M&F Group's).

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 candidates, azeliragon, TTP273 and TTP399;
- seek to obtain regulatory approvals for our lead drug candidates;
- prepare for the potential commercialization of our lead drug candidates;
- expand our research and development activities and advance our clinical programs; and
- maintain, expand and protect our intellectual property portfolio.

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 will need to raise additional capital to fund continuing drug development prior to the commercialization of any of our drug candidates, including to finance the adaptive Phase 2/3 trial of azeliragon for the treatment of mild-AD in patients with type 2 diabetes. 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. We are evaluating several financing strategies to fund the proposed clinical trial of azeliragon for the treatment of mild-AD in patients with type 2 diabetes, including direct equity investments and future public offerings of our common stock. 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. Our revenue has been primarily derived from up-front proceeds and research fees under collaboration and license agreements.

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 related to regulatory filings for our drug candidates. We recognize research and development expenses as they are incurred. Our direct research and development expenses consist primarily of external costs such as fees paid to investigators, consultants, central laboratories and clinical research organizations ("CRO(s)"), in connection with our clinical trials, and costs related to acquiring and manufacturing clinical trial materials. Our indirect research and development costs consist primarily of salaries, benefits and related overhead expenses for personnel in research and development functions and depreciation of leasehold improvements, laboratory equipment and computers. Since we typically use our employee and infrastructure resources across multiple research and development programs such costs are not allocated to the individual projects.

From our inception through December 31, 2018, we have incurred approximately $564.9 million in research and development expenses.

Our research and development expenses by project for the years ended December 31, 2018, 2017 and 2016 were as follows (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Direct research and development expense:			
Azeliragon	$13,507	$28,206	$29,430
TTP399	879	418	2,598
TTP273	109	352	3,838
Other projects	586	1,001	1,353
Indirect research and development expense	7,954	9,663	8,529
Total research and development expense	$23,035	$39,640	$45,748

We plan to continue to incur significant research and development expenses for the foreseeable future as we continue the development of azeliragon and further advance the development of our other drug candidates, subject to the availability of additional funding. In December 2018, we initiated a corporate restructuring to use external resources rather than internal resources in the development of our drug candidates. This restructuring includes a significant reduction in our workforce, which is expected to result in lower personnel costs in future periods, but some of these expected reductions may be offset by higher costs for outsourced services, severance payments and other related expenses.

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;
- our ability to enroll patients in our clinical trials;
- 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, 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.

Our general and administrative expenses have increased and will continue to increase as we operate as a public company and commercialize our drug candidates. Such increases have been driven by higher costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants.

Interest Expense, Net

Interest expense, net primarily consists of our cash and non-cash interest expense related to our Loan Agreement. Cash interest on the Loan Agreement is recognized at a floating interest rate equal to 10.5% plus the amount by which the one-month London Interbank Offer Rate ("LIBOR") exceeds 0.5%. Non-cash interest expense represents the amortization of the costs incurred in connection with the Loan Agreement, the allocated fair value of the warrants to purchase shares of our Class A Common Stock issued in connection with the Loan Agreement (the "Warrants") and the accretion of the final interest payment (which will be paid in cash upon loan maturity), all of which are recognized in our Consolidated Statement of Operations using the effective interest method.

Other Income (Expense), Net

Other income (expense), net primarily consists of gains and losses related to the adjustment of the fair value of the warrants issued to MacAndrews in connection with the Letter Agreements.

Results of Operations

Comparison of the year ended December 31, 2018 and 2017

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

(dollars in thousands)	Year Ended		
Statement of operations data:	2018	2017	Change
Revenue	$12,434	$291	$12,143
Operating expenses:			
Research and development	23,035	39,640	(16,605)
General and administrative	9,223	11,333	(2,110)
Total operating expenses	32,258	50,973	(18,715)
Operating loss	(19,824)	(50,682)	30,858
Interest income	61	117	(56)
Interest expense	(3,290)	(3,092)	(198)
Other expense, net	(592)	(190)	(402)
Loss before income taxes	(23,645)	(53,847)	30,202
Income tax provision	200	800	(600)
Net loss before noncontrolling interest	(23,845)	(54,647)	30,802
Less: net loss attributable to noncontrolling interest	(15,934)	(38,503)	22,569
Net loss attributable to vTv Therapeutics Inc.	$(7,911)	$(16,144)	$8,233

Revenues

Revenues were $12.4 million and $0.3 million for the years ended December 31, 2018 and 2017, respectively. The revenue earned during each of these years relates to our license agreements. We recognize the portion of the consideration received allocated to the license deliverable for each of these agreements over the requisite knowledge transfer or research service periods which were completed during 2018 for both the Huadong and Newsoara License Agreements. The portion of revenue allocated to the other deliverables under the license agreements will be recognized as performance occurs. A minimal amount of revenue was recognized in 2017 for the Huadong and Reneo License Agreements as those agreements were entered into in December 2017.

Research and Development Expenses

Research and development expenses were $23.0 million and $39.6 million for the years ended December 31, 2018 and 2017, respectively. The decrease in research and development expenses during this period of $16.6 million, or 41.9%, was primarily due to:

- A decrease in clinical trial costs of $14.7 million for azeliragon from 2017, which was mainly driven by decreases of $12.0 million related to the termination of our STEADFAST and OLE studies in early April 2018, decreases of $1.9 million related to the cost of other completed or discontinued adjunct studies for azeliragon and decreases in compound manufacturing costs of $1.4 million. These decreases were offset by increases of $0.6 million related to the cost of consultants used to provide analysis of the STEADFAST Study results and advice in advance of discussions with regulatory agencies;
- An increase in clinical trial costs of $0.5 million for TTP399 from 2017, which was driven by higher spending on the simpliciT-1 trial which began in late 2017 and is currently enrolling patients; and
- A decrease in other research and development costs of $1.7 million, primarily driven by a decrease in the expense related to share-based awards and incentive-based compensation costs expected to be paid to our employees.

General and Administrative Expenses

General and administrative expenses were $9.2 million and $11.3 million for the years ended December 31, 2018 and 2017, respectively. The decrease in general and administrative expenses during this period of $2.1 million, or 18.6%, was primarily due to decreases in expenses for share-based awards, incentive-based compensation and professional services.

Interest Expense, Net

Interest expense, net was $3.3 million and $3.1 million for the years ended December 31, 2018 and 2017, respectively. Interest expense primarily relates to our Loan Agreement which bears interest at 10.5% plus the amount by which the one-month LIBOR exceeds 0.5%.

Comparison of the Years Ended December 31, 2017 and 2016

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

(dollars in thousands)	Year Ended		
Statement of operations data:	2017	2016	Change
Revenue	$291	$634	$(343)
Operating expenses:			
Research and development	39,640	45,748	(6,108)
General and administrative	11,333	9,906	1,427
Total operating expenses	50,973	55,654	(4,681)
Operating loss	(50,682)	(55,020)	4,338
Interest income	117	87	30
Interest expense	(3,092)	(398)	(2,694)
Other expense, net	(190)	(22)	(168)
Loss before income taxes	(53,847)	(55,353)	1,506
Income tax provision	800	—	800
Net loss before noncontrolling interest	(54,647)	(55,353)	706
Less: net loss attributable to noncontrolling interest	(38,503)	(39,001)	498
Net loss attributable to vTv Therapeutics Inc.	$(16,144)	$(16,352)	$208

Revenues

Revenues were $0.3 million and $0.6 million for the years ended December 31, 2017 and 2016, respectively. The revenue earned during the year ended December 31, 2017 primarily relates to the Huadong and Reneo License Agreements, which were entered into in December 2017. The revenue earned during the year ended December 31, 2016 was primarily attributable to our former license agreement with Calithera. We recognize the portion of the consideration received allocated to the license deliverable for each of these agreements over the requisite knowledge transfer or research service periods. The portion of revenue allocated to the other deliverables under the license agreements will be recognized as performance occurs.

Research and Development Expenses

Research and development expenses were $39.6 million and $45.7 million for the years ended December 31, 2017 and 2016, respectively. The decrease in research and development expenses during this period of $6.1 million, or 13.4%, was primarily due to:

- A decrease in clinical trial costs of $1.2 million for azeliragon from 2016, which was mainly driven by decreases of $2.6 million related to the timing of drug-drug interaction and other supporting studies. These studies were conducted primarily in 2016 and were completed in early 2017. Additionally, we saw decreases of $0.9 million in compound manufacturing costs for drug product from 2016 as drug product was manufactured in 2016 for the support of the STEADFAST Study and the open-label extension ("OLE") trial. Such decreases were offset by an increase of $1.2 million in cost related to the OLE trial as patients completing the STEADFAST Study elect to continue in the OLE study and an increase of $0.9 million related to the cost of consultants engaged to assist primarily with the conduct of the STEADFAST Study;
- A decrease in clinical trial costs of $2.2 million for TTP399 from 2016, which was mainly driven by lower costs for the AGATA Study due to its completion in August 2016, partially offset by spending on the simpliciT-1 trial, which began in late 2017;
- A decrease in clinical trial costs of $3.5 million for TTP273 from 2016, due to the completion of the LOGRA study in December 2016; and
- An increase in other research and development costs of $1.1 million, primarily driven by an increase in the expense related to share-based awards and other compensation costs.

General and Administrative Expenses

General and administrative expenses were $11.3 million and $9.9 million for the years ended December 31, 2017 and 2016, respectively. The increase in general and administrative expenses during this period of $1.4 million, or 14.4%, was primarily due to increases in professional and legal fees of $0.3 million primarily related to the license agreements entered into in 2017 coupled with increases in compensation costs of approximately $0.9 million due to grants of additional share-based compensation awards as well as the impact of additional personnel hired in both years.

Interest Expense, Net

Interest expense, net was $3.1 million and $0.4 million for the years ended December 31, 2017 and 2016, respectively. Interest expense primarily relates to our Loan Agreement which was entered into in late October 2016 and which bears interest at 10.5% plus the amount by which the one-month LIBOR exceeds 0.5%. The increase in such interest expense for the year ended December 31, 2017 relates to both the borrowing of the second tranche in March 2017 as well as the period of time for which the loan was outstanding in each year.

Liquidity and Capital Resources

Liquidity and Going Concern

As of December 31, 2018, we had an accumulated deficit of $233.9 million. Since our inception, we have experienced a history of negative cash flows from operating activities. We anticipate that we will continue to incur losses for the foreseeable future as we continue our clinical trials. Further, we expect that we will need additional capital to continue to fund our operations. Our currently available sources of liquidity include our unrestricted balance of cash and cash equivalents of $1.7 million and the $8.5 million of remaining funds available under the Letter Agreements as of December 31, 2018. Based on our current operating plan, we believe that our current cash and cash equivalents will allow us to meet our liquidity requirements into March 2019. These factors raise substantial doubt regarding our ability to continue as a going concern. In addition to available cash and cash equivalents and available funds discussed above, we are seeking possible additional partnering opportunities for our GKA, GLP-1r

and other drug candidates which we believe may provide additional cash for use in our operations and the continuation of the clinical trials for our drug candidates. We are evaluating several financing strategies to fund the proposed clinical trial of azeliragon for the treatment of mild-AD in patients with type 2 diabetes, including direct equity investments and future public offerings of our common stock. The timing and availability of such financing are not yet known.

Letter Agreements

The Company has entered into the December Letter Agreement and the Prior Letter Agreements (collectively, the "Letter Agreements") with M&F Group. Under the terms of the Letter Agreements, the Company has or had the right to sell to M&F Group shares of its Class A Common Stock at a specified price per share, and M&F Group has or had the right (exercisable up to three times)

to require the Company to sell to it shares of Class A Common Stock at the same price. An aggregate of $20.0 million worth of Class A Common Stock were sold under the Prior Letter Agreements and a further $10.0 million worth of Class A Common Stock may be sold under the December Letter Agreement (whether at the Company's or M&F Group's option). In addition, in connection with the entrance into these Letter Agreements, the Company also issued to M&F Group warrants (the "Letter Agreement Warrants") to purchase additional shares of the Company's Class A Common Stock. On October 26, 2018, we entered into amendments with M&F Group to the Letter Agreement Warrants associated with the Prior Letter Agreements, which removed certain anti-dilution provisions of those Letter Agreement Warrants.

Certain terms of these Letter Agreements are set forth in the table below:

	December 5, 2017 Letter Agreement	July 30, 2018 Letter Agreement	December 11, 2018 Letter Agreement
Specified purchase price per share	$4.38	$1.33	$1.84
Expiration date of letter agreement	December 5, 2018	July 30, 2019	December 11, 2019
Shares available to be issued under related warrants	198,267	518,654	340,534
Exercise price of related warrants	$5.04	$1.53	$2.12
Expiration date of related warrants	December 5, 2024	July 30, 2025	December 11, 2025
Total shares issued as of December 31, 2018	2,283,105	7,518,797	815,217
Remaining shares to be issued as of December 31, 2018	—	—	4,619,566

Debt Transaction

In October 2016, we and vTv LLC entered into the Loan Agreement with Horizon Technology Finance Corporation and Silicon Valley Bank, under which we have borrowed $20.0 million. Each loan tranche bears interest at a floating rate equal to 10.5% plus the amount by which the one-month LIBOR exceeds 0.5%.

We borrowed the first tranche of $12.5 million upon the close of the Loan Agreement in October 2016. The first tranche requires only monthly interest payments until May 1, 2018, followed by equal monthly payments of principal plus accrued interest through the scheduled maturity date on May 1, 2020. In addition, a final payment for the first tranche loan equal to $0.8 million will be due on May 1, 2020, or such earlier date specified in the Loan Agreement. We borrowed the second tranche of $7.5 million in March 2017. The second tranche requires only monthly interest payments until October 1, 2018, followed by equal monthly payments of principal plus accrued interest through the scheduled maturity date on October 1, 2020. In addition, a final payment for the second tranche loan equal to $0.5 million will be due on October 1, 2020, or such earlier date specified in the Loan Agreement. The availability of the third tranche of $5.0 million expired unused on June 30, 2017.

If we repay all or a portion of the loan prior to the applicable maturity date, we will pay the Lenders a prepayment penalty fee, based on a percentage of the then outstanding principal balance equal to 4.0% during the first 18 months following the funding of the second tranche and 2.0% thereafter.

In connection with the Loan Agreement, we have issued to the Lenders warrants to purchase shares of our Class A common stock (the "Warrants"). On October 28, 2016, we issued Warrants to purchase 152,580 shares of our Class A common stock at a per share exercise price of $6.39 per share, which aggregate exercise price represents 6.0% of the

principal amount borrowed under the first tranche of the Loan Agreement and 3.0% of the amount available under the second tranche of the Loan Agreement. On March 24, 2017, in connection with the funding of the second tranche, we issued Warrants to purchase 38,006 shares of our Class A common stock at a per share exercise price of $5.92 per share, which aggregate exercise price represents 3.0% of the principal amount of the second tranche. In each instance, the Warrants have an exercise price equal to the lower of (a) the volume weighted average price per share of our Class A common stock, as reported on the principal stock exchange on which our Class A common stock is listed, for 10 trading days prior to the issuance of the applicable Warrants or (b) the closing price of a share of our Class A common stock on the trading day prior to the issuance of the applicable Warrants. The Warrants will expire seven years from their date of issuance.

The Loan Agreement includes customary affirmative and restrictive covenants, including, but not limited to, restrictions on the payment of dividends or other equity distributions and the incurrence of debt or liens upon the assets of the Company or its subsidiaries. The Loan Agreement does not contain any financial maintenance covenants other than a requirement to maintain a minimum cash balance of not less than $2.5 million in a deposit account pledged to secure the Loan Agreement and subject to an account control agreement. The minimum cash balance covenant was included as part of an amendment to the Loan Agreement in connection with our entry into the Huadong License Agreement in December 2017. The Loan Agreement includes customary events of default, including payment defaults, covenant defaults and material adverse change default. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5% will be applied to the outstanding loan balances, and the Lenders may

declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. As a result of the termination of the STEADFAST Study, we granted the Lenders a first priority security interest in all of our intellectual property, subject to certain limited exceptions.

Cash Flows

	Year Ended December 31,	
	2018	2017
(dollars in thousands)		
Net cash used in operating activities	$(26,856)	$(44,560)
Net cash provided by (used in) investing activities	7	(25)
Net cash provided by financing activities	16,612	7,500
Net decrease in cash and cash equivalents	$(10,237)	$(37,085)

Operating Activities

For the year ended December 31, 2018, our net cash used in operating activities decreased $17.7 million from the prior year. The decrease in uses of cash was primarily driven by lower spending on our clinical trials during 2018 coupled with the impact of changes in working capital.

Investing Activities

For the years ended December 31, 2018 and 2017, net cash used in investing activities was insignificant.

Financing Activities

For the year ended December 31, 2018, net cash provided by financing activities was $16.6 million compared to net cash provided by financing activities of $7.5 million for the year ended December 31, 2017, resulting in an increase of $9.1 million. This increase was driven by the need for additional sources of financing in 2018 to support our ongoing operations and debt service requirements.

Future Funding Requirements

To date, we have not generated any revenue from drug product sales. We do not know when, or if, we will generate any revenue from drug product sales. We do not expect to generate revenue from drug sales unless and until we obtain regulatory approval of and commercialize any of our drug candidates. At the same time, we expect our expenses to continue or 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. 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 on our current operating plan, we believe that our current cash and cash equivalents and other committed sources of funds under the Letter Agreements will allow us to meet our liquidity requirements into March 2019. In addition to the available cash and cash equivalents and other sources of liquidity, we are seeking possible additional partnering opportunities for our GKA, GLP-1r and other drug candidates which we believe may provide additional cash for use in our operations and the continuation of the clinical trials for our drug candidates. We are also

evaluating several financing strategies to fund the proposed clinical trial of azeliragon for the treatment of mild-AD in patients with type 2 diabetes, including direct equity investments and future public offerings of our common stock. The timing and availability of such financing are not yet known. 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 our planned adaptive Phase 2/3 trial to evaluate azeliragon as a potential treatment of mild-AD in patients with type 2 diabetes;
- the willingness of the FDA to rely upon our completed and planned clinical and preclinical studies and other work, as the basis for review and approval of our drug candidates;

- 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 M&F TTP Holdings Two LLC 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 other than those available through the Letter Agreements. However, we are evaluating several financing strategies to fund the proposed clinical trial of azeliragon for the treatment of mild-AD in patients with type 2 diabetes, including direct equity investments and future public offerings of our common stock. 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 that will further limit or restrict 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 obtain additional funding, we could be forced to delay, reduce or eliminate our research and development programs or commercialization efforts, which could adversely affect our business prospects.

Off-Balance Sheet Arrangements

We have entered into the December Letter Agreement with M&F Group which, as of December 31, 2018, provide us the right to sell to M&F Group an additional 4,619,566 shares of our Class A Common Stock at a price equal to $1.84 per share. Further, M&F Group has the right (exercisable up to three times) to require us to sell to it shares of Class A Common Stock at the same price. As of December 31, 2018, we had received funding of $21.5 million under the Letter Agreements and, in exchange, had issued a total of 10,617,119 shares of our Class A Common Stock.

Discussion of Critical Accounting Policies

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, we believe that the following accounting policies related to revenue recognition, research and

development, income taxes, and share-based compensation are the most critical for fully understanding and evaluating our financial condition and results of operations.

Basis of Presentation

The Company is a holding company, and its principal asset is a controlling equity interest in vTv LLC, the Company's principal operating subsidiary. The Company has determined that vTv LLC is a VIE for accounting purposes and that the Company is the primary beneficiary of vTv LLC because (through its managing member interest in vTv LLC and the fact that the senior management of the Company is also the senior management of vTv LLC) it has the power to direct all of the activities of vTv LLC, which include those that most significantly impact vTv LLC's economic performance. The Company has therefore consolidated vTv LLC's results under the VIE accounting model in its consolidated financial statements.

Revenue Recognition

The majority of our revenue results from its license and collaboration agreements associated with the development of investigational drug products. We account for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. For each contract meeting these criteria, we identify the performance obligations included within the contract. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. We then recognize revenue under each contract as the related performance obligations are satisfied.

The transaction price under the contract is determined based on the value of the consideration expected to be received in exchange for the transferred assets or services. Development, regulatory and sales milestones included in our collaboration agreements are considered to be variable consideration. The amount of variable consideration expected to be received is included in the transaction price when it becomes probable that the milestone will be met. For contracts with multiple performance obligations, the contract's transaction price is allocated to each performance obligation using our best estimate of the standalone selling price of each distinct good or service in the contract. The primary method used to estimate standalone selling price is the expected cost plus margin approach. Revenue is recognized over the related period over which we expect the services to be provided using a proportional performance model or a straight-line method of recognition if there is no discernable pattern over which the services will be provided.

See Note 2 "Summary of Significant Accounting Policies", to the Consolidated Financial Statements in Item 15 of Part IV of this Annual Report on Form 10-K for further information regarding the adoption of ASC Topic 606, "Revenue From Contracts With Customers" and the related changes in the recognition of revenue that were adopted on January 1, 2018.

Research and Development

Major components of research and development costs include cash compensation, 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 similar conditions. The objective of our accrual policy is to match the recording of expenses in our 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 we make 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.

Income Taxes

In connection with the IPO, vTv Therapeutics Inc. was formed. From August 1, 2015, vTv Therapeutics Inc. has been subject to corporate level income taxes. Prior to July 30, 2015, our predecessor entities were taxed as partnerships and all their income and deductions flowed through and were subject to tax at the partner level.

vTv Therapeutics Inc. holds vTv Units and is required to recognize deferred tax assets and liabilities for the difference between the financial reporting and tax basis of its investment in vTv LLC.

Our income tax expense, deferred tax assets and liabilities and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. We are subject to income taxes in both the United States and various state jurisdictions. Significant judgments and estimates are required in determining the consolidated income tax expense.

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events included in the financial statements. Under this method, we determine deferred tax assets and liabilities on the basis of differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period in which the enactment date occurs.

We recognize deferred tax assets to the extent we believe these assets are more-likely-than-not to be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent results of operations.

We record uncertain tax positions on the basis of a two-step process in which (1) we determine whether it is more-likely-than-not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions meeting the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

Interest and penalties related to income taxes are included in the benefit (provision) for income taxes in our Consolidated Statement of Operations. We have not incurred any significant interest or penalties related to income taxes in any of the periods presented.

On December 22, 2017, the US government enacted comprehensive tax reform commonly referred to as the Tax Cuts and Jobs Act ("TCJA"). Under ASC 740, the effects of changes in tax rates and laws are recognized in the period which the new legislation is enacted. Among other things, the TCJA (1) reduced the US statutory corporate income tax rate from 35% to 21% effective January 1, 2018, (2) eliminated the corporate alternative minimum tax, (3) eliminated the Section 199 deduction, and (4) changed rules related to uses and limitations of net operating loss carryforwards beginning after December 31, 2017.

The SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118"), which provides guidance on accounting for the tax effects of TCJA. The purpose of SAB 118 was to address any uncertainty or diversity of view in applying ASC 740 in the reporting period in which the TCJA was enacted. Additionally, SAB 118 provided a measurement period that should not extend beyond one year from the TCJA enactment date for companies to complete the accounting under ASC 740. Based on the reduced corporate tax rate of 21%, we recorded a provisional decrease in its deferred tax assets of $5.8 million with a corresponding adjustment to the valuation allowance during the year ended December 31, 2017. During 2018, we finalized the accounting for the tax effects of TCJA with no material changes to the provisional estimate recorded.

Share-Based Compensation

Compensation expense for share-based compensation awards issued is based on the fair value of the award at the date of grant, and compensation expense is recognized for those awards earned over the service period. The grant date fair value of stock option awards is estimated using the Black-Scholes option pricing formula. Due to the lack of sufficient historical trading information with respect to our own shares, we estimate expected volatility based on the

historical volatility of our own stock coupled with a portfolio of selected stocks of companies believed to have market and economic characteristics similar to our own. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. Due to a lack of historical exercise data, we estimate the expected life of our outstanding stock options using the simplified method specified under Staff Accounting Bulletin Topic 14.D.2. The fair value of restricted stock units ("RSU") grants are based on the market value of our Class A Common Stock on the date of grant. We also estimate the amount of share-based awards that are expected to be forfeited based on historical employee turnover rates.

Effect of Recent Accounting Pronouncements

See discussion of recent accounting pronouncements in Note 2, "Summary of Significant Accounting Policies", to the Consolidated Financial Statements in Item 15 of Part IV of this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our Loan Agreement bears interest at a floating rate equal to 10.5% plus the amount by which the one-month London Interbank Offer Rate ("LIBOR") exceeds 0.5%. A one percent increase in the variable rate of interest on the Loan Agreement would increase interest expense by approximately $0.2 million annually based on the amounts currently outstanding. We do not currently hedge our interest rate exposure.

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. 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.

Foreign Currency Risk

We do not have any material foreign currency exposure.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item is included in our Financial Statements and Supplementary Data listed in Item 15 of Part IV of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, management has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934) as of December 31, 2018. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2018, our disclosure controls and procedures were effective in causing material information relating to us (including our consolidated subsidiaries) to be recorded, processed, summarized and reported by management on a timely basis and to ensure the quality and timeliness of our public disclosures with SEC disclosure obligations.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, with the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error and mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of controls.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or because the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance

with generally accepted accounting principles. Our internal control over financial reporting includes those written policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles;
- provide reasonable assurance that receipts and expenditures are being made only in accordance with management and director authorization; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. Management based this assessment on criteria described in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management determined that as of December 31, 2018, we maintained effective internal control over financial reporting.

Changes to Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Website Availability of Reports and other Corporate Governance Information

The Company maintains a comprehensive corporate governance program, including Corporate Governance Guidelines for its Board of Directors, Board Guidelines for Assessing Director Independence and charters for its Audit Committee, Nominating and Corporate Governance Committee and Compensation Committee. The Company maintains a corporate website, www.vtvtherapeutics.com, where stockholders and other interested persons may review, without charge, among other things, corporate governance materials and certain SEC filings, which are generally available on the same business day as the filing date with the SEC on the SEC's website http://www.sec.gov. The contents of our website are not made a part of this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION
None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE
The information required by this item is incorporated by reference to our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2018.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2018.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2018.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2018.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2018.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The following documents are included on pages F-1 through F-27 attached hereto and are filed as part of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

Not applicable

(a)(3) List of Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference from Exhibit 3.1 to the Company's Form 8-K, filed August 4, 2015 (File No. 001-37524)).
3.2	Amended and Restated By-laws (incorporated by reference from Exhibit 3.2 to the Company's Form 8-K, filed August 4, 2015 (File No. 001-37524)).
4.1	Form of Warrant to Purchase Class A Common Stock (incorporated by reference from Exhibit 4.1 to the Company's Form 10-K, filed February 24, 2017 (File No. 001-37524)).
4.2	Common Stock Purchase Warrant (incorporated by reference from Exhibit 4.2 to the Company's Form 10-K, filed February 27, 2018 (File No. 001-37524)).
10.1	Reimbursement of Fees and Expenses Letter Agreement, dated July 16, 2015, by and between vTv Therapeutics Inc. and MacAndrews & Forbes Group, LLC (incorporated by reference from Exhibit 10.6 to Amendment No. 5 to the Company's Registration Statement on Form S-1, filed July 23, 2015 (File No. 333-204951)).
10.2	Reorganization Agreement, dated as of July 29, 2015, among vTv Therapeutics Inc., vTv Therapeutics LLC, vTvx Holdings I LLC, vTvx Holdings II LLC and vTv Therapeutics Holdings LLC (incorporated by reference from Exhibit 10.1 to the Company's Form 8-K, filed August 4, 2015 (File No. 001-37524)).

10.3	Amended and Restated Limited Liability Company Agreement of vTv Therapeutics LLC, dated July 29, 2015 (incorporated by reference from Exhibit 10.2 to the Company's Form 8-K, filed August 4, 2015 (File No. 001-37524)).
10.4	Investor Rights Agreement, dated as of July 29, 2015, among vTv Therapeutics Inc., vTv Therapeutics Holdings LLC and other stockholders party thereto from time to time (incorporated by reference from Exhibit 10.3 to the Company's Form 8-K, filed August 4, 2015 (File No. 001-37524)).
10.5	Exchange Agreement, dated as of July 29, 2015, among vTv Therapeutics LLC, vTv Therapeutics Inc. and vTv Therapeutics Holdings LLC (incorporated by reference from Exhibit 10.4 to the Company's Form 8-K, filed August 4, 2015 (File No. 001-37524)).
10.6	Tax Receivable Agreement, dated as of July 29, 2015, among vTv Therapeutics Inc. and the other persons named therein (incorporated by reference from Exhibit 10.5 to the Company's Form 8-K, filed August 4, 2015 (File No. 001-37524)).
10.7	Form of Indemnification Agreement (incorporated by reference from Exhibit 10.7 to Amendment No. 4 to the Company's Registration Statement on Form S-1, dated July 23, 2015 (File No. 333-204951)).
10.8†	Executive Chairman Agreement, dated as of July 16, 2015, by and between vTv Therapeutics Inc. and Jeff Kindler (incorporated by reference from Exhibit 10.13 to Amendment No. 4 to the Company's Registration Statement on Form S-1, filed July 20, 2015 (File No. 333-204951)).

Exhibit Number	Description
10.9†	Employment Agreement, dated as of July 16, 2015, by and between vTv Therapeutics LLC and Stephen Holcombe, and for certain limited purposes specified therein, vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.14 to Amendment No. 4 to the Company's Registration Statement on Form S-1, filed July 20, 2015 (File No. 333-204951)).
10.10†	Employment Agreement, dated as of July 16, 2015, by and between vTv Therapeutics LLC and Rudy Howard, and for certain limited purposes specified therein, vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.15 to Amendment No. 4 to the Company's Registration Statement on Form S-1, filed July 20, 2015 (File No. 333-204951)).
10.11†	vTv Therapeutics Inc. 2015 Omnibus Equity Incentive Plan (incorporated by reference from Exhibit 10.6 to the Company's Form 8-K, filed August 4, 2015 (File No. 001-37524)).
10.12†	vTv Therapeutics Inc. Form of Nonqualified Option Award Agreement (incorporated by reference from Exhibit 10.7 to the Company's Form 8-K, filed August 4, 2015 (File No. 001-37524)).

Exhibit Number	Description
10.13†	Employment Agreement, dated as of December 1, 2015, by and between vTv Therapeutics LLC and Larry Altstiel, and for certain limited purposes specified therein, vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.13 to the Company's Form 10-K, filed March 4, 2016 (File No. 001-37524)).
10.14††	Agreement Concerning Glucokinase Activator Project, dated as of February 20, 2007, by and between Novo Nordisk A/S and TransTech Pharma, Inc. (incorporated by reference from Exhibit 10.8 to Amendment No. 1 to the Company's Registration Statement on Form S-1, dated June 19, 2015 (File No. 333-204951)).
10.15††	New Exclusive License Agreement, dated May 14, 2015, by and between The Trustees of Columbia University in the City of New York and TransTech Pharma, LLC (incorporated by reference from Exhibit 10.9 to Amendment No. 1 to the Company's Registration Statement on Form S-1, dated July 23, 2015 (File No. 333-204951)).
10.16††	Venture Loan and Security Agreement dated as of October 28, 2016 by and among the Company, vTv Therapeutics LLC, Horizon Technology Finance Corporation and Silicon Valley Bank (incorporated by reference from Exhibit 4.1 to the Company's Form 10-K, filed February 24, 2017 (File No. 001-37524)).
10.17	First Amendment of Venture Loan and Security Agreement and Consent, dated as of December 20, 2017, by and among the Company, vTv Therapeutics LLC, Horizon Credit II LLC and Silicon Valley Bank (incorporated by reference from Exhibit 10.17 to the Company's Form 10-K, filed February 27, 2018 (File No. 001-37524)).
10.18	Letter Agreement, dated as of December 5, 2017, by and between MacAndrews & Forbes Group LLC and vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.18 to the Company's Form 10-K, filed February 27, 2018 (File No. 001-37524)).
10.19††	License and Research Agreement, dated as of December 21, 2017, by and between Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. And vTv Therapeutics LLC (incorporated by reference from Exhibit 10.19 to the Company's Form 10-K, filed February 27, 2018 (File No. 001-37524)).
10.20††	License and Research Agreement, dated as of December 21, 2017, by and between Reneo Pharmaceuticals, Inc. and vTv Therapeutics LLC (incorporated by reference from Exhibit 10.20 to the Company's Form 10-K, filed February 27, 2018 (File No. 001-37524)).
10.21††	License Agreement, dated as of May 31, 2018, by and between Newsoara Biopharma Co., Ltd. and vTv Therapeutics LLC (incorporated by reference from Exhibit 10.1 to the Company's Form 10-Q, filed August 3, 2018 (File No. 001-37524)).
10.22	Form of Securities Purchase Agreement to Purchase Class A Common Stock, under the December 5, 2017 Letter Agreement, by and between MacAndrews & Forbes Group LLC and vTv Therapeutics LLC (incorporated by reference from Exhibit 10.2 to the Company's Form 10-Q, filed August 3, 2018 (File No. 001-37524)).
10.23	Letter Agreement, dated as of July 30, 2018, by and between MacAndrews & Forbes Group LLC and vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.1 to the Company's Form 10-Q, filed November 8, 2018 (File No. 001-37524)).

	Form of Securities Purchase Agreement to Purchase Class A Common Stock, under the July 30, 2018 Letter Agreement, by and between MacAndrews & Forbes Group LLC and vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.2 to the Company's Form 10-Q, filed November 8, 2018 (File No. 001-37524)).
10.24*	Letter Agreement, dated as of December 11, 2018, by and between MacAndrews & Forbes Group LLC and vTv Therapeutics Inc.
10.25*	Form of Securities Purchase Agreement to Purchase Class A Common Stock, under the December 11, 2018 Letter Agreement, by and between MacAndrews & Forbes Group LLC and vTv Therapeutics Inc.
21.1*	Subsidiaries of vTv Therapeutics Inc.
23.1*	Consent of Ernst & Young LLP, Independent Registered Pubic Accounting Firm.
31.1*	Certification of President and Chief Executive Officer required by Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer required by Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit Number	Description
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	XBRL Taxonomy Extension Definition Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase

† Management contract or compensatory plan or arrangement
‡ Confidential treatment received with respect to portions of this exhibit.
* Filed herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 26, 2019

VTV THERAPEUTICS INC.
(Registrant)

By: /s/ Stephen L. Holcombe
Stephen L. Holcombe
President and Chief Executive Officer

By: /s/ Rudy C. Howard
Rudy C. Howard
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Jeffrey B. Kindler Jeffrey B. Kindler	Executive Chairman	February 26, 2019
/s/ Stephen L. Holcombe Stephen L. Holcombe	President and Chief Executive Officer (Principal Executive Officer)	February 26, 2019
/s/ Rudy C. Howard Rudy C. Howard	Chief Financial Officer (Principal Financial and Accounting Officer)	February 26, 2019
/s/ Steven M. Cohen Steven M. Cohen	Director	February 26, 2019
/s/ John A. Fry John A. Fry	Director	February 26, 2019
/s/ Craig C. Parker Craig C. Parker	Director	February 26, 2019
/s/ Paul G. Savas Paul G. Savas	Director	February 26, 2019
/s/ Noel J. Spiegel Noel J. Spiegel	Director	February 26, 2019
/s/ Howard L. Weiner Howard L. Weiner	Director	February 26, 2019

INDEX TO FINANCIAL STATEMENTS

The financial statements and other disclosures contained in this report include those of vTv Therapeutics Inc. ("we", the "Company" or the "Registrant"), which is the registrant, and those of vTv Therapeutics LLC ("vTv LLC"), which is the principal operating subsidiary of the Registrant. Unless the context suggests otherwise, references in this Annual Report on Form 10-K to the "Company", "we", "us" and "our" refer to vTv Therapeutics Inc. and its consolidated subsidiaries.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of vTv Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of vTv Therapeutics Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, changes in redeemable noncontrolling interest and stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, to date, the Company has not generated any product revenue, has not achieved profitable operations, has insufficient liquidity to sustain operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2000.

Raleigh, North Carolina

February 26, 2019

vTv Therapeutics Inc.

Consolidated Balance Sheets

(dollars in thousands, except per share and share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 1,683	$ 11,758
Restricted cash and cash equivalents	—	162
Accounts receivable, net	—	8,000
Prepaid expenses and other current assets	666	442
Current deposits	1,124	—
Total current assets	3,473	20,362
Restricted cash and cash equivalents, long-term	2,500	2,500
Property and equipment, net	70	283
Long-term investments	2,480	2,480
Long-term deposits	36	2,292
Total assets	$ 8,559	$ 27,917
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,702	$ 13,901
Current portion of deferred revenue	1,752	8,757
Current portion of notes payable	9,383	4,271
Total current liabilities	18,837	26,929
Notes payable, net of current portion	6,330	15,316
Deferred revenue, net of current portion	1,067	4,497
Warrant liability, related party	2,436	492
Other liabilities	260	290
Total liabilities	28,930	47,524
Commitments and contingencies		
Redeemable noncontrolling interest	62,482	131,440
Stockholders' deficit:		
Class A Common Stock, $0.01 par value; 100,000,000 shares authorized, 20,347,065 and 9,693,254 shares outstanding as of December 31, 2018 and December 31, 2017, respectively	203	97
Class B Common Stock, $0.01 par value; 100,000,000 shares authorized, 23,094,221 and 23,119,246 shares outstanding as of December 31, 2018 and December 31, 2017, respectively	232	232
Additional paid-in capital	150,595	127,682
Accumulated deficit	(233,883)	(279,058)
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(82,853)	(151,047)
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	$ 8,559	$ 27,917

The accompanying notes are an integral part of the consolidated financial statements.

vTv Therapeutics Inc.

Consolidated Statements of Operations

(in thousands, except per share and share data)

	Years Ending December 31,		
	2018	2017	2016
Revenue	$12,434	$291	$634
Operating expenses:			
Research and development	23,035	39,640	44,953
Research and development – related party	—	—	795
General and administrative	9,223	11,333	9,906
Total operating expenses	32,258	50,973	55,654
Operating loss	(19,824)	(50,682)	(55,020)
Other income (loss)	46	—	(22)
Other expense – related party	(638)	(190)	—
Interest income	61	117	87
Interest expense	(3,290)	(3,092)	(398)
Loss before income taxes and noncontrolling interest	(23,645)	(53,847)	(55,353)
Income tax provision	200	800	—
Net loss before noncontrolling interest	(23,845)	(54,647)	(55,353)
Less: net loss attributable to noncontrolling interest	(15,934)	(38,503)	(39,001)
Net loss attributable to vTv Therapeutics Inc.	$(7,911)	$(16,144)	$(16,352)
Net loss attributable to vTv Therapeutics Inc. common shareholders	$(8,650)	$(16,144)	$(16,352)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	$(0.69)	$(1.67)	$(1.71)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	12,449,236	9,693,254	9,545,527

The accompanying notes are an integral part of the consolidated financial statements.

vTv Therapeutics Inc.

Consolidated Statements of Changes in Redeemable Noncontrolling Interest and Stockholders' Deficit

(in thousands, except share data)

	Redeemable Noncontrolling Interest	Class A Common Stock Shares	Class A Common Stock Amount	Class B Common Stock Shares	Class B Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balances at December 31, 2015	$ 161,531	9,156,686	$ 92	23,655,814	$ 237	$ 117,686	$ (195,985)	$ (77,970)
Net loss	(39,001)	—	—	—	—	—	(16,352)	(16,352)
Share-based compensation	—	—	—	—	—	2,641	—	2,641
Issuance of warrants to purchase Class A Common Stock	—	—	—	—	—	721	—	721
Exchange of Class B Common Stock for Class A Common Stock	(3,164)	536,568	5	(536,568)	(5)	3,164	—	3,164
Change in redemption value of noncontrolling interest	3,149	—	—	—	—	—	(3,149)	(3,149)
Balances at December 31, 2016	122,515	9,693,254	97	23,119,246	232	124,212	(215,486)	(90,945)
Net loss	(38,503)	—	—	—	—	—	(16,144)	(16,144)
Share-based compensation	—	—	—	—	—	3,645	—	3,645
Issuance of warrants to purchase Class A Common Stock	—	—	—	—	—	167	—	167
Issuance of Letter Agreement and warrants to purchase Class A Common Stock -	—	—	—	—	—	(342)	—	(342)

related party								
Change in redemption value of noncontrolling interest	47,428	—	—	—	—	—	(47,428)	(47,428)
Balances at December 31, 2017	131,440	9,693,254	97	23,119,246	232	127,682	(279,058)	(151,047)
Net loss	(15,934)	—	—	—	—	—	(7,911)	(7,911)
Cumulative effect of accounting change	—	—	—	—	—	—	213	213
Share-based compensation	—	—	—	—	—	2,676	—	2,676
Exchange of Class B Common Stock for Class A Common Stock	(151)	25,025	—	(25,025)	—	151	—	151
Issuance of Class A Common Stock to a related party under the Letter Agreements	—	10,617,119	106	—	—	21,394	—	21,500
Issuance of Letter Agreement and warrants to purchase Class A Common Stock - related party	—	—	—	—	—	(1,308)	—	(1,308)
Vesting of restricted stock units	—	11,667	—	—	—	—	—	—
Change in redemption value of noncontrolling interest	(52,873)	—	—	—	—	—	52,873	52,873
Balances at December 31, 2018	$ 62,482	20,347,065	$ 203	23,094,221	$ 232	$ 150,595	$ (233,883)	$ (82,853)

The accompanying notes are an integral part of the consolidated financial statements.

vTv Therapeutics Inc.

Consolidated Statements of Cash Flows

(in thousands)

	2018	2017	2016
Cash flows from operating activities:			
Net loss before noncontrolling interest	$(23,845)	$(54,647)	$(55,353)
Adjustments to reconcile net loss before noncontrolling interest to net cash used in operating activities:			
Gain on disposal of property and equipment, net	(12)	(11)	(2)
Depreciation expense	218	197	265
Share-based compensation expense	2,676	3,645	2,641
Change in fair value of warrants, related party	638	190	—
Amortization of debt discount	1,014	1,029	154
Changes in assets and liabilities:			
Accounts receivable	8,000	(8,000)	69
Prepaid expenses and other assets	(1,135)	170	502
Employee loans receivable – related party	—	—	49
Long-term deposits	2,256	(358)	(261)
Accounts payable and accrued expenses	(6,199)	2,448	4,786
Accounts payable and accrued expenses – related party	—	—	(880)
Deferred revenue	(10,435)	10,753	(198)
Other liabilities	(32)	24	19
Net cash used in operating activities	(26,856)	(44,560)	(48,209)
Cash flows from investing activities:			
Proceeds from sale of assets	12	32	4
Purchases of property and equipment	(5)	(57)	(87)
Net cash provided by (used in) investing activities	7	(25)	(83)
Cash flows from financing activities:			
Issuance of Class A Common Stock to a related party under the Letter Agreements	21,500	—	—
Proceeds from debt issuance	500	7,500	12,500
Debt issuance costs	—	—	(673)
Repayment of notes payable	(5,388)	—	(33)
Net cash provided by financing activities	16,612	7,500	11,794
Net decrease in cash, cash equivalents and restricted cash and cash equivalents	(10,237)	(37,085)	(36,498)
Total cash, cash equivalents and restricted cash and cash equivalents, beginning of year	14,420	51,505	88,003
Total cash, cash equivalents and restricted cash and cash equivalents, end of year	$4,183	$14,420	$51,505
Supplemental cash flow information:			
Cash paid for interest	$2,276	$2,064	$242
Cash paid for income taxes	$1,000	$—	$—
Non-cash activities:			
Receipt of investment as partial consideration for license agreement	$—	$2,480	$—
Change in redemption value of noncontrolling interest	$(52,873)	$47,428	$3,149

Exchange of vTv Therapeutics Inc. Class B Common Stock and vTv Therapeutics, LLC			
member units for vTv Therapeutics Inc. Class A Common Stock	$151	$—	$3,164
Issuance of Letter Agreements and warrants to purchase vTv Therapeutics Inc. Class A			
Common Stock to a related party	$1,308	$302	$—
Issuance of warrants to purchase vTv Therapeutics Inc. Class A Common Stock	$—	$—	$923

The accompanying notes are an integral part of the consolidated financial statements.

vTv Therapeutics Inc.

Notes to Consolidated Financial Statements

(dollar amounts are in thousands, unless otherwise noted)

Note 1: Description of Business and Basis of Presentation

Description of Business

vTv Therapeutics Inc. (the "Company," the "Registrant," "we" or "us"), was incorporated in the state of Delaware in April 2015. The Company was formed to discover and develop orally administered small molecule drug candidates to fill significant unmet medical needs.

Principles of Consolidation

vTv Therapeutics Inc. is a holding company, and its principal asset is a controlling equity interest in vTv Therapeutics LLC ("vTv LLC"), the Company's principal operating subsidiary, which is a clinical-stage biopharmaceutical company engaged in the discovery and development of orally administered small molecule drug candidates to fill significant unmet medical needs.

The Company has determined that vTv LLC is a variable-interest entity ("VIE") for accounting purposes and that vTv Therapeutics Inc. is the primary beneficiary of vTv LLC because (through its managing member interest in vTv LLC and the fact that the senior management of vTv Therapeutics Inc. is also the senior management of vTv LLC) it has the power and benefits to direct all of the activities of vTv LLC, which include those that most significantly impact vTv LLC's economic performance. vTv Therapeutics Inc. has therefore consolidated vTv LLC's results pursuant to Accounting Standards Codification Topic 810, "Consolidation" in its Consolidated Financial Statements. Various holders own non-voting interests in vTv LLC, representing a 53.2% economic interest in vTv LLC, effectively restricting vTv Therapeutics Inc.'s interest to 46.8% of vTv LLC's economic results, subject to increase in the future, should vTv Therapeutics Inc. purchase additional nonvoting common units ("vTv Units") of vTv LLC or should the holders of vTv Units decide to exchange such units (together with shares of the Company's Class B common stock, par value $0.01 ("Class B Common Stock")) for shares of Class A Common Stock (or cash) pursuant to the Exchange Agreement among the Company, vTv LLC and the holders of vTv Units party thereto (the "Exchange Agreement"). vTv Therapeutics Inc. has provided financial and other support to vTv LLC in the form of its purchase of vTv Units with the net proceeds of the IPO in 2015, its agreeing to be a co-borrower under the Venture Loan and Security Agreement (the "Loan Agreement") with Horizon Technology Finance Corporation and Silicon Valley Bank (together, the "Lenders") which was entered into in 2016 and its entrance into the letter agreements with MacAndrews and Forbes Group LLC ("M&F Group"), a related party and an affiliate of MacAndrews & Forbes Incorporated (together with its affiliates "MacAndrews"), in December 2017, July 2018 and December 2018 (the "Letter Agreements"). vTv Therapeutics Inc. will not be required to provide financial or other support for vTv LLC outside of its obligations pertaining to the Loan Agreement as a co-borrower. However, vTv Therapeutics Inc. will control its business and other activities through its managing member interest in vTv LLC, and its management is the management of vTv LLC. The creditors of vTv LLC do not have any recourse to the general credit of vTv Therapeutics Inc. except as allowed under the provisions of the Loan Agreement. Nevertheless, because vTv Therapeutics Inc. will have no material assets other than its interests in vTv LLC, any financial difficulties at vTv LLC could result in vTv Therapeutics Inc. recognizing a loss.

Going Concern and Liquidity

To date, the Company has not generated any product revenue and has not achieved profitable operations. The continuing development of the Company's drug candidates will require additional financing. From its inception through December 31, 2018, the Company has funded its operations primarily through a combination of debt and equity financings, research collaboration agreements, upfront and milestone payments for license agreements and private placements of preferred equity. As of December 31, 2018, the Company had an accumulated deficit of $233.9 million and has generated net losses in each year of its existence. The Company's currently available sources of liquidity include the Company's cash and cash equivalents balance as of December 31, 2018 of $1.7 million and the $8.5 million of remaining funds available under the Letter Agreements, which management believes will allow the Company to continue its operations and activities for a period of less than twelve months from the issuance of these Consolidated Financial Statements.

Based on the Company's current operating plan, management believes that the current cash and cash equivalents and remaining funds under the Letter Agreements will allow the Company to meet its liquidity requirements into March 2019. These conditions raise substantial doubt about the Company's ability to continue as a going concern. While both studies within the Phase 3 STEADFAST study failed to meet their co-primary endpoints, we have initiated start-up activities for an adaptive Phase 2/3 trial to evaluate azeliragon as a potential treatment of mild-AD in patients with type 2 diabetes. The Company is evaluating several financing

strategies to fund this clinical trial, including direct equity investments and future public offerings of our common stock. The timing and availability of such financing are not yet known.

The Company's financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Consolidated Financial Statements do not include adjustments to reflect the possible future effects on the recoverability and classification of recorded assets or the amounts of liabilities that might be necessary should the Company be unable to continue as a going concern.

Note 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 grant date fair value of equity awards, the fair value of warrants to purchase shares of its Class A Common Stock, the fair value of its Class B Common Stock, the useful lives of property and equipment 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.

Reclassifications

To facilitate comparison of information across periods, certain reclassifications have been made to prior period amounts to conform to the current period's presentation.

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 these cash accounts frequently exceed insured limits.

Accounts receivable as of December 31, 2017, consisted entirely of the upfront payment due in connection with the License Agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("Huadong") (the "Huadong License Agreement") which was fully received in January 2018. There were no accounts receivable at December 31, 2018 and 2016.

Three customers represented 100% of the revenue earned during the year ended December 31, 2018. Four customers represented 100% of the revenue earned during the year ended December 31, 2017. Two customers represented 100% of the revenue earned during the year ended December 31, 2016.

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 that has been received through a research, development and commercialization agreement with JDRF International ("JDRF") (the "JDRF Agreement") but has not yet been utilized to fund the development activities required under the JDRF Agreement. Restricted cash and cash equivalents, long-term relates to the minimum balance that the Company must maintain in a deposit account pledged to secure the Loan Agreement and subject to an account control agreement pursuant to the Loan Agreement, as amended.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Consolidated Balance Sheets as of December 31, 2018 and 2017 that sum to the total of the same such amounts shown in the Consolidated Statements of Cash Flows (in thousands):

	2018	2017
Cash and cash equivalents	$1,683	$11,758
Restricted cash and cash equivalents	—	162
Restricted cash and cash equivalents, long-term	2,500	2,500
Total cash, cash equivalents and restricted cash and cash equivalents shown in the consolidated statement of cash flows	$4,183	$14,420

Collaboration Revenue and Accounts Receivable

The majority of the Company's collaboration revenue and accounts receivable relates to its agreements to license certain of its potential drug products for development. See Note 3 for further discussion of the Company's collaboration agreements.

Accounts receivable are stated at net realizable value. 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.

Property and Equipment and other Long-lived Assets

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:

Asset Category	Useful Life (in years)
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

The Company periodically assesses it property and equipment and other long-lived assets for impairment in accordance with the relevant accounting guidance and recorded an impairment charge of $0.1 million during the year ended December 31, 2018. No such charges were recognized during the years ended December 31, 2017 and 2016. There were no assets held for sale at December 31, 2018 or 2017.

Investments

In connection with the Reneo License Agreement, the Company received common stock and certain participation rights representing a minority equity interest in Reneo that is classified as a long-term investment in the Company's Consolidated Balance Sheet as of December 31, 2017. Upon acquisition, on December 21, 2017, this investment was recognized at its fair value of $2.5 million. This investment is accounted for under the cost method because the

Company owns less than 20% of the voting equity and does not have the ability to exercise significant influence over Reneo.

On January 1, 2018, the Company adopted ASU No. 2016-01, “Recognition and Measurement of Financial Assets and Financial Liabilities”. This guidance requires equity investments to be measured at fair value with changes in fair value recognized in net income. Since it does not have a readily determinable market value, the Company has elected to measure its investment in Reneo at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment.

No adjustments have been made to the value of the Company’s investment in Reneo since its acquisition either due to impairment or based on observable price changes.

Revenue Recognition

On January 1, 2018, the Company adopted ASC Topic 606, "Revenue From Contracts With Customers" ("ASC Topic 606"), using the modified retrospective method applied to those contracts which were not completed as of the adoption date. Results for reporting periods beginning after January 1, 2018 are presented under ASC Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting under ASC Topic 605.

The Company recorded a net reduction to its opening accumulated deficit of $0.2 million as of January 1, 2018 due to the cumulative impact of adopting ASC Topic 606. This impact related to the recognition of an asset for the incremental costs of obtaining contracts.

The majority of the Company's revenue results from its license and collaboration agreements associated with the development of investigational drug products. The Company accounts for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. For each contract meeting these criteria, the Company identifies the performance obligations included within the contract. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. The Company then recognizes revenue under each contract as the related performance obligations are satisfied.

The transaction price under the contract is determined based on the value of the consideration expected to be received in exchange for the transferred assets or services. Development, regulatory and sales milestones included in the Company's collaboration agreements are considered to be variable consideration. The amount of variable consideration expected to be received is included in the transaction price when it becomes probable that the milestone will be met. For contracts with multiple performance obligations, the contract's transaction price is allocated to each performance obligation using the Company's best estimate of the standalone selling price of each distinct good or service in the contract. The primary method used to estimate standalone selling price is the expected cost plus margin approach. Revenue is recognized over the related period over which the Company expects the services to be provided using a proportional performance model or a straight-line method of recognition if there is no discernable pattern over which the services will be provided.

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.

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. Research and development costs 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 Consolidated Statements of Operations as the Company receives the related goods or services.

Research and development costs that are reimbursed under a cost-sharing arrangement are reflected as a reduction of research and development expense.

Patent Costs

Patent costs, including related legal costs, are expensed as incurred and recorded within general and administrative operating expenses on the Consolidated Statements of Operations.

Income Taxes

From its formation on August 1, 2015, vTv Therapeutics Inc. has been subject to corporate level income taxes. Prior to July 30, 2015, the Company's predecessor entities were taxed as partnerships and all their income and deductions flowed through and were subject to tax at the partner level.

vTv Therapeutics Inc. is required to recognize deferred tax assets and liabilities for the difference between the financial reporting and tax basis of its investment in vTv LLC.

The Company's income tax expense, deferred tax assets and liabilities and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. The Company is subject to income taxes in both the United States and various state jurisdictions. Significant judgments and estimates are required in determining the consolidated income tax expense.

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period in which the enactment date occurs.

The Company recognizes deferred tax assets to the extent it believes these assets are more-likely-than-not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent results of operations.

The Company records uncertain tax positions on the basis of a two-step process in which (1) it determines whether it is more-likely-than-not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions meeting the more-likely-than-not recognition threshold, it recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

Interest and penalties related to income taxes are included in the benefit (provision) for income taxes in the Company's Consolidated Statements of Operations. The Company has not incurred any significant interest or penalties related to income taxes in any of the periods presented.

Noncontrolling Interest

The Company records the redeemable noncontrolling interest represented by the vTv Units and the Class B Common stock at the higher of (1) its initial fair value plus accumulated earnings/losses associated with the noncontrolling

interest or (2) the redemption value as of the balance sheet date. See discussion and additional detail of the redeemable noncontrolling interest at Note 11.

Segment and Geographic Information

Operating segments are defined as an enterprise's components (business activities from which it earns revenue and incurs expenses) for which discrete financial information is (1) available; and (2) 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 Executive Officer. The Company's business operates in one reportable segment comprised of one operating segment.

Share-Based Compensation

Compensation expense for share-based compensation awards issued is based on the fair value of the award at the date of grant, and compensation expense is recognized for those awards earned over the service period. The grant date fair value of stock option awards is estimated using the Black-Scholes option pricing formula. Due to the lack of sufficient historical trading information with

respect to its own shares, the Company estimates expected volatility based on the historical volatility of its own stock as well as a portfolio of selected stocks of companies believed to have market and economic characteristics similar to its own. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. Due to a lack of historical exercise data, the Company estimates the expected life of its outstanding stock options using the simplified method specified under Staff Accounting Bulletin Topic 14.D.2. The fair value of restricted stock units ("RSU") grants are based on the market value of the Class A Common Stock on the date of grant. The Company also estimates the amount of share-based awards that are expected to be forfeited based on historical employee turnover rates.

Comprehensive Income

The Company does not have any components of other comprehensive income recorded within its Consolidated Financial Statements, and, therefore, does not separately present a statement of comprehensive income in its Consolidated Financial Statements.

Recently Issued Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue From Contracts With Customers", that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The Company adopted this guidance as of January 1, 2018 using the modified retrospective transition method. See Note 2 – "Revenue Recognition" for further details.

In January 2016, the FASB issued ASU No. 2016-01, "Recognition and Measurement of Financial Assets and Financial Liabilities", which amends ASC 825-10, "Financial Instruments – Overall". This ASU amends various aspects of the recognition, measurement, presentation and disclosure of financial instruments. This ASU is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted this guidance in the first quarter of fiscal 2018. The Company has elected to use the measurement alternative, defined as cost, less impairments, adjusted by observable price changes. The adoption of this guidance did not have a material impact on the Company's Consolidated Financial Statements. See Note 2 – "Investments" for further details.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"), which clarifies the changes to terms or conditions of a share-based payment award that require an entity to apply modification accounting. ASU 2017-09 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. The Company adopted this guidance in the first quarter of fiscal 2018. The adoption of this guidance did not have a material impact on the Company's Consolidated Financial Statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)" ("ASU 2016-02"), which increases transparency and comparability among companies accounting for lease transactions. The most significant change of this update will require the recognition by a lessee of lease assets and liabilities on its balance sheet for operating lease arrangements with lease terms greater than 12 months. This update will require a modified retrospective application which includes a number of optional practical expedients related to the identification and classification of leases commenced before the effective date. This ASU is effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2018. The adoption of this guidance will result in the recognition of additional assets and liabilities of approximately $0.3 million related to the Company's operating leases within its Consolidated Balance Sheets.

Note 3: Collaboration Agreements

Reneo License Agreement

On December 21, 2017, the Company entered into the Reneo License Agreement, under which Reneo obtained an exclusive, worldwide, sublicensable license to develop and commercialize the Company's peroxisome proliferation activated receptor delta (PPAR-) agonist program, including the compound HPP593, for therapeutic, prophylactic or diagnostic application in humans. Under the terms of the Reneo License Agreement, Reneo paid the Company an upfront cash payment of $3.0 million. The Company is eligible to receive additional potential development, regulatory and sales-based milestone payments totaling up to $94.5 million. In addition, Reneo is obligated to pay the Company royalty payments at mid-single to low-double digit rates, based on tiers of annual net sales of licensed products. Such royalties will be payable on a licensed product-by-licensed product and country-by-country basis until the latest of expiration of the licensed patents covering a licensed product in a country, expiration of data exclusivity rights for a licensed product in a country or a specified number of years after the first commercial sale of a licensed product in a country. As

additional consideration, the Company has also received common stock and certain participation rights representing a minority equity interest in Reneo.

Pursuant to the terms of the Reneo License Agreement, the Company is required to provide technology transfer services for a defined period after the effective date. In accordance with ASC Topic 606, the Company identified all of the performance obligations at the inception of the Reneo License Agreement. The significant obligations were determined to be the license and the technology transfer services. The Company has determined that the license and technology transfer services represent a single performance obligation because they were not capable of being distinct on their own. The transaction price has been fully allocated to this combined performance obligation. The remaining milestone payments that the Company is eligible to receive have not been included in the transaction price as of December 31, 2018, as it is not considered probable that such payments will be received. The unrecognized amount of the transaction price allocated to this performance obligation as of December 31, 2018 was $1.7 million.

The Company determined that there was no discernable pattern in which the technology services would be provided during the transfer services period. As such, the Company determined that the straight-line method would be used to recognize revenue over the transfer service period. The remainder of this performance obligation will be recognized over approximately 5.5 months. For the years ended December 31, 2018 and 2017, $3.7 million and $0.1 million of revenue has been recognized related to this combined performance obligation, respectively. No such amounts were recognized for the year ended December 31, 2016.

Huadong License Agreement

On December 21, 2017, the Company entered into a License Agreement with Huadong (the “Huadong License Agreement”), under which Huadong obtained an exclusive and sublicensable license to develop and commercialize the Company’s glucagon-like peptide-1 receptor agonist (“GLP-1r”) program, including the compound TTP273, for therapeutic uses in humans or animals, in China and certain other Pacific Rim countries, including Australia and South Korea (collectively, the “Huadong License Territory”). Additionally, under the Huadong License Agreement, the Company obtained a non-exclusive, sublicensable, royalty-free license to develop and commercialize certain Huadong patent rights and know-how related to the Company’s GLP-1r program for therapeutic uses in humans or animals outside of the Huadong License Territory. Under the terms of the Huadong License Agreement, Huadong paid the Company an initial license fee of $8.0 million and is obligated to pay potential development and regulatory milestone payments totaling up to $25.0 million, with an additional potential regulatory milestone of $20.0 million if Huadong receives regulatory approval for a central nervous system indication. In addition, the Company is eligible for an additional $50.0 million in potential sales-based milestones, as well as royalty payments ranging from low-single to low-double digit rates, based on tiered sales of licensed products.

Under the Huadong License Agreement, the Company is also responsible for conducting a Phase 2 multi-region clinical trial (the “Phase 2 MRCT”) including sites in both the United States and Huadong License Territory for the purpose of assessing the safety and efficacy of TTP273 in patients with type 2 diabetes. The Phase 2 MRCT will be designed to satisfy the requirements of the China Food and Drug Administration necessary in order for Huadong to begin a Phase 3 clinical trial in China. The Company will be responsible for contributing up to $3.0 million in connection with the Phase 2 MRCT.

In accordance with ASC Topic 606, the Company identified all of the performance obligations at the inception of the Huadong License Agreement. The significant performance obligations were determined to be (i) the exclusive license to develop and commercialize the Company’s GLP-1r program, (ii) technology transfer services related to the chemistry and manufacturing know-how for a defined period after the effective date (iii) the obligation to sponsor and conduct the Phase 2 MRCT, (iv) the Company’s obligation to participate on a joint development committee, and (v) other obligations considered to be de minimis in nature.

The transaction price has been allocated to these performance obligations based on their relative standalone selling prices, which were estimated using an expected cost plus margin approach. The remaining milestone payments that the Company is eligible to receive have not been included in the transaction price as of December 31, 2018, as it is not considered probable that such payments will be received.

The Company has determined that the license and technology transfer services related to the chemistry and manufacturing know-how represent a combined performance obligation because they were not capable of being distinct on their own. The Company also determined that there was no discernable pattern in which the technology transfer services would be provided during the transfer service period. As such, the Company determined that the straight-line method would be used to recognize revenue for this performance obligation over the transfer service period. In November 2018, the Company received notification from Huadong that the Company had satisfied its obligations related to the technology transfer services. As such, this performance obligation is considered complete as of December 31, 2018 and all of revenue associated with it has been recognized. For the years ended December 31, 2018 and 2017, $6.8 million and $0.1 million of revenue has been recognized related to this combined performance obligation, respectively. No such revenue was recognized for the year ended December 31, 2016.

The Company also determined that the obligation to sponsor and conduct a portion of the Phase 2 MRCT should be treated as a separate performance obligation. A portion of the total consideration received under the Huadong License Agreement was allocated

to this performance obligation based on its estimated standalone selling price. Since the Company has not yet begun the Phase 2 MRCT trial, the entire amount remains deferred as of December 31, 2018 and revenue will be recognized using the proportional performance model over the period during which the Company conducts the Phase 2 MRCT trial. The unrecognized amount of the transaction price allocated to this performance obligation as of December 31, 2018 was $1.0 million. No revenue for this performance obligation has been recognized as of December 31, 2018.

The Company also determined that the obligation to participate in the joint development committee (the "JDC") to oversee the development of products and the Phase 2 MRCT in accordance with the development plan should be treated as a separate performance obligation. A portion of the total consideration received under the Huadong License Agreement was allocated to this performance obligation based on its estimated standalone selling price. A portion of this amount remains deferred as of December 31, 2018 and revenue will be recognized using the proportional performance model over the period of the Company's participation on the JDC. An immaterial amount of revenue for this performance obligation has been recognized during the year ended December 31, 2018. The unrecognized amount of the transaction price allocated to this performance obligation as of December 31, 2018 was $0.1 million. No revenue was recognized for this performance obligation for the years ended December 31, 2017 and 2016.

Newsoara License Agreement

On May 31, 2018, the Company entered into a license agreement with Newsoara Biopharma Co., Ltd., ("Newsoara") (the "Newsoara License Agreement"), under which Newsoara obtained an exclusive and sublicensable license to develop and commercialize the Company's phosphodiesterase type 4 inhibitors ("PDE4") program, including the compound HPP737, in China and other Pacific Rim countries (collectively, the "Newsoara License Territory"). Additionally, under the Newsoara License Agreement, the Company obtained a non-exclusive, sublicensable, royalty-free license to develop and commercialize certain Newsoara patent rights and know-how related to the Company's PDE4 program for therapeutic uses in humans outside of the Newsoara License Territory. Under the terms of the Newsoara License Agreement, Newsoara paid the Company an upfront cash payment of $2.0 million. The Company is eligible to receive additional potential development, regulatory and sales-based milestone payments totaling up to $63.0 million. In addition, Newsoara is obligated to pay the Company royalty payments at high-single to low-double digit rates, based on tiers of annual net sales of licensed products. Such royalties will be payable on a licensed product-by-licensed product and country-by-country basis until the latest of expiration of the licensed patents covering a licensed product in a country, expiration of data exclusivity rights for a licensed product in a country or a specified number of years after the first commercial sale of a licensed product in a country.

Pursuant to the terms of the Newsoara License Agreement, the Company is required to provide technology transfer services for a defined period after the effective date. In accordance with ASC Topic 606, the Company identified all of the performance obligations at the inception of the Newsoara License Agreement. The significant obligations were determined to be the license and the technology transfer services. The Company has determined that the license and technology transfer services represent a single performance obligation because they were not capable of being distinct on their own. The transaction price has been fully allocated to this combined performance obligation. The remaining milestone payments that the Company is eligible to receive have not been included in the transaction price as of December 31, 2018, as it is not considered probable that such payments will be received.

The Company determined that there was no discernable pattern in which the technology services would be provided during the transfer services period. As such, the Company determined that the straight-line method would be used to recognize revenue over the transfer service period. The total $2.0 million of the transaction price allocated to this performance obligation was recognized during the year ended December 31, 2018. No revenue was recognized for this performance obligation for the years ended December 31, 2017 and 2016.

JDRF Agreement

In August 2017, the Company entered into the JDRF Agreement to support the funding of the simplici-T1 Study, an adaptive Phase 1b/2 study to explore the effects of TTP399 in type 1 diabetics. We initiated this study in the fourth quarter of 2017. According to the terms of the JDRF Agreement, JDRF will provide research funding of up to $3.0 million based on the achievement of research and development milestones, with the total funding provided by JDRF not to exceed approximately one-half of the total cost of the project. Additionally, the Company has the obligation to make certain milestone payments to JDRF upon the commercialization, licensing, sale or transfer of TTP399 as a treatment for type 1 diabetes.

Payments that the Company receives from JDRF under this agreement are recorded as restricted cash and current liabilities and recognized as an offset to research and development expense, based on the progress of the project, and only to the extent that the restricted cash is utilized to fund such development activities. As of December 31, 2018, the Company had received funding under this agreement of $0.8 million, and research and development costs were offset by $0.8 million.

Calithera License Agreement

In March 2015, the Company entered into the Calithera License Agreement under which Calithera obtained an exclusive, worldwide sublicenseable license to develop and commercialize certain of our hexokinase II inhibitors for any therapeutic, prophylactic, preventative or diagnostic use. Under the terms of the Calithera License Agreement, Calithera paid the Company an initial license fee of $0.6 million and a total of $0.3 million for employees of the Company to assist with the development of additional hexokinase inhibitors. This agreement was terminated, at the option of Calithera, effective December 21, 2017.

Contract Liabilities

Contract liabilities related to the Company's collaboration agreements consisted of the following (in thousands):

	December 31, 2018	December 31, 2017
Current portion of deferred revenue	$ 1,752	$ 8,757
Deferred revenue, net of current portion	1,067	4,497
Total contract liabilities	$ 2,819	$ 13,254
Revenue recognized in the period from:		
Amounts included in contract liability at the beginning of the period	$ 10,434	$ 21

There were no changes in the estimated transaction prices for the related contracts during the year ended December 31, 2018.

Note 4: Share-Based Compensation

In conjunction with the Company's initial public offering ("IPO"), the board of directors of vTv Therapeutics Inc. (the "Board of Directors") and sole stockholder adopted a long-term equity incentive plan, the vTv Therapeutics Inc. 2015 Omnibus Equity Incentive Plan (the "Plan"). The Plan provides for the grant of stock options, restricted stock, restricted stock units and other awards based on our Class A Common Stock to management, other key employees, consultants and non-employee directors on terms and subject to conditions as established by our Compensation Committee. In settlement of its obligations under this plan, the Company will issue new shares of Class A Common Stock. The maximum number of shares of the Company's Class A Common Stock that has been approved and may be subject to awards under the Plan is 3.25 million, subject to adjustment in accordance with terms of the Plan.

The Company has issued non-qualified stock option awards and restricted stock units to certain employees, consultants and non-employee directors of the Company. These awards generally vest ratably over a three-year period and the option awards expire after a term of ten years from the date of grant. For the years ended December 31, 2018, 2017 and 2016, the Company recognized $2.7 million, $3.6 million and $2.6 million of compensation expense related to share-based awards, respectively. Given that the Company has established a full valuation allowance against its deferred tax assets, the Company has recognized no tax benefit related to these awards. As of December 31, 2018, the Company had total unrecognized stock-based compensation expense of approximately $1.3 million, which is expected to be recognized on a straight-line basis over a weighted average period of 1.3 years. The weighted average grant date fair value for all option grants during the years ended December 31, 2018, 2017 and 2016 was $2.28, $4.15 and $4.05

per option, respectively.

The aggregate intrinsic value of the in-the-money awards outstanding as of December 31, 2018 was $0.1 million, of which an immaterial amount related to vested stock options and $0.1 million related to unvested stock options.

The Company uses the Black-Scholes option pricing model to calculate the fair value of stock options granted. The fair value of stock options granted was estimated using the following assumptions during the years ended December 31, 2018, 2017 and 2016:

	For the Year Ended December 31,		
	2018	2017	2016
Expected volatility	71.15% - 99.23%	68.72% - 85.93%	81.57% - 87.23%
Expected life of option, in years	5.7 - 6.0	5.8 - 6.0	5.0 - 6.0
Risk-free interest rate	2.69% - 2.84%	1.87% - 2.24%	1.22% - 1.45%
Expected dividend yield	0.00%	0.00%	0.00%

The following table summarizes the activity related to the stock option awards for the year ended December 31, 2018 (in thousands, except per share amounts):

	Number of Shares	Weighted-Average Exercise Price
Awards outstanding at December 31, 2017	1,960,732	$ 8.50
Granted	102,750	3.25
Forfeited	(295,979)	6.27
Awards outstanding at December 31, 2018	1,767,503	$ 8.57
Options exercisable at December 31, 2018	1,180,735	$ 10.12
Weighted average remaining contractual term	7.1 Years	
Options vested and expected to vest at December 31, 2018	1,737,666	$ 8.62
Weighted average remaining contractual term	7.5 Years	

The following table summarizes the activity related to the awards of RSUs for the year ended December 31, 2018:

	Number of Shares	Weighted-Average Grant Date Fair Value
Awards outstanding at December 31, 2017	35,000	$ 5.81
Vested	(11,667)	5.81
Awards outstanding at December 31, 2018	23,333	$ 5.81
RSUs expected to vest at December 31, 2018	23,012	$ 5.81

As of December 31, 2018, the Company had total unrecognized stock-based compensation expense for its outstanding RSU awards of approximately $0.1 million, which is expected to be recognized over a weighted-average period of 1.2 years.

Compensation expense related to the grants of stock options is included in research and development and general and administrative expense as follows (in thousands):

	2018	2017	2016
Research and development	$994	$1,485	$975
General and administrative	1,682	2,160	1,666
Total share-based compensation expense	$2,676	$3,645	$2,641

Note 5: Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2018	2017
Prepaid insurance	$571	$251
Prepaid - other	95	191
Total	$666	$442

Note 6: Property and Equipment

Property and equipment consists of the following (in thousands):

	December 31,	
	2018	2017
Laboratory equipment	$5,690	$6,275
Leasehold improvements	1,548	1,679
Computers and hardware	329	323
Software	691	691
Furniture and office equipment	243	431
Total property and equipment	8,501	9,399
Less: accumulated depreciation and amortization	(8,431)	(9,116)
Property and equipment, net	$70	$283

Depreciation expense, including amounts pertaining to assets held under capital leases, was $0.2 million, $0.2 million and $0.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Note 7: Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following (in thousands):

	December 31,	
	2018	2017
Accounts payable	$2,899	$2,269
Accrued development costs	3,835	8,586
Accrued compensation and related costs	826	1,990
Accrued other	142	1,056
Total	$7,702	$13,901

Note 8: Notes Payable

Notes payable consist of the following (in thousands):

	December 31, 2018	December 31, 2017
Notes payable under the Loan Agreement	$ 14,897	$ 20,000
Short-term financing	216	—
Accreted final payment (unamortized debt discount)	600	(413)
Total notes payable	15,713	19,587
Less: Current portion	(9,383)	(4,271)
Total notes payable, net of current portion	$ 6,330	$ 15,316

In October 2016, the Company entered into the Loan Agreement with Horizon Technology Finance Corporation and Silicon Valley Bank, under which the Company and vTv LLC borrowed $20.0 million.

Each loan tranche bears interest at a floating rate equal to 10.5% plus the amount by which the one-month LIBOR exceeds 0.5%.

The Company borrowed the first tranche of $12.5 million upon close of the Loan Agreement in October 2016. The first tranche required only monthly interest payments until May 1, 2018 followed by equal monthly payments of principal plus accrued interest through the scheduled maturity date on May 1, 2020. In addition, a final payment for the first tranche loan equal to $0.8 million will be due on May 1, 2020, or such earlier date specified in the Loan Agreement. The Company borrowed the second tranche of $7.5 million in March 2017. The second tranche requires only monthly interest payments until October 1, 2018, followed by equal monthly payments of principal plus accrued interest through the scheduled maturity date on October 1, 2020. In addition, a final

payment for the second tranche loan equal to $0.5 million will be due on October 1, 2020, or such earlier date specified in the Loan Agreement. The availability of the third tranche of $5.0 million expired unused on June 30, 2017.

If the Company repays all or a portion of the loan prior to the applicable maturity date, it will pay the Lenders a prepayment penalty fee, based on a percentage of the then outstanding principal balance equal to 4.0% during the first 18 months following the funding of the second tranche and 2.0% thereafter.

In connection with the Loan Agreement, the Company has issued to the Lenders warrants to purchase shares of the Company's Class A Common Stock (the "Warrants"). On October 28, 2016, the Company issued Warrants to purchase 152,580 shares of its Class A Common Stock at a per share exercise price of $6.39 per share, which aggregate exercise price represents 6.0% of the principal amount borrowed under the first tranche of the Loan Agreement and 3.0% of the principal amount available under the second tranche of the Loan Agreement. On March 24, 2017, in connection with the funding of the second tranche, the Company issued Warrants to purchase 38,006 shares of its Class A Common Stock at a per share exercise price of $5.92 per share, which aggregate exercise price represents 3.0% of the principal amount of the second tranche of the Loan Agreement. In each instance, the Warrants have an exercise price equal to the lower of (a) the volume weighted average price per share of the Company's Class A Common Stock, as reported on the principal stock exchange on which the Company's Class A Common Stock is listed, for 10 trading days prior to the issuance of the applicable Warrants or (b) the closing price of a share of the Company's Class A Common Stock on the trading day prior to the issuance of the applicable Warrants. The Warrants will expire seven years from their date of issuance.

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of its assets. As a result of the termination of the STEADFAST Study, the Company granted the Lenders a first priority security interest in all of the Company's intellectual property, subject to certain limited exceptions. The Company has agreed not to pledge or otherwise encumber its intellectual property assets, subject to certain exceptions.

The Loan Agreement includes customary affirmative and restrictive covenants, including, but not limited to, restrictions on the payment of dividends or other equity distributions and the incurrence of debt or liens upon the assets of the Company or its subsidiaries. The Loan Agreement does not contain any financial maintenance covenants other than a requirement to maintain a minimum cash balance of not less than $2.5 million in a deposit account pledged to secure the Loan Agreement and subject to an account control agreement. The minimum cash balance covenant was included as part of an amendment to the Loan Agreement in connection with our entry into the Huadong License Agreement in December 2017. The Loan Agreement includes customary events of default, including payment defaults, covenant defaults, and material adverse change default. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5% will be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

The Company incurred $0.7 million of costs in connection with the Loan Agreement in the year ended December 31, 2016. These costs, along with the allocated fair value of the Warrants issued of $0.9 million, were treated as a debt discount, and are offset against the carrying value of the notes payable in the Company's Consolidated Balance Sheets as of December 31, 2018 and 2017. These costs will be recognized as interest expense over the term of the first tranche using the effective interest method. The final payment for the first and second loan tranches of $0.8 million and $0.5 million, respectively, will be accrued as additional interest expense, using the effective interest method, over the term of the relevant tranche.

The Company recorded interest expense related to the Loan Agreement of $3.1 million, $3.1 million and $0.4 million for the years ended December 31, 2018, 2017 and 2016, respectively. The annual effective interest rate on the note payable, including the amortization of the debt discounts and accretion of the final payments, is 17.7%.

Principal payments due under the terms of the Loan Agreement are as follows (in thousands):

2019	$9,383
2020	5,730
2021	—
2022	—
2023	—
Total	$15,113

Note 9: Commitments and Contingencies

Legal Matters

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. If a specific contingent liability is determined to be probable and can be reasonably estimated, the Company accrues and discloses the amount. The Company is not currently a party to any material legal proceedings.

Columbia University Agreement

In May 2015, the Company entered into a worldwide exclusive agreement with Columbia University ("Columbia") to license certain intellectual property from Columbia. Under the agreement, the Company is obligated to pay to Columbia (1) an annual fee of $0.1 million from 2015 through 2021, (2) a potential regulatory milestone payment of $0.8 million and (3) potential royalty payments at a single digit royalty rate based on net sales of licensed products as defined in the agreement. In December 2018, the Company notified Columbia of its intent to terminate this license agreement.

Novo Nordisk

In February 2007, the Company entered into an Agreement Concerning Glucokinase Activator Project with Novo Nordisk A/S (the "Novo License Agreement") 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, the Company obtained certain worldwide rights to Novo Nordisk's GKA program, including rights to preclinical and clinical compounds such as TTP399. Under the terms of the Novo License Agreement, the Company has additional potential developmental and regulatory milestone payments totaling up to $115.0 million for approval of a product. The Company may also be obligated to pay an additional $75.0 million in potential sales-based milestones, as well as royalty payments, at mid-single digit royalty rates, based on tiered sales of commercialized licensed products.

Huadong License Agreement

Under the terms of the Huadong License Agreement, vTv LLC is responsible for sponsoring the Phase 2 MRCT including sites in both US and the Huadong License Territory for the purpose of assessing the safety and efficacy of TTP273 in patients with type 2 diabetes. The Phase 2 MRCT will be designed to satisfy the requirements of the China Food and Drug Administration necessary in order for Huadong to begin a Phase 3 clinical trial in China. vTv LLC will be responsible for contributing up to $3.0 million in connection with the Phase 2 MRCT.

Lease Agreements

The Company leases various equipment and facilities under operating leases expiring at various dates through 2019. Rent expense for non-cancelable operating leases was $0.5 million, $0.5 million and $0.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2018 were as follows (in thousands):

Year Ending December 31,	Operating

	Leases
2019	$ 366
2020	—
2021	—
2022	—
2023 and thereafter	—
Total	$ 366

The Company has recognized an asset retirement obligation for an obligation in its facility lease that requires the Company to return the property to the same or similar condition at the end of the lease as existed when the Company began using the facility. Asset retirement obligations recorded as a component of other noncurrent liabilities in the Consolidated Balance Sheets were $0.2 million at both December 31, 2018 and 2017. An immaterial amount of accretion and depreciation expense was recognized in the years ended December 31, 2018, 2017 and 2016.

Note 10: Stockholders' Equity

On July 29, 2015, the Company amended and restated its certificate of incorporation to authorize 100,000,000 shares of Class A Common Stock, 100,000,000 shares of Class B Common Stock and 50,000,000 shares of preferred stock, par value $0.01 per share.

Holders of 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 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 the Company's 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 vTv Units not held by the Company. Holders of Class B Common Stock are not entitled to receive dividends and will not be entitled to receive any distributions upon the liquidation, dissolution or winding up of the Company.

Letter Agreement Warrants

The Company has entered into the letter agreement between vTv and M&F Group dated as of December 11, 2018 (the "December Letter Agreement") and the letter agreements (the "Prior Letter Agreements") with M&F Group in December 2017 and July 2018 (collectively, the "Letter Agreements"). Under the terms of the Letter Agreements, the Company has or had the right to sell to M&F Group shares of its Class A Common Stock at a specified price per share, and M&F Group has or had the right (exercisable up to three times) to require the Company to sell to it shares of Class A Common Stock at the same price. An aggregate of $20.0 million worth of Class A Common Stock were sold under the Prior Letter Agreements and a further $10.0 million worth of Class A Common Stock may be sold under the December Letter Agreement (whether at the Company's or M&F Group's option). In addition, in connection with the entrance into these Letter Agreements, the Company also issued to M&F Group warrants (the "Letter Agreement Warrants") to purchase additional shares of the Company's Class A Common Stock. Certain terms of each of these Letter Agreements are set forth in Note 12.

The Letter Agreement Warrants were recorded as warrant liability, related party within the Company's Consolidated Balance Sheets based on their fair value. The issuance of the Letter Agreement Warrants was considered to be a cost of equity recorded as a reduction to additional paid-in capital. During the years ended December 31, 2018 and 2017 the Company recognized an expense of $0.6 million and $0.2 million, respectively, related to the change in fair value of the Letter Agreement Warrants. This expense was recognized as a component of other expense, related party in the Consolidated Statements of Operations. No such expense was recognized for the year ended December 31, 2016.

Fair value of the Letter Agreement Warrants was calculated as of their issuance date using the methods described in Note 18 using the following assumptions:

	December 5, 2017	July 30, 2018	December 11, 2018
Expected volatility	90.0%	95.29%	104.46%
Expected life of option, in years	7.0	7.0	7.0
Risk-free interest rate	2.8%	2.94%	2.77%

Expected dividend yield	0.00%	0.00%	0.00%

Loan Agreement Warrants

On October 28, 2016, the Company entered into the Loan Agreement as discussed in Note 8. In connection with the Loan Agreement, the Company issued to the Lenders Warrants to purchase a total of 152,580 shares of the Company's Class A Common Stock at an exercise price of $6.39 per share. Additionally, upon funding of the second tranche on March 24, 2017, the Company issued Warrants to purchase 38,006 shares of its Class A Common Stock at a per share exercise price of $5.92 per share, which aggregate exercise price represents 3.0% of the amount available under the second tranche of the Loan Agreement. In each instance, the Warrants have an exercise price equal to the lower of (a) the volume weighted average price per share of the Company's Class A Common Stock, as reported on the principal stock exchange on which the Company's Class A Common Stock is listed, for 10 trading days prior to the issuance of the applicable Warrants or (b) the closing price of a share of the Company's Class A Common Stock on the trading day prior to the issuance of the applicable Warrants. The Warrants will expire seven years from their date of issuance.

The Warrants issued with a determinable number of shares and exercise price were recorded as a component of additional paid-in capital within the Company's Consolidated Balance Sheet as of December 31, 2016 based on their relative fair value. The Warrants issued for a variable number of shares were recorded as a component of other liabilities within the Consolidated Balance Sheet as of December 31, 2016. This related liability was adjusted to its fair value on a periodic basis until the associated warrants qualified for equity classification upon the funding of the second tranche of the Loan Agreement on March 24, 2017. For the years ended December 31, 2017 and 2016, the Company recognized additional interest expense within the Consolidated Statements of Operations of a de minimis amount related to the adjustment of the Warrants to their fair value.

Fair value of the Warrants was calculated as of October 28, 2016 using the methods described in Note 18 using the following assumptions:

Expected volatility	82.54%
Expected life of option, in years	7.0
Risk-free interest rate	1.63%
Expected dividend yield	0.00%

Note 11: Redeemable Noncontrolling Interest

The Company is subject to the Exchange Agreement with respect to the vTv Units representing the outstanding 53.2% noncontrolling interest in vTv LLC (see Note 1). The Exchange Agreement requires the surrender of an equal number of vTv Units and Class B Common Stock for (i) shares of Class A Common Stock on a one-for-one basis or (ii) cash (based on the fair market value of the Class A Common Stock as determined pursuant to the Exchange Agreement), at the Company's option (as the managing member of vTv LLC), subject to customary conversion rate adjustments for stock splits, stock dividends and reclassifications. The exchange value is determined based on a 20 day volume weighted average price of the Class A Common Stock as defined in the Exchange Agreement, subject to customary conversion rate adjustments for stock splits, stock dividends and reclassifications.

The redeemable noncontrolling interest is recognized at the higher of (1) its initial fair value plus accumulated earnings/losses associated with the noncontrolling interest or (2) the redemption value as of the balance sheet date. At December 31, 2018 and 2017, the redeemable noncontrolling interest was recorded based on the redemption value as of the balance sheet date of $62.5 million and $131.4 million, respectively.

Note 12: Related-Party Transactions

MacAndrews & Forbes Incorporated

MacAndrews directly or indirectly controls 23,084,267 shares of Class B Common Stock. Further, as of December 31, 2018, MacAndrews directly or indirectly holds 13,232,785 shares of the Company's Class A Common Stock. As a result, MacAndrews' holdings represent approximately 83.6% of the combined voting power of the Company's outstanding common stock.

The Company has entered into several agreements with MacAndrews or its affiliates as further detailed below:

Letter Agreements

The Company has entered into the Letter Agreements with M&F Group. Under the terms of the Letter Agreements, the Company has or had the right to sell to M&F Group shares of its Class A Common Stock at a specified price per share, and M&F Group has or had the right (exercisable up to three times) to require the Company to sell to it shares of Class A Common Stock at the same price. An aggregate of $20.0 million worth of Class A Common Stock were sold under the Prior Letter Agreements and a further $10.0 million worth of Class A Common Stock may be sold under the December Letter Agreement (whether at the Company's or M&F Group's option). In addition, in connection with the entrance into these Letter Agreements, the Company also issued to M&F Group the Letter Agreement Warrants to purchase additional shares of the Company's Class A Common Stock.

Certain terms of these Letter Agreements are set forth in the table below:

	December 5, 2017 Letter Agreement	July 30, 2018 Letter Agreement	December 11, 2018 Letter Agreement
Specified purchase price per share	$4.38	$1.33	$1.84
Expiration date of letter agreement	December 5, 2018	July 30, 2019	December 11, 2019
Shares available to be issued under related warrants	198,267	518,654	340,534
Exercise price of related warrants	$5.04	$1.53	$2.12
Expiration date of related warrants	December 5, 2024	July 30, 2025	December 11, 2025
Total shares issued as of December 31, 2018	2,283,105	7,518,797	815,217
Remaining shares to be issued as of December 31, 2018	—	—	4,619,566

Each of the December 5, 2017 and July 30, 2018 Letter Agreements resulted in a deemed capital contribution to the Company as the fair value of the financial instrument received by the Company exceeded the fair value of those financial instruments issued to MacAndrews. The December 11, 2018 Letter Agreement resulted in a deemed distribution to MacAndrews as the fair value of the financial instruments issued to MacAndrews exceeded the fair value of the financial instrument received by the Company. This deemed distribution has been reflected as a reduction to the net loss attributable to common shareholders of vTv Therapeutics Inc. for computing net loss per share.

Exchange Agreement

Pursuant to the terms of the Exchange Agreement, but subject to the Amended and Restated LLC Agreement of vTv Therapeutics LLC, the vTv Units (along with a corresponding number of shares of the Class B Common Stock) are exchangeable for (i) shares of the Class A Common Stock on a one-for-one basis or (ii) cash (based on the fair market value of the Company's Class A Common Stock as determined pursuant to the Exchange Agreement), at the Company's 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. As of December 31, 2018, MacAndrews has not exchanged any shares under the provisions of this agreement.

Tax Receivable Agreement

The Tax Receivable Agreement among the Company, M&F TTP Holdings Two LLC, as successor in interest to vTv Therapeutics Holdings ("M&F") and M&F TTP Holdings LLC provides for the payment by the Company to M&F (or certain of 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 the Company actually realizes (or, in some circumstances, the Company is deemed to realize) as a result of (a) the exchange of Class B Common Stock, together with the corresponding number of vTv Units, for shares of the Company's Class A Common Stock (or for cash), (b) tax benefits related to imputed interest deemed to be paid by the Company as a result of the Tax Receivable Agreement and (c) certain tax benefits attributable to payments under the Tax Receivable Agreement. As no shares have been exchanged by MacAndrews pursuant to the Exchange Agreement (discussed above), the Company has not recognized any liability nor has it made any payments pursuant to the Tax Receivable Agreement as of December 31, 2018.

Investor Rights Agreement

The Company is party to an investor rights agreement with M&F, as successor in interest to vTv Therapeutics Holdings (the “Investor Rights Agreement”). The Investor Rights Agreement provides M&F with certain demand, shelf and piggyback registration rights with respect to its shares of Class A Common Stock and also provides M&F with certain governance rights, depending on the size of its holdings of Class A Common Stock. Under the Investor Rights Agreement, M&F was initially entitled to nominate a majority of the members of the Board of Directors and designate the members of the committees of the Board of Directors.

PharmaCore, Inc.

Prior to its acquisition by Cambrex Corporation in October 2016, certain controlling shareholders of the Company also controlled PharmaCore, Inc. (“PharmaCore”) and PharmaCore was therefore considered to be a related party. The Company purchased chemistry and Good Manufacturing Practices manufacturing services from PharmaCore. Total purchases from PharmaCore, while it was considered to be a related party were $0.8 million for the year ended December 31, 2016.

Note 13: 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 $0.2 million, $0.1 million and $0.2 million to the plan for the years ended December 31, 2018, 2017 and 2016, respectively.

Note 14: Income Taxes

From August 1, 2015, vTv Therapeutics Inc. has been subject to U.S. federal income taxes as well as state taxes. The Company recorded an income tax provision of $0.2 million and $0.8 million for the years ended December 31, 2018 and December 31, 2017, respectively, representing foreign withholding taxes incurred in connection with payments received under license agreements with foreign entities. The Company did not record an income tax provision for the year ended December 31, 2016.

As discussed in Note 12, the Company is party to a tax receivable agreement with a related party which provides for the payment by the Company to M&F (or certain of 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 the Company actually realizes (or, in some circumstances, the Company is deemed to realize) as a result of certain transactions. As no transactions have occurred which would trigger a liability under this agreement, the Company has not recognized any liability related to this agreement as of December 31, 2018.

On December 22, 2017, the US government enacted comprehensive tax reform commonly referred to as the Tax Cuts and Jobs Act ("TCJA"). Under ASC 740, the effects of changes in tax rates and laws are recognized in the period which the new legislation is enacted. Among other things, the TCJA (1) reduced the US statutory corporate income tax rate from 35% to 21% effective January 1, 2018, (2) eliminated the corporate alternative minimum tax, (3) eliminated the Section 199 deduction, and (4) changed rules related to uses and limitations of net operating loss carryforwards beginning after December 31, 2017.

The SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118"), which provides guidance on accounting for the tax effects of TCJA. The purpose of SAB 118 was to address any uncertainty or diversity of view in applying ASC 740 in the reporting period in which the TCJA was enacted. Additionally, SAB 118 provided a measurement period that should not extend beyond one year from the TCJA enactment date for companies to complete the accounting under ASC 740. Based on the reduced corporate tax rate of 21%, the Company recorded a provisional decrease in its deferred tax assets of $5.8 million with a corresponding adjustment to the valuation allowance for the year ended December 31, 2017. During 2018, the Company finalized the accounting for the tax effects of TCJA with no material changes to the provisional estimate recorded.

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows (in thousands):

	December 31,		
	2018	2017	2016
U.S. statutory tax benefit	$(4,966)	$(18,846)	$(19,374)
Partnership income (federal) not subject to tax to the Company	3,346	13,475	13,651
Foreign withholding tax	200	800	—

State taxes (net of federal benefit)	(224)	55	—
Impact of the Tax Act	—	5,847	—
Research and development tax credit	(1,122)	—	—
Other	(168)	—	—
Change in valuation allowance	3,134	(531)	5,723
Provision for income taxes	$200	$800	$—
Effective income tax rate	-0.8%	-1.5%	0.0%

Significant components of our net deferred tax assets/(liabilities) are as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$12,749	$9,023
Investment in partnerships	(122)	470
Charitable contributions	11	11
Total deferred tax assets	12,638	9,504
Valuation allowance	(12,638)	(9,504)
Net deferred tax assets	$—	$—

The Company assesses the available positive evidence and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of existing deferred tax assets. A significant piece of objective negative evidence evaluated was the Company's recent operating losses. Such objective evidence limits the ability to consider other subjective evidence, such as forecasts of profitability. On the basis of this evaluation, the Company concluded that its deferred tax assets were not realizable on a more-likely-than-not basis and recorded a full valuation allowance. During the year ended December 31, 2018, the Company's valuation allowance increased by $3.1 million.

The Company has federal net operating loss carryforwards of $50.5 million that will be available to offset future taxable income. Approximately, $40.0 million of these carryforwards expire in varying amounts starting in 2035 to 2037, if not utilized and are available to offset 100% of future taxable income. The remaining $10.5 million may be carried forward indefinitely but are only available to offset 80% of future taxable income

The Company applies applicable authoritative guidance which prescribes a comprehensive model for the manner in which a company should recognize, measure, present and disclose in its financial statements all material uncertain tax positions that the Company has taken or expects to take on a tax return. As of December 31, 2018, the Company had no uncertain tax positions. There are no uncertain tax positions for which it is reasonably possible that the total amount of unrecognized tax benefits will significantly increase or decrease within twelve months of December 31, 2018.

The Company files U.S. federal, Connecticut, New York, North Carolina and Virginia tax returns. The earliest open tax years that are still subject to examination by the IRS and the aforementioned state tax authorities are 2015 to 2018.

Note 15: Restructuring

In December 2018, the Company initiated a corporate restructuring to align with a strategic decision to continue the development of its drug candidates using external resources rather than internal resources. The restructuring will allow the Company to reduce costs while continuing to conduct clinical trials, to support existing partnerships that are advancing development of additional assets, and to pursue new licensing and partnership opportunities. This restructuring included a significant reduction in its workforce. The Company expects to complete the reductions in headcount, including the payment of employee severance and benefits, in the second quarter of 2019. The Company expects these actions to result in cash charges of approximately $0.8 million for employee severance and related costs.

As of and during the year ended December 31, 2018, the Company had recognized an accrual and related expense of $0.3 million related to these severance benefits. The related expense has been recognized as a component of research

and development and general and administrative expense within the Consolidated Statements of Operations based on the responsibilities of the impacted employees. The related accrual is recorded as a component of accounts payable and accrued expenses within the Consolidated Balance Sheets.

Note 16: Net Loss per Share

Basic loss per share is computed by dividing net loss attributable to vTv Therapeutics Inc. by the weighted-average number of shares of Class A Common Stock outstanding during the period. Diluted loss per share is computed giving effect to all potentially dilutive shares. Diluted loss per share for the years ended December 31, 2018, 2017 and 2016 is the same as basic loss per share as the inclusion of potentially issuable shares would be antidilutive.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share of Class A Common Stock is as follows (amounts in thousands, except per share amounts):

	Year Ended December 31,		
	2018	2017	2016
Numerator:			
Net loss	$(23,845)	$(54,647)	$(55,353)
Less: Net loss attributable to noncontrolling interests	(15,934)	(38,503)	(39,001)
Net loss attributable to vTv Therapeutics Inc.	(7,911)	(16,144)	(16,352)
Less: Deemed distribution to related party (Note 12)	(739)	—	—
Net loss attributable to common shareholders of vTv Therapeutics Inc.	$(8,650)	$(16,144)	$(16,352)
Denominator:			
Weighted-average vTv Therapeutics Inc. Class A Common Stock, basic and diluted	12,449,236	9,693,254	9,545,527
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	$(0.69)	$(1.67)	$(1.71)

Potentially dilutive securities not included in the calculation of dilutive net loss per share are as follows:

	Year Ended December 31,		
	2018	2017	2016
Class B Common Stock [1]	23,094,221	23,119,246	23,119,246
Common stock options granted under the Plan	1,767,503	1,960,732	1,096,101
Restricted stock units	23,333	35,000	—
Common stock options granted under the Letter Agreement	4,619,566	2,283,105	—
Common stock warrants	1,248,041	388,853	152,580
Total	30,752,664	27,786,936	24,367,927

(1) Shares of Class B Common Stock do not share in the Company's earnings and are not participating securities. Accordingly, separate presentation of loss per share of Class B Common Stock under the two-class method has not been provided. Each share of Class B Common Stock (together with a corresponding vTv Unit) is exchangeable for one share of Class A Common Stock.

Note 17: Quarterly Financial Data (Unaudited)

The following interim financial information presents our 2018 and 2017 results of operations on a quarterly basis (in thousands, except per share amounts):

	2018 March 31	June 30	September 30	December 31
Revenues	$2,064	$2,473	$3,375	$4,522
Operating loss	(9,134)	(8,858)	(1,481)	(351)
Net loss before noncontrolling interest	(9,960)	(9,596)	(1,961)	(2,328)
Net loss attributable to vTv Therapeutics Inc.	(2,952)	(3,072)	(796)	(1,091)
Net loss attributable to vTv Therapeutics Inc. common shareholders	(2,952)	(3,072)	(796)	(1,830)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	$(0.30)	$(0.31)	$(0.06)	$(0.10)

	2017 March 31	June 30	September 30	December 31
Revenues	$30	$13	$15	$233
Operating loss	(13,754)	(12,615)	(11,541)	(12,772)
Net loss before noncontrolling interest	(14,286)	(13,414)	(12,355)	(14,592)
Net loss attributable to vTv Therapeutics Inc.	(4,220)	(3,963)	(3,650)	(4,311)
Net loss attributable to vTv Therapeutics Inc. common shareholders	(4,220)	(3,963)	(3,650)	(4,311)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	$(0.44)	$(0.41)	$(0.38)	$(0.44)

Note 18: 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.

The fair value of the Company’s Loan Agreement is considered to approximate its carrying value because it bears interest at a variable interest rate.

The Company measures the value of its investment in Reneo at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment. Since acquiring the Reneo investment in December 2017, there have been no observable price changes in identical or similar investments, nor were there any indications of impairment. As such, the value of the Company’s investment in Reneo

has not been remeasured.

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. The following table summarizes the conclusions reached regarding fair value measurements as of December 31, 2018, 2017 and 2016 (in thousands):

	Balance at December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liability, related party [1]	$ 2,436	$ —	$ —	$ 2,436
Total	$ 2,436	$ —	$ —	$ 2,436

	Balance at December 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liability, related party [2]	$ 492	$ —	$ —	$ 492
Total	$ 492	$ —	$ —	$ 492

(1) Fair value determined using the Black-Scholes option pricing model. Expected volatility is based on a portfolio of selected stocks of companies believed to have market and economic characteristics similar to its own. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of valuation.

(2) Fair value determined using an option pricing model based on the Company's current capitalization. Expected volatility is based on a portfolio of selected stocks of companies believed to have market and economic characteristics similar to its own. The risk-free rate is based on the yield of U.S. government securities with the same term as the option as of the valuation date.

Changes in Level 3 Instruments for the years ended December 31, 2018, 2017 and 2016

	Balance at January	Net Change in fair value included in earnings	Purchases / Issuance	Sales / Repurchases	Balance at December 31,
2018					
Warrant liability, related party	$492	$ 638	$ 1,306	$ —	$ 2,436
Total	$492	$ 638	$ 1,306	$ —	$ 2,436
2017					
Warrant liability	$167	$ —	$ —	$ (167)	$ —
Warrant liability, related party	—	190	302	—	492
Total	$167	$ 190	$ 302	$ (167)	$ 492
2016					
Warrant liability	$—	$ —	$ 167	$ —	$ 167
Total	$—	$ —	$ 167	$ —	$ 167

There were no transfers into or out of level 3 instruments and/or between level 1 and level 2 instruments during the years ended December 31, 2018, 2017 and 2016.

The fair value of the Letter Agreement Warrants was determined using the Black-Scholes option pricing model or option pricing models based on the Company's current capitalization. Expected volatility is based on a portfolio of selected stocks of companies believed to have market and economic characteristics similar to its own. The risk-free

rate is based on the U.S. Treasury yield curve in effect at the time of valuation. Significant inputs utilized in the valuation of the Letter Agreement Warrants were:

	December 31, 2018	December 31, 2017
Expected volatility	108.53% - 115.04%	90.00%
Risk-free interest rate	2.59% - 2.69%	2.40%

Changes in the unobservable inputs noted above would impact the amount of the liability for the Letter Agreement Warrants. For the Company's warrants, increases (decreases) in the estimates of the Company's annual volatility would increase (decrease) the liability and an increase (decrease) in the annual risk-free rate would increase (decrease) the liability.

Note 18: Subsequent Events

Subsequent to December 31, 2018, the Company exercised its right to cause MacAndrews & Forbes Group LLC to purchase an additional 2,445,651 shares of its Class A Common Stock at a per share price of $1.84 pursuant to the terms of the December Letter Agreement for $4.5 million in cash.