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, 2020

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.)**
3980 Premier Dr, Suite 310 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	Trading Symbol	Name of each exchange on which registered
Class A Common Stock (Par Value $0.01)	VTVT	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 whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth 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 whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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 the last business day of the Registrant's most recently completed second quarter, June 30, 2020, was $29,590,387 (based on the closing sale price as reported on the NASDAQ).

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 24, 2021.

Class of Stock	Shares Outstanding
Class A common stock, par value $0.01 per share	57,550,710
Class B common stock, par value $0.01 per share	23,094,221

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement relating to its 2021 Annual Meeting of Stockholders to be filed within 120 days after December 31, 2020 are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

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vTv THERAPEUTICS INC. AND SUBSIDIARIES
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FOR THE FISCAL YEAR ENDED DECEMBER 31, 2020

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 the negatives 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.

Summary of Principal Risk Factors

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows, and prospects. These risks are discussed more fully in "Part I – Item 1A, Risk Factors" below and include, but are not limited to, risks related to:

Our Financial Position and Need for Additional Capital

- our ability to achieve or maintain profitability;
- our ability to generate revenue in absence of any products approved for sale;
- our need for additional capital to continue the development and commercialization of our drug candidates;
- the impact of raising additional capital to our stockholders and the rights of our drug candidates.

The Development and Regulatory Approval of Our Drug Candidates

- the potential failure of our clinical trials or our inability to receive regulatory approval for our drug candidates;
- the identification of serious adverse or unacceptable side effects which are determined to be drug-related;
- the impact of changes in law or regulatory policy on the approval of our drug candidates;
- the impact of delays in the commencement, enrollment and completion of our clinical trials;
- our ability to submit an NDA for the drug candidates we are developing;

Risks Relating to the Commercialization of Our Drug Candidates

- the acceptance of drug candidates in the market, if approved by the appropriate regulatory agencies;
- our ability to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our drug candidates;
- the impact of ongoing obligations and continued regulatory review for our drug candidates post-commercialization;
- competition with other products;
- the impact of healthcare cost containment initiatives and the growth of managed care;
- our ability to obtain marketing approval for our drug candidates and obtain profitable pricing once approved;
- the impact of healthcare laws and regulations on our relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors;
- our ability to obtain approval to commercialize products outside the United States;

Risks Relating to Our Dependence on Third Parties

- our ability to establish and maintain collaborative relationships to further the development of our drug candidates;

- the professional conduct of third parties we rely on to conduct, supervise and monitor certain of our clinical trials;
- our dependence on limited sources of supply for the components used in TTP399 and our other drug candidates;
- our reliance on third-party manufacturers to produce our drug candidates;

Risks Relating to Our Intellectual Property

- our ability to continue to protect proprietary rights to our intellectual property;
- the unauthorized disclosure of our trade secrets or other confidential information;
- the impact of changes to the patent laws in the United States and other jurisdictions;
- the impact of litigation for infringing intellectual property rights of third parties;
- the impact of litigation to protect or enforce our patents or other intellectual property;
- our ability to enforce our intellectual property rights throughout the world;
- our ability to obtain patent term extensions for our drug candidates;

Risks Relating to Employee Matters and Managing Growth

- the impact of expanding our operations and managing growth;
- our ability to attract and retain key personnel;
- the impact of our employees, independent contractors, principal investigators, CROs, consultants and collaborators in the event that they engage in misconduct or other improper activities;

Other Risks Relating to Our Business

- the impact of the widespread outbreak of an illness or any other communicable disease, or any other public health crisis;
- the impact of COVID-19 on our clinical trials, the operations of our licensees and our financial results;
- the impact of using our financial and human resources to pursue a particular research program or drug candidate and failing to capitalize on programs or drug candidates that may be more profitable or for which there is a greater likelihood of success;
- the impact of product liability lawsuits;
- the exposure to uninsured liabilities;
- our ability to remain competitive given the rapidly changing market for our proposed drug candidates;
- the impact of computer system failures, cyber-attacks or a deficiency in our cyber-security;

Risks Related to our Common Stock

- the impact of MacAndrews’ substantial influence over our business;
- the potential for conflicts of interest with our directors who have relationships with MacAndrews;
- our ability to pay cash dividends;
- the potential for securities class action litigation;
- the impact of research and reports that equity research analysts publish about us and our business;
- the impact of substantial sales of shares into the market at any time;
- the dilution created by future sales and issuances of our Class A common stock or rights to purchase Class A common stock;
- our reliance upon our “smaller reporting company” status;
- our exemption from certain corporate governance requirements since we are a “controlled company”;
- the existence of provisions in our governing documents or state law which may delay or prevent our acquisition by a third party;
- our obligation to make payments under the Tax Receivable Agreement;

- our ability to make distributions from vTv LLC to satisfy our obligations;
- the benefits conferred upon M&F that will not benefit Class A common stockholders to the same extent as it will benefit MacAndrews.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage pharmaceutical company focused on treating metabolic and inflammatory diseases to minimize their long-term complications and improve the lives of patients. We have an innovative pipeline of first-in-class small molecule clinical and pre-clinical drug candidates for the treatment of a wide range of diseases. Our pipeline is led by our programs for the treatment of type 1 diabetes (*TTP399*) and for psoriasis (*HPP737*). We completed the Simplici-T1 Study, an adaptive Phase 1b/2 study supported by JDRF International ("JDRF"), to explore the effects of *TTP399* in patients with type 1 diabetes at the beginning of 2020. In February 2020, we reported positive results from the Phase 2 - Part 2 confirming phase of this study which achieved its primary objective by demonstrating statistically significant improvements in HbA1c (long-term blood sugar) for *TTP399* compared to placebo. We are working on the design for pivotal and registrational studies for *TTP399*, with input from the FDA. In addition to the pivotal studies of *TTP399*, we are currently conducting a Phase 1 mechanistic study of *TTP399* in patients with type 1 diabetes to determine the impact of *TTP399* on ketone body formation during a period of acute insulin withdrawal.

We are also conducting a multiple ascending dose Phase 1 study of *HPP737*, an orally administered phosphodiesterase type 4 ("PDE4") inhibitor, to assess the pharmacokinetics, pharmacodynamics, safety and tolerability of *HPP737* in healthy volunteers as part of our psoriasis program. The goal of this study is to confirm the maximum tolerated dose with minimal or no gastrointestinal ("GI") intolerance in the form of nausea, vomiting or diarrhea. We expect to complete this study in the second quarter of 2021.

On December 15, 2020, the Company announced that the Phase 2 Elevage study of *azeliragon* in people with mild Alzheimer's disease and type 2 diabetes did not meet its primary objective of demonstrating an improvement in cognition as assessed by the 14-item Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-cog14) relative to placebo. The Company is discontinuing its development of *azeliragon* for Alzheimer's disease, but is exploring the possibility of *azeliragon* as a drug candidate for other indications, including the prevention of type 1 diabetes.

In addition to our internal development programs, we are furthering the clinical development of four other programs: a small molecule GLP-1r agonist, the PDE4 inhibitor, HPP737, a PPAR-delta agonist, and an Nrf2 activator through partnerships with pharmaceutical partners via licensing arrangements.

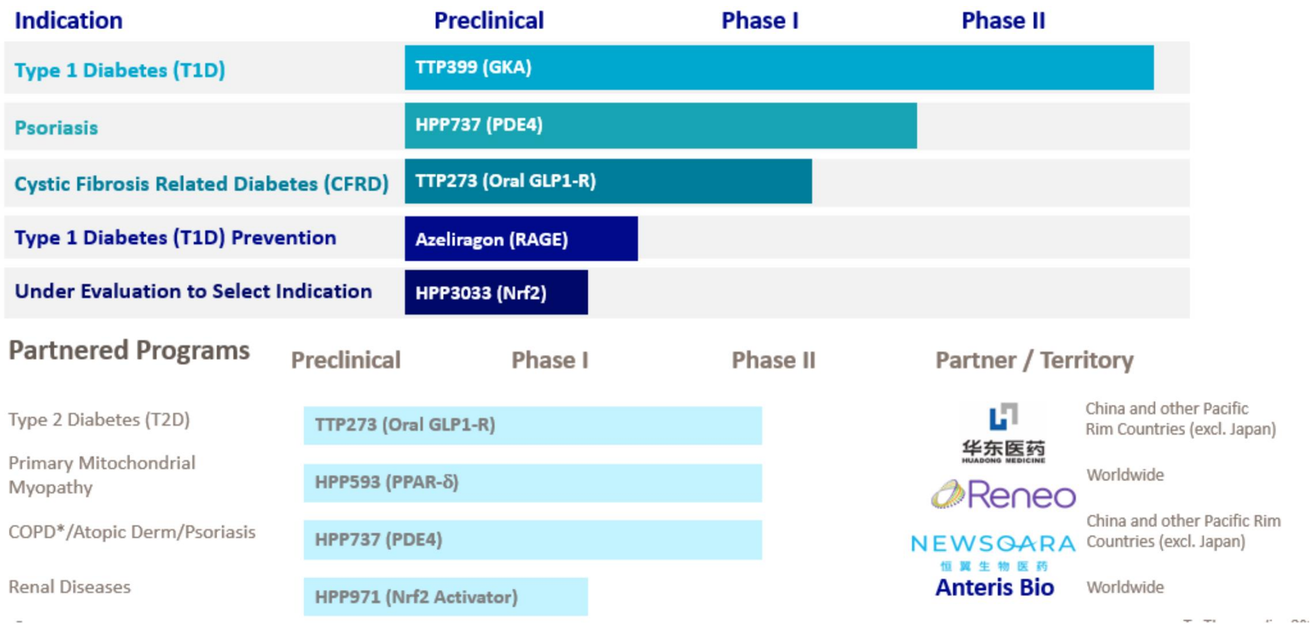
Impact of COVID-19

We have been actively monitoring the COVID-19 pandemic and its impact on our business, employees, patients, partners, suppliers and vendors. Our financial results for the three and twelve months ended December 31, 2020 were not significantly impacted by COVID-19. Though our financial results were not significantly impacted, COVID-19 precautions directly and indirectly impacted the timelines for the clinical trials conducted during 2020 and may impact the timelines of the trials currently in process.

vTv has continued to make adjustments that allow us to maintain our business operations despite current circumstances, including establishing remote working options for all employees. Given the current scope of the pandemic, we cannot predict the impact of the progression of the COVID-19 outbreak on future clinical trial and financial results due to a variety of factors, including the continued good health of our employees, the ability of our third party suppliers, vendors, manufacturers and partners to continue to operate and provide services, the ability of our clinical trial sites to continue or resume operations, any further government and/or public actions taken in response to the pandemic and the ultimate duration of the COVID-19 outbreak/pandemic.

Our Pipeline

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



* Chronic obstructive pulmonary disease

Our Strategy

Our goal is to advance the development of our differentiated pipeline of orally administered, small molecule drug candidates to treat metabolic and inflammatory diseases to minimize their long-term complications and to improve the lives of patients. As key components of our strategy, we are focused on:

- ***Continuing to advance TTP399 as a potential treatment for type 1 diabetes***. In February 2020, we announced positive results from 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. The study achieved its primary objective by demonstrating statistically significant improvements in HbA1c (long-term blood sugar) for TTP399 compared to placebo. We are working on the design for pivotal and registrational studies for *TTP399*, with input from the FDA. In addition to the pivotal studies of *TTP399*, we are currently conducting a Phase 1 mechanistic study in patients with type 1 diabetes to determine the impact of *TTP399* on ketone body formation during a period of acute insulin withdrawal.
- ***Beginning to advance HPP737 as potential treatment of psoriasis.*** We are conducting a multiple ascending dose Phase 1 study of *HPP737*, an orally administered phosphodiesterase type 4 (“PDE4”) inhibitor, to assess the pharmacokinetics, pharmacodynamics, safety and tolerability of *HPP737* in healthy volunteers as part of our psoriasis program. The goal of this study is to confirm the maximum tolerated dose with minimal or no GI intolerance in the form of nausea, vomiting, or diarrhea. If successful, we plan to initiate a Phase 2 proof of concept study to assess the efficacy and safety of *HPP737* as a potential treatment for psoriasis.
- ***Pursuing TTP273 as a treatment of cystic fibrosis-related diabetes.*** We are planning an adaptive Phase 1b/2 clinical trial assessing the pharmacokinetics, pharmacodynamics, safety and tolerability of *TTP273* and are seeking a funding partner to enable the conduct of this clinical trial.
- ***Seeking additional strategic collaborations and additional funding to support the continued development and commercialization of our development programs***. We will continue to seek additional funding to support the further development of our drug candidates. Such support may come from strategic collaborations with non-profit research funding organizations such as JDRF International or from collaboration agreements with other pharmaceutical companies.
- ***Continuing to monitor and support existing partnerships for pipeline programs***. Our partners developing our GLP-1r, PPAR-δ, PDE4, and Nrf2 programs continue to advance these programs in their respective licensed territories. We continue

to support and monitor these partnerships. For example, following the successful completion of a Phase 1 study and the receipt of orphan designation for the PPAR-δ drug candidate, Reneo Pharmaceuticals, Inc. recently completed a $95 million Series B offering to initiate a global Phase 2 clinical trial in primary mitochondrial myopathies in early 2021.

Our Type 1 Diabetes Program –TTP399

Diabetes Overview

Type 1 diabetes is an autoimmune disease in which a person's pancreas stops producing insulin (a hormone that enables people to get energy from food). Type 1 diabetes results when the body's immune system attacks and destroys the insulin-producing cells in the pancreas called beta cells. While the causes of type 1 diabetes 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 Type 1 Diabetes and Their Limitations

Patients with type 1 diabetes have difficulty achieving and maintaining consistent glycemic control, defined as HbA_{1c} < 7% as recommended by the American Diabetes Association (ADA). In order to maintain appropriate glycemic control, patients with type 1 diabetes are required to constantly monitor their blood glucose levels, closely manage their diet, and administer insulin via injection in response. While technology has advanced to help people with type 1 diabetes manage the burden of this monitoring and insulin administration process, including continuous glucose monitors and insulin pumps, patient outcomes have not improved: approximately 80% of people with type 1 diabetes fail to achieve the ADA's recommended HbA1c levels. Failure to maintain glycemic control results in dangerous excursions into hyperglycemia or hypoglycemia that are potentially fatal. In addition, the accumulated impact of these glycemic excursions can raise a patient's risk of potentially serious and life-threatening long-term complications, such as cardiovascular disease, blindness, kidney failure, and nerve damage.

A number of existing treatment options for type 2 diabetes have been investigated to treat type 1 diabetes, generally without success. While a pair of SGLT-1/2 and SGLT-2 inhibitors were recently approved in Europe and Japan with label restrictions to certain sub-groups of people with type 1 diabetes, these therapies have not been approved in the U.S. due to safety risks primarily relating to diabetic ketoacidosis ("DKA"). Alternative therapeutic modalities, including monoclonal antibodies, are under clinical investigation and have demonstrated evidence of the potential to delay the onset of type 1 diabetes. Such alternatives have not completed clinical development or received regulatory approval nor do they address the unmet need of existing patients with type 1 diabetes or those that eventually become patients with type 1 diabetes following any therapeutic delay in disease onset.

With insulin and pramlintide injection as the only treatment options approved in the United States for type 1 diabetes, there is an unmet medical need to provide people with type 1 diabetes additional, especially oral, treatment options that can help them to reduce HbA1c, or the incidence of hypoglycemia (blood glucose levels below normal) or DKA.

The Role of Glucokinase Activation in Diabetes

Glucokinase ("GK") is a key regulator of glucose homeostasis and acts as the physiological glucose sensor, changing its conformation, activity, and/or intracellular location in parallel with changes in glucose concentrations. GK has two 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 β-cells). Second, GK acts as a biological sensor for changes in serum glucose levels and modulates changes in liver glucose metabolism that in turn regulates the balance between hepatic glucose production and glucose consumption, and modulates changes in insulin secretion by the β-cells. GK activation is attractive as a potential therapy for the treatment of type 1 diabetes and has a mechanism of action entirely distinct from currently marketed oral anti-diabetic drugs ("OAD").

TTP399

TTP399 is an orally administered, small molecule, liver-selective glucokinase activator ("GKA") in development as a new potential OAD for the treatment of type 1 diabetes. TTP399 has a novel mechanism of action: liver-selective activation of GK that seeks to provide intensive glycemic control and a reduction in the risk of hypoglycemia. Our trials for *TTP399* to date suggest that our liver-selective 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. 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*, one of which was six months in duration. In our Phase 1 and 2 clinical trials, *TTP399* was well tolerated with negligible incidence of hypoglycemia.

Positive Phase 2 Simplici-T1 Study

In February 2020, we announced positive results from 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 ("T1D") over a 12 week period. The study was designed to evaluate whether *TTP399* is well tolerated and can improve daily glucose profiles and

HbA_{1c} in people living with T1D when administered as an oral add-on to insulin therapy. The Simplici-T1 Study achieved its primary objective by demonstrating statistically significant improvements in HbA_{1c} for *TTP399* compared to placebo.

TTP399 was well tolerated with similar incidences of treatment-emergent adverse events overall and by system organ class in both treatment groups. The study had no report of diabetic ketoacidosis in either treatment group. There was no incidence of severe hypoglycemia in the treated group and one incident in the placebo group. Patients taking *TTP399* experienced fewer symptomatic hypoglycemic episodes: two subjects taking *TTP399* reported at least one event compared to eight subjects taking placebo.

Clinical Development Plan

In light of the positive results of our Simplici-T1 Study, we requested a Type C meeting with the FDA to discuss the trial design and other requirements for the next stage of development for *TTP399*. The Company received written responses from the FDA in June and September 2020. Based upon the responses provided, the Company plans to conduct a placebo-controlled six-month clinical trial in approximately 400 subjects, followed by a second placebo-controlled six-month clinical trial to be initiated thereafter. The Company would also include a six-month open label extension in the first clinical trial to provide patient data of the necessary duration to support the safety and efficacy of *TTP399*. In its response, the FDA confirmed that the effect size of *TTP399* on events of hypoglycemia as demonstrated in the Phase 2 SimpliciT-1 Study are clinically meaningful and that a reduction in events of hypoglycemia would be an acceptable clinical endpoint for evaluation of a therapy for the treatment of type 1 diabetes.

Finally, the Company is conducting a phase 1 mechanistic study of *TTP399* in patients with type 1 diabetes to determine the impact of *TTP399* on ketone body formation during a period of acute insulin withdrawal. The Company proposed the mechanistic study to the FDA and the FDA recommended that the study be performed in support of the planned pivotal trials. The results of this mechanistic study will provide additional evidence to support the effects of *TTP399* on diabetic ketoacidosis ("DKA") in patients with type 1 diabetes. We expect to report top-line results in the second or third quarter of 2021.

Our Psoriasis Program – PDE4 Inhibitor

Psoriasis Overview

Psoriasis is a chronic autoimmune inflammatory disease in which the growth cycle of skin is accelerated due to an imbalance in pro-inflammatory and anti-inflammatory cytokines. This results in the proliferation of skin cells and the development of raised, red, silvery scale plaques (i.e. plaque psoriasis, psoriasis vulgaris) that has not only medical implications but an impact on a patient's quality of life. While the specific inciting events for this pro-inflammatory process are unknown psoriasis may be caused by autoimmunity and genetic predisposition. Events such as trauma to the skin, stress, illness or infection that triggers the immune systems, obesity, and weather have been identified as triggers for flare ups.

Current Treatment for Psoriasis and Their Limitations

Topical therapies including glucocorticoids and vitamin D analogs are the mainstay of treatment for mild psoriasis. The continuous long-term use of glucocorticoids is limited by the risk of skin thinning / atrophy and the potential for systemic absorption. Vitamin D analogs are often added to glucocorticoids to improve glucocorticoid efficacy while allowing for reduction in glucocorticoid dose. Moderate to severe disease is treated with systemic therapies including oral PDE4 inhibition, immunosuppressants, retinoids, and biologics (ex: anti-TNF agents, IL-17 inhibitors, IL-23 inhibitors). Biologics, while realizing high efficacy rates in treating psoriasis, are associated with administration by injection, high cost, need for laboratory monitoring and increased risk of infection.

Inhibitors of PDE4 act by increasing intracellular concentrations of cyclic adenosine monophosphate ("cAMP"), which has a broad range of anti-inflammatory effects. PDE4 activity is increased in the skin of patients with psoriasis leading to up-regulation of immune modulatory, pro-inflammatory genes and cytokines including interleukin-17 (IL-17), interleukin-23 (IL-23), and tumor necrosis factor-alpha (TNF-α). Treatments for psoriasis are aimed at reducing pro-inflammatory cytokine activity. The therapeutic potential of oral PDE4 inhibitors has been limited by dose limiting AEs such as nausea, vomiting, diarrhea and headache.

HPP737

HPP737 is an orally administered, potent and selective, non-CNS penetrant PDE4 inhibitor that addresses inflammatory diseases and offers the potential for an improved tolerability profile and efficacy over commercially available PDE4 inhibitors. *HPP737* has shown potent inhibition of IL-17a and TNF-α production in in vitro studies and activity in several animal models of inflammation. *HPP737* has completed Phase 1 single-ascending dose and initial multiple-ascending dose studies, in which it was well tolerated at all doses tested in healthy volunteers. Clinical data generated to date supports achieving target engagement (reduction in ex vivo LPS stimulated TNF-α) at *HPP737* plasma concentrations predicted to be efficacious from preclinical models.

Clinical Development Plan

We are conducting a subsequent multiple ascending dose Phase 1 study of *HPP737*, an orally administered phosphodiesterase type 4 ("PDE4") inhibitor, to assess the pharmacokinetics, pharmacodynamics, safety and tolerability of *HPP737* in healthy volunteers as part of our psoriasis development program. The goal of this study is to continue multiple-dose escalation to define a maximum tolerated dose characterized by minimal or no GI intolerance (i.e., nausea, vomiting or diarrhea). We expect to complete this study in the second quarter of 2021.

Our Dementia Program – *Azeliragon*

Phase 2 Elevage Study in Patients with Mild-AD and Type 2 Diabetes

Based on a subgroup analysis from the previously conducted Phase 3 STEADFAST Study, we conducted a Phase 2 study to evaluate *azeliragon* as a potential treatment of mild-AD in patients with type 2 diabetes (the "Elevage Study"). The Elevage Study did not meet its primary objective of demonstrating an improvement in cognition as assessed by the 14-item Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-cog14) relative to placebo.

Future Development of Azeliragon

Upon the failure of the Elevage Study, we have discontinued the development of *azeliragon* for the treatment of Alzheimer's disease. However, we are evaluating the potential for its use in other indications. We currently have an ongoing pre-clinical collaboration with the University of Queensland Australia and Yale University to evaluate the use of *azeliragon* for the prevention of type 1 diabetes in animal models. We may also pursue other strategic opportunities for the further development of *azeliragon*, when and if they arise.

Our Cystic Fibrosis Related Diabetes Program – GLP-1r Agonist

Cystic Fibrosis Related Diabetes Overview

Cystic fibrosis related diabetes ("CFRD") shares some features with both type 1 and type 2 diabetes but is distinct, and is likewise categorized as diabetes due to other causes, specifically a disease of the exocrine pancreas by the American Diabetes Association. In people with cystic fibrosis ("CF"), the thick, sticky mucus that is characteristic of the disease causes scarring of the pancreas. This scarring prevents the pancreas from producing normal amounts of insulin. The damaged pancreas also responds to insulin signaling in a delayed manner. The delay and blunting of the insulin response in patients with CFRD results in post-prandial hyperglycemia.

The Role of GLP-1r Activation in Cystic Fibrosis Related Diabetes

GLP-1, an incretin hormone that is released by the gut in response to nutrients, lowers postprandial glucose by promoting insulin secretion. Abnormally low postprandial stimulation of incretins has been described in CF patients and improvement in postprandial hyperglycemia has been demonstrated following prandial administration of GLP-1 agonists or DPP-4 inhibitors. Nevertheless, the use of existing GLP-1 mimetics that are available for the treatment of type 2 diabetes to treat CFRD is limited by the GI side effects and undesired weight loss associated with these agents.

TTP273

TTP273 is an orally available, small molecule GLP-1 receptor agonist which has been demonstrated to reduce postprandial glucose excursion in response to an oral glucose test or mixed meal tolerance test in both pre-clinical and clinical studies. We believe that *TTP273* could be used to treat postprandial hyperglycemia in CFRD patients and CF patients with abnormal post-prandial glucose excursions without inducing hypoglycemia or GI side effects. An oral therapy such as *TTP273* is needed because the current method of treatment of CFRD is injected insulin, which comes with associated risks of hypoglycemia and poses additional burdens on patients. Other available oral therapies for type 2 diabetes are not recommended for the treatment of CFRD due to side effects such as hypoglycemia, weight loss, or nausea. In particular, the GLP-1 mimetics currently in the market have been demonstrated to result in increased GI side effects and undesired weight loss, both of which are major drawbacks for patients with CFRD.

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*, a predecessor orally administered GLP-1r agonist. In our Phase 1 and Phase 2 clinical trials, *TTP273* has been demonstrated to be well-tolerated with lower incidences of GI side effects, such as nausea and vomiting, than placebo with minimal weight loss, especially in non-obese patients.

We are currently planning an adaptive Phase 1b/2 clinical trial assessing the pharmacokinetics, pharmacodynamics, safety and tolerability of *TTP273*, but the final design may be adjusted based on the feedback received, if any, from the FDA and are seeking a funding partner to enable the conduct of this clinical trial.

Our Nrf2/Bach1 Modulator Program

The Role of Nrf2/Bach1 Modulators

Chronic, unresolved inflammation, oxidative stress, and resulting fibrosis are key features of many diseases. Inflammation is an integral component of the normal immune response that occurs when cells encounter harmful stimuli, such as invading pathogens, damaged cells, or irritants. During inflammation, cells activate inflammatory processes and complexes that increase the production of cytokines, which are proteins that recruit and activate immune cells.

Inflammation and mitochondrial metabolism are closely associated. The mitochondria are often called the “powerhouses” of the cell as they produce the energy that the cell needs to function. This energy is produced by converting fatty acids and glucose into adenosine triphosphate (ATP) by a process called oxidative phosphorylation. During inflammation, mitochondrial metabolism is temporarily reprogrammed to suppress oxidative phosphorylation. Instead of primarily making ATP, the mitochondria divert fatty acids and glucose to increase the production of proinflammatory mediators. During this reprogramming, the mitochondria release chemically-reactive molecules called reactive oxygen species (ROS) that can directly attack pathogens and amplify the production of cytokines.

In a normal immune response, the resolution of inflammation begins after the harmful stimuli have been eliminated. Nrf2 is a protein that plays a key role in the resolution of inflammation by regulating the expression of specific genes involved in mitochondrial metabolism, redox balance, and cytokine production. When activated, Nrf2 promotes the resolution of inflammation by normalizing mitochondrial metabolism, restoring redox balance, and suppressing cytokine production.

In many chronic and genetic diseases, Nrf2 activity is suppressed, and the resolution of inflammation fails to occur or is inadequate, leading to persistent mitochondrial dysfunction, excess production of ROS, and production of cytokines. These processes cause chronic inflammation, which can ultimately lead to tissue damage and loss of organ function.

To date, therapeutic agents seeking to active Nrf2, such as such as Bardoxolone or Tecfidera, have relied on reactive, electrophilic biological targets that may present safety and tolerability issues. Non-electrophilic activation of the Nrf2 pathway via targeting the Bach1 transcriptional repressor provides an alternative mechanism by which to increase the activation of Nrf2 to reduce the oxidative stress and inflammation associated with many acute and chronic diseases.

Bach1 is a transcriptional repressor that controls the expression of certain genes involved in the body’s antioxidant response processes. Genetic knock-out models of Bach1 have shown increased expression of multiple antioxidant proteins such as heme oxygenase-1 (HMOX1), leading to a significant level of cellular, tissue and organ protection in a wide variety of mouse models. Hemin and the hemin mimetic cobalt protoporphyrin IX (“CoPP”) are Bach1 ligands that have served as useful tool compounds to investigate the role of Bach1 inhibition in a variety of disease settings. Both molecules have been shown to have beneficial effects on oxidative stress and inflammatory-mediated pathologies in a number of animal models. Further, the ubiquity of the response suggests that the observed tissue protective effects are not related to the underlying causes of a particular disease, but instead are an intrinsic outcome of Bach1 modulation along with Nrf2 activation.

HPP3033

Our candidate, *HPP3033*, represents a novel, non-electrophilic therapeutic approach to activating the Nrf2 pathway that has the potential to be used in the treatment of chronic diseases associated with oxidative stress. We are currently evaluating *HPP3033* and other Nrf2 activator compounds in various preclinical studies.

Partnered Development Programs

PPAR-δ and Reneo Pharmaceuticals, Inc.

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-δ) 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.

GLP-1r and Huadong

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 territories, 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 $22.0 million, as amended in January 2021. Additionally, we are eligible to receive additional potential regulatory milestone of $20.0 million if Huadong receives regulatory approval for a central nervous system indication. Further, 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 original Huadong License Agreement, we had the obligation to conduct a Phase 2 multi-region clinical trial (the "Phase 2 MRCT"), should Huadong require us to do so. We were also responsible for contributing up to $3.0 million in connection with the Phase 2 MRCT, if it occurs. However, the Huadong License Agreement was amended in January 2021 to remove these obligations.

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.

PDE4 and Newsoara Biopharma

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 territories (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 $58.5 million, as amended. 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.

Nrf2 and Anteris Bio

On December 11, 2020, we entered into a license agreement with Anteris Bio, Inc. (“Anteris”) (the “Anteris License Agreement”), under which Anteris obtained a worldwide, exclusive and sublicensable license to develop and commercialize vTv LLC’s Nrf2 activator, *HPP971*.

Under the terms of the Anteris License Agreement, Anteris paid vTv LLC an initial license fee of $2.0 million. vTv LLC is eligible to receive additional potential development, regulatory, and sales-based milestone payments totaling up to $151.0 million. Anteris is also obligated to pay vTv royalty payments at a double-digit rate based on annual net sales of licensed products. Such royalties will be payable on a licensed product-by-licensed product 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, vTv LLC received a minority ownership interest in Anteris.

Under the terms of the Anteris License Agreement, Anteris will be responsible for the 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 Anteris License Agreement, unless terminated earlier, will continue until expiration of all royalty obligations of Anteris to vTv LLC. Either party may terminate the Anteris License Agreement for the other party’s uncured material breach. Anteris may terminate the Anteris License Agreement at will upon prior written notice. Either party may terminate the Anteris License Agreement for the other party’s insolvency.

Inbound Partnerships

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. In February 2020, we reported positive results from the Phase 2 confirming portion of the Simplici-T1 Study. See “Our Type 1 Diabetes Program –TTP399 – Positive Phase 2 Simplici-T1 Study” above for further details. According to the terms of the JDRF Agreement, JDRF provided research funding of $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*. This agreement was amended in May 2019 to create milestone payments applicable to certain specific and non-specific areas of therapeutic use. Under the terms of the Novo License Agreement, the Company has additional potential developmental and regulatory milestone payments totaling up to $9.0 million for approval of a product for the treatment of type 1 diabetes, $50.5 million for approval of a product for the treatment of type 2 diabetes, or $115.0 million for approval of a product in any other indication. 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.

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. We do not have multiple sources of supply for the components used in our drug candidates.

Intellectual Property

Patents

The IP portfolio for *azeliragon* includes issued patents in the U.S. directed to *azeliragon* as a composition of matter and methods of use to treat various indications. 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”). The IP portfolio for *azeliragon* also includes patent families 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 which can only be applied to a single patent following approval.

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, if 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. The IP portfolio for *TTP399* also includes patent families covering crystal forms, salt forms, and solid formulations of *TTP399* as well as combinations of *TTP399* with metformin, DPP-4 inhibitors, or GLP-1r agonists .The IP portfolio also includes 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 2040.

The IP portfolio for *HPP737* includes issued patents in the U.S. generically covering *HPP737* as a composition of matter and methods of use to treat various indications. The issued U.S. patent generically covering *HPP737* as a composition of matter will expire no earlier than 2029 but may expire as late as 2034, if we obtain and apply the maximum possible extension under the Hatch-Waxman Act following approval. The IP portfolio for *HPP737* also includes a patent family covering the specific structure of *HPP737* and another patent family covering a crystalline form of *HPP737*. Any patents issuing from these two patent families will expire in 2040.

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, but 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 *TTP273* also includes patent families covering crystalline, non-crystalline, and salt forms of *TTP273*, synthetic precursors to, and method of manufacture of *TTP273*, as well as combinations of *TTP273* and metformin, and dosage regimens of *TTP273*. These additional patent families have expiration dates ranging from 2032 through potentially 2040.

The IP portfolio for the Nrf2/Bach1 program includes issued patents in over 25 countries and regions, including the U.S., Europe, Japan, Canada, Australia, and China, directed to *HPP971* and *HPP3033* as compositions of matter. The issued U.S. patent covering *HPP971* and *HPP3033* as compositions of matter will expire no earlier than 2032, but may expire as late as 2037, if we obtain and apply the maximum possible extension under the Hatch-Waxman Act following approval. Patents covering *HPP971* and *HPP3033* as a composition of matter outside the United States will expire no earlier than 2031 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 the Nrf2/Bach1 program also includes patent families covering backup compounds, methods of use in combination with other Nrf2 activator compounds such as dimethyl fumarate and bardoxolone, and methods to treat sickle cell diseases, osteoporosis, and refractive ocular disorders. These additional patent families have expiration dates ranging from 2034 through potentially 2041.

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.

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. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. 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. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, and availability of reimbursement.

Potential Competing Products – Type 1 Diabetes

If approved, we expect that our type 1 diabetes investigational drug candidate will compete with other oral non-insulin agents that are currently being developed or which have limited approval in certain jurisdictions. These include SGLT-1/2 inhibitors, such as sotagliflozin, being developed by Lexicon and SGLT-2 inhibitors such as AstraZeneca's dapagliflozin, both of which are approved for limited use in the European Union and Japan as well as Eli Lilly/Boehringer Ingelheim's empagliflozin, which is not currently approved for the treatment of type 1 diabetes. None of these treatments are approved for use in type 1 diabetes in the United States.

Potential Competing Products – Psoriasis

If approved, we expect that our psoriasis candidate will compete with Otezla (apremilast), the only PDE4 inhibitor currently approved to treat psoriasis and marketed by Amgen Inc., topical PDE4 inhibitor drug candidates currently in development, if approved, including roflumilast being developed by Arcutis Biotherapeutics, anti-TNF biologics approved to treat psoriasis, including Enbrel (etanercept), Remicade (infliximab), and Humira (adalimumab), and anti-TNF biosimilars currently in development.

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.

Collaboration Revenue and Customers

The majority of our collaboration revenue for the years ended December 31, 2020, 2019 and 2018 is related to our licenses of certain compounds in the pre-clinical stage or clinical stage, including the Anteris License Agreement, Huadong License Agreement, the Reneo License Agreement and the Newsoara License Agreement. Revenue recognized in these periods relates to initial consideration received in the form of upfront payments and equity interests, research activities performed by our personnel, and the achievement of development milestones.

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 European Union ("EU"), extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, 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. For a full discussion of the regulatory framework for the approval and regulation of investigational drug candidates, and applicable domestic and foreign healthcare law, please see "Part 1 – Item 1 – Business - Government Regulation and Product Approvals" in our Annual Report on Form 10-K filed on February 21, 2020.

Human Capital

As of December 31, 2020, we had 25 employees, of which at least 13 hold graduate degrees (including 9 doctorate degrees) and 13 are engaged in full-time research and development activities. None of our employees are represented by a labor union, and we consider our employee relations to be good. We continually evaluate our business needs and opportunities and balance in house expertise and capacity with external expertise and capacity. Currently, we rely on third-party contract research organizations and contract manufacturers for the conduct of our studies.

Our Corporate Information

We were incorporated under the laws of the State of Delaware in 2015. Our principal executive offices are located at 3980 Premier Drive, Suite 310, 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 pharmaceutical 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 $8.5 million, $17.9 million and $8.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had a total accumulated deficit of approximately $290.0 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 *TTP399*, 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 TTP399 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 *TTP399* 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 the ongoing and planned trials for our drug candidates and prior to the commercialization of any of our drug candidates. We are seeking possible additional partnering opportunities and grants 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 also continue to evaluate other financing strategies to fund our ongoing trials. Such financing strategies include 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 our Controlled Equity Offering℠ Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor Fitzgerald”) (the “ATM Offering”) and our purchase agreement with Lincoln Park Capital Fund, LLC (“Lincoln Park”) (the “LPC Purchase Agreement”). Under both of these arrangements, the Company has the right to sell shares of the Company’s Class A Common Stock, subject to certain limitations and conditions as set forth in the related agreements. As of February 24, 2021, there remains $5.5 million of availability under the ATM offering. While the LPC Purchase Agreement allows for sales of up to $47.0 million, we only have 441,726 remaining shares registered under this agreement as of February 24, 2020. Though we can register additional shares for sale under this agreement, such sales may be limited by the conditions set forth in the LPC Purchase Agreement. We also will need to raise substantial additional capital in the future to conduct further clinical trials of *TTP399* 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 planned registrational trial(s) for *TTP399* as a potential treatment of type 1 diabetes and our multiple ascending dose phase 1 study of *HPP737* in healthy volunteers as part of our psoriasis program;
- 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 ATM Offering and LPC Purchase 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.

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

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

We are a clinical stage pharmaceutical 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 TTP399* and our other drug candidates. We have not yet obtained regulatory approvals for any of our drug candidates. Consequently, any statements about our future success or viability are not based on any substantial operating history or commercialized products. Our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. As a result, we may never successfully develop and commercialize a product, which could lead to a material adverse effect on the value of any investment in our securities.

Risks Relating to the Development, Regulatory Approval, and Commercialization of Our Drug Candidates

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For example, the Phase 2 Elevage Study in mild Alzheimer’s disease and type 2 diabetes did not meet its primary endpoints. 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 our drug candidates do not achieve the primary efficacy endpoints or demonstrate safety, the prospects for approval of these candidates would be materially and adversely affected. If our 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.

We cannot be certain that any of our 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 our 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, the Phase 2 Elevage Study in mild Alzheimer’s disease and type 2 diabetes did not meet its primary endpoints. Our clinical development programs for our drug candidates may not lead to regulatory approval from the FDA and similar foreign regulatory agencies. This failure to obtain regulatory approvals would prevent our drug candidates from being marketed and would prevent us from generating revenue from our drug candidates, which would have a material and adverse effect on our business.

All of our drug candidates require regulatory review and approval prior to commercialization, and generally, only a small percentage of pharmaceutical products under development are ultimately approved for commercial sale. Moreover, any delays in the regulatory review or approval of our drug candidates would delay market launch, increase our cash requirements and result in additional operating losses.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain, and failure to comply with applicable regulatory requirements can, among other things, result in the suspension of regulatory approval as well as possible civil and criminal sanctions. We may be unable to submit any new drug application (“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. 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 registrational 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 registrational 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.

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.

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 our 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 our 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 TTP399 and our 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.

Further, 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.

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.

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.

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.

Oral non-insulin agents that are currently being developed to treat type 1 diabetes that may compete with *TTP399* include SGLT-1/2 inhibitors, such as sotagliflozin, being developed by Lexicon and SGLT-2 inhibitors such as AstraZeneca's dapagliflozin and Eli Lilly/Boehringer Ingelheim's empagliflozin. Some of these SGLT-1 and SGLT-2 inhibitors have been approved for certain sub-groups of type 1 diabetics in Europe and Japan, but these therapies have not yet been approved for use in the U.S. due to safety risks including those pertaining to diabetic ketoacidosis.

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.

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.

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 of 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 any of our 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/or commercialization of our drug candidates, including *TTP399*. Failure to obtain a collaborative relationship for these candidates, particularly in the European Union and for other markets requiring extensive sales efforts, may significantly impair the potential for our drug candidates. 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 TTP399 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 TTP399 or our other drug candidates. If we obtain regulatory approval for TTP399 or our other drug candidates, we would need to expand the supply of their 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.

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 novelty, non-obviousness, definiteness and 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 pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain.

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. 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 Development, Regulatory Approval, and 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. 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.

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

The widespread outbreak of an illness or any other communicable disease, or any other public health crisis, could adversely affect our business, results of operations and financial condition.

We could be negatively affected by the widespread outbreak of an illness or any other communicable disease, or any other public health crisis that results in economic and trade disruptions, including the disruption of global supply chains. In March 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. Due to the spread of COVID-19, many countries around the world and jurisdictions in the United States have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Further, “non-essential” businesses have been required to close operations or shift to a remote working environment.

Due to the various restrictions put into effect by governments around the world, including the United States and Canada, health professionals may reduce staffing and reduce or postpone meetings with clients in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations.

Quarantines, stay-at-home orders and other limitations can disrupt our research and administrative functions, regardless of whether we are actually forced to close our own facilities. Similar disruptions may also affect other organizations and persons that we collaborate with or whose services we are dependent on. The need for our employees and business partners to work remotely also creates greater potential for risks related to cybersecurity, confidentiality and data privacy.

With respect to the COVID-19 outbreak specifically, such outbreak could also potentially affect the operations of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned clinical trials. Further, it may also slow potential enrollment of our ongoing clinical trials. The COVID-19 outbreak and mitigation measures also have had, and may continue to have, an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

The extent to which the COVID-19 outbreak impacts our future business and operations will depend on developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact. As a result, there can be no assurance as to the manner and extent to which the COVID-19 outbreak (or other large-scale disruption) could impact our operations, results and financial condition.

The recent outbreak of COVID-19 may materially and adversely affect our clinical trials, the operations of our licensees and our financial results.

The extent to which COVID-19 may impact our clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, or the effectiveness of actions to contain and treat for COVID-19. The continued spread of COVID-19 globally could adversely impact recruitment for our ongoing clinical trials or our ability to recruit patients for future planned clinical trials. COVID-19 may also affect the employees and operations of third-party contract research organizations located in affected geographies that we rely upon to carry out such enrollments and trials. Further, it may delay the initiation of any additional clinical trials we are planning for which we require additional approval or are seeking guidance from the FDA or other regulatory agencies. The negative impacts of COVID-19 in these instances may result in delays to our operational plans, increases in our operating expenses, and may have a material adverse effect on our financial results.

Additionally, COVID-19 may hinder the ability of our license partners to continue the development of our licensed product candidates. This may result in the delay or the inability of the partners to execute on their development plans which, in turn, may cause delays in or the inability to achieve the clinical, regulatory and sales milestones which trigger payments to us under the terms of our license agreements. This may have a material adverse effect on our financial results and operations as the related milestone payments may not be received at the expected time, if at all.

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* and *TTP399*. 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 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.

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.

One of our directors is affiliated with MacAndrews. This director 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. 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;
- the availability of cash or financing to continue our clinical trials and other operations;
- 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.

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, 2020, 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 36,606,212 shares of our Class A common stock. As a result, MacAndrews and its affiliates hold shares representing approximately 77.4% 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.

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. On August 3, 2020, we filed a registration statement under the Securities Act to register a further 3,750,000 shares of our Class A common stock reserved for issuance under our 2015 Plan, as amended.

We also have issued warrants to purchase 1,823,917 shares of our Class A common stock to MacAndrews. Further, 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. Pursuant to the investor rights agreement, we filed a shelf registration statement on Form S-3 in June 2019 to register certain shares previously issued to MacAndrews.

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 or the exercise of outstanding warrants, 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 LPC Purchase Agreement, the ATM Offering, or pursuant to warrants issued to M&F Group and our previous lenders, and such sales could result in substantial dilution to existing investors.

We incur significant costs and devote substantial management time as a result of operating as a public company and additional resources would be required if we lose our "smaller reporting company" and "non-accelerated filer" status.

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.

However, we are currently a "smaller reporting company" and "non-accelerated filer" under the current SEC rules. As such we take advantage of exemptions from certain reporting requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Should we lose these statuses, we may no longer be exempt from these requirements and expect that compliance with the 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(b) of the Sarbanes-Oxley Act. In that regard, we currently do not have an internal audit function. We will continue to qualify as a smaller reporting company as long as 1) our public float is less than $250 million, or 2) we have less than $100 million in annual revenues and public float of less than $700 million. We cannot predict if investors will find our Class A common stock less attractive if we choose to rely on these exemptions.

However, for as long as we remain a "smaller reporting company" and "non-accelerated filer", we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that do not qualify under these categories 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 as long as we remain eligible to do so under the related rules.

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 is located in High Point, North Carolina, where we lease 12,786 square feet of office space in the Premier Center office park. The initial term of the lease for this space continues through February 2025 and includes a one-time termination option at the end of three years and an option to renew for an additional five years.

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.

Holders

As of February 24, 2021, there were approximately 22 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, 2020. 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	4,489,191	$ 4.39	2,475,809
Equity compensation plans not approved by security holders			
Total	4,489,191		2,475,809

Issuer Purchases of Equity Securities

There have been no repurchases of the Company’s common stock during the fourth fiscal quarter of fiscal 2020.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable to a smaller reporting company.

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 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 pharmaceutical company focused on treating metabolic and inflammatory diseases to minimize their long-term complications and improve the lives of patients. We have an innovative pipeline of first-in-class small molecule clinical and pre-clinical drug candidates for the treatment of a wide range of diseases.

Our pipeline is led by our programs for the treatment of type 1 diabetes (*TTP399*) and for psoriasis (*HPP737*). We completed the Simplici-T1 Study, an adaptive Phase 1b/2 study supported by JDRF International ("JDRF"), to explore the effects of *TTP399* in patients with type 1 diabetes at the beginning of 2020. In February 2020, we reported positive results from the Phase 2 - Part 2 confirming phase of this study which achieved its primary objective by demonstrating statistically significant improvements in HbA1c (long-term blood sugar) for *TTP399* compared to placebo. We are working on the design for pivotal and registrational studies for *TTP399*, with input from the FDA. In addition to the pivotal studies of *TTP399*, we are conducting a phase 1 mechanistic study in patients with type 1 diabetes to determine the impact of *TTP399* on ketone body formation during a period of acute insulin withdrawal.

In addition, we are conducting a multiple ascending dose phase 1 study of *HPP737*, an orally administered phosphodiesterase type 4 ("PDE4") inhibitor, to assess the pharmacokinetics, pharmacodynamics, safety and tolerability of *HPP737* in healthy volunteers as part of our psoriasis program. The goal of this study is to confirm the maximum tolerated dose with minimal or no gastrointestinal intolerance in the form of nausea, vomiting, or diarrhea. We expect to complete this study in the second quarter of 2021.

On December 15, 2020, the Company announced that the Phase 2 Elevage study of *azeliragon* in people with mild Alzheimer's disease and type 2 diabetes did not meet its primary objective of demonstrating an improvement in cognition as assessed by the 14-item Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-cog14) relative to placebo.

We are planning an adaptive Phase 1b/2 clinical trial assessing the pharmacokinetics, pharmacodynamics, safety and tolerability of *TTP273*, an orally administered non-peptidic agonist that targets the glucagon-like peptide 1 receptor ("GLP-1r"), in patients with cystic fibrosis related diabetes and are seeking a funding partner to enable the conduct of this clinical trial.

In addition to our internal development programs, we are furthering the clinical development of four other programs, a small molecule GLP-1r agonist, a PDE4 inhibitor, a PPAR-delta agonist, and an Nrf2 activator through partnerships with pharmaceutical partners via licensing arrangements. 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 territories, 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. In May 2018, we 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 our phosphodiesterase type 4 inhibitors ("PDE4") program, including the compound *HPP737*, in China and other Pacific Rim territories. In December 2020, we entered into a License Agreement with Anteris Bio, Inc. ("Anteris") (the "Anteris License Agreement"), under which Anteris obtained a worldwide, exclusive and sublicensable license to develop and commercialize vTv LLC's Nrf2 activator, *HPP971*. For more information regarding the Huadong License Agreement, Reneo License Agreement and the Newsoara License Agreement, see Part 1 – Item 1 – "Business – Partnered Development Programs" of this Annual Report.

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, 2020, 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 Boehringer Ingelheim from 2001 to 2006;
- the receipt of $169.2 million of upfront, milestone and research fees during 2006 to 2010 under a license and research agreement with Pfizer, Inc., which was terminated in 2011;
- the receipt of $55.7 million of upfront, milestone and research expense reimbursements from 2010 to 2013 under a license agreement for our GKA programs with an affiliate of Forest Laboratories, Inc., which was terminated in 2013;
- various borrowings totaling $114.7 million from November 2011 through March 2014 from entities affiliated with MacAndrews, which were converted to Series F and Series B preferred units of 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 "Letter Agreements") with M&F Group in December 2017, July 2018, December 2018, March 2019, September 2019 and December 2019 under which we received a total of $59.0 million and through which we had the right to sell to M&F Group shares of our Class A common stock at prices ranging from $1.33 to $4.38 per share, 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 dollar value maximum of Class A common stock that may be sold under each Letter Agreement, whether at our option or M&F Group's);
- equity issuances of $13.0 million under the ATM Offering; and
- equity issuances of $1.9 million under the LPC Purchase Agreement.

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, *TTP399* and *HPP737*;
- 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 planned registrational trial(s) of *TTP399* in patients with type 1 diabetes as well as any future studies of *HPP737* in patients with psoriasis. 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 our planned and ongoing clinical trials, 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, 2020, we have incurred approximately $591.0 million in research and development expenses.

Our research and development expenses by project for the years ended December 31, 2020, 2019 and 2018 were as follows (in thousands):

	Years Ended December 31,		
	2020	**2019**	**2018**
Direct research and development expense:			
Azeliragon	$ 6,103	$ 7,233	$ 13,507
TTP399	917	2,762	879
HPP737	493	56	46
Other projects	683	578	649
Indirect research and development expense	2,819	4,490	7,954
Total research and development expense	$ 11,015	$ 15,119	$ 23,035

We plan to continue to incur significant research and development expenses for the foreseeable future as we continue the development of *TTP399* and *HPP737* and further advance the development of our other drug candidates, subject to the availability of additional funding.

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.

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 was 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

In this section, we discuss the results of our operations for the year ended December 31, 2020 compared to the year ended December 31, 2019. For a discussion of the year ended December 31, 2019 compared to the year ended December 31, 2018, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2019.

Comparison of the year ended December 31, 2020 and 2019

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

(dollars in thousands) **Statement of operations data:**	**Year Ended** **2020**	**2019**	**Change**
Revenue	$ 6,414	$ 2,764	$ 3,650
Operating expenses:			
Research and development	11,015	15,119	(4,104)
General and administrative	7,251	8,537	(1,286)
Total operating expenses	18,266	23,656	(5,390)
Operating loss	(11,852)	(20,892)	9,040
Interest income	12	53	(41)
Interest expense	(692)	(1,827)	1,135
Other (expense) income, net	(270)	828	(1,098)
Loss before income taxes	(12,802)	(21,838)	9,036
Income tax provision	—	100	(100)
Net loss before noncontrolling interest	(12,802)	(21,938)	9,136
Less: net loss attributable to noncontrolling interest	(4,303)	(8,894)	4,591
Net loss attributable to vTv Therapeutics Inc.	$ (8,499)	$ (13,044)	$ 4,545

Revenues

Revenues were $6.4 million and $2.8 million for the years ended December 31, 2020 and 2019, respectively. The revenue recognized in 2020 is primarily attributable to the upfront payment and fair value of the equity interest received by the Company in connection with the Anteris License Agreement. The revenue earned during 2019 primarily relates to the recognition of amounts deferred at the initiation of our license agreements which were related to the transfer of technology performance obligations. The technology service period for our license agreement with Reneo ended in the second quarter of 2019. Further, in 2019 we recognized an additional $1.0 million of revenue related to the satisfaction of a milestone within our license agreement with Newsoara.

Research and Development Expenses

Research and development expenses were $11.0 million and $15.1 million for the years ended December 31, 2020 and 2019, respectively. The decrease in research and development expenses during this period of $4.1 million, or 27.1%, was primarily due to:

- A decrease in clinical trial costs of $1.1 million for *azeliragon* from 2019. This decrease was mainly driven by a decrease in spending for the Elevage study as it was in the start-up/enrollment stage in 2019 and patients completed the trial in 2020;
- A decrease in clinical trial costs of $1.8 million for *TTP399* from 2019, which was caused by a decrease in spending for the SimpliciT-1 trial. This study completed in January 2020 and costs incurred in 2020 related to consulting and other costs

involved in planning for the next trial(s) as well as the incurrence of certain manufacturing costs to get drug product ready for these trials; and

- A decrease in other research and development costs of $1.7 million, which was primarily driven by decreases in compensation costs of approximately $1.1 million due to the reversal of certain performance-based compensation accruals, and lower cash and share-based compensation costs. Additionally, facility costs decreased approximately $0.2 million due to the relocation and shut down of the company's former laboratory space in late 2019. We also experienced decreases in other costs related to the curtailment of expenses, particularly travel, because of COVID-19.

General and Administrative Expenses

General and administrative expenses were $7.3 million and $8.5 million for the years ended December 31, 2020 and 2019, respectively. The decrease in general and administrative expenses during this period of $1.3 million, or 15.1%, was primarily due to decreases of $1.3 million for compensation cost which was caused, in part, by the reversal of certain performance-based compensation accruals which are no longer expected to be paid ($0.7 million) and lower share-based compensation expense ($0.3 million). Decreases in facility costs attributable to the relocation of our corporate headquarters were offset by increases in costs for professional services.

Interest Expense, Net

Interest expense, net was $0.7 million and $1.8 million for the years ended December 31, 2020 and 2019, respectively. Interest expense primarily relates to our Loan Agreement which bore interest at 10.5% plus the amount by which the one-month LIBOR exceeds 0.5%. The decrease in interest expense from 2019 to 2020 was driven by the continued repayment of principal amounts outstanding in accordance with the terms of the Loan Agreement.

Liquidity and Capital Resources

Liquidity and Going Concern

As of December 31, 2020, we had an accumulated deficit of $290.0 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. As of December 31, 2020, our currently available sources of liquidity include our unrestricted balance of cash and cash equivalents of $5.7 million. Based on our current operating plan, we believe that our current cash and cash equivalents, availability under the ATM Offering and amounts raised under the LPC Purchase Agreement through February 24, 2021 will allow us to meet our liquidity requirements through the end of the third quarter of 2021. 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 our planned and ongoing clinical trials, 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

Under the terms of the Letter Agreements entered into in prior years, the Company 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 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. As of December 31, 2020, an aggregate of $59.0 million worth of Class A Common Stock had been sold under the Letter Agreements. In connection with the entrance into several of these Letter Agreements, the Company issued to M&F Group a total of 1,823,917 warrants (the "Letter Agreement Warrants") to purchase additional shares of the Company's Class A Common Stock.

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 borrowed $20.0 million. Each loan tranche bore interest at a floating rate equal to 10.5% plus the amount by which the one-month LIBOR exceeds 0.5%. Additionally, each tranche included a final interest payments of $0.8 million which was paid upon the maturity of the respective tranche. As of December 31, 2020, all amounts outstanding under the Loan Agreement had been paid.

In connection with the Loan Agreement, we 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, and 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. The Warrants will expire seven years from their date of issuance.

Cash Flows

(dollars in thousands)	Year Ended December 31, 2020	Year Ended December 31, 2019
Net cash used in operating activities	$ (18,000)	$ (23,018)
Net cash provided by investing activities	—	242
Net cash provided by financing activities	19,470	22,870
Net increase in cash and cash equivalents	$ 1,470	$ 94

Operating Activities

For the year ended December 31, 2020, our net cash used in operating activities decreased $5.0 million from the prior year. The decrease in uses of cash was primarily driven by lower spending on our clinical trials during 2020 coupled with the impact of changes in working capital.

Investing Activities

No cash was provided by or used in investing activities for the year ended December 31, 2020. During the year ended December 31, 2019, we disposed of lab equipment for which we received proceeds of approximately $0.3 million.

Financing Activities

For the year ended December 31, 2020, net cash provided by financing activities was $19.5 million compared to net cash provided by financing activities of $22.9 million for the year ended December 31, 2019, resulting in a decrease of $3.4 million. This decrease was reflective of lower proceeds from the sale of stock to support our ongoing operations and lower 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, availability under the ATM Offering and amounts raised under the LPC Purchase Agreement through February 24, 2021 will allow us to meet our liquidity requirements through the end of the third quarter of 2021. 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 future clinical trials of *TTP399* and *HPP737*, 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 registrational trial(s) to evaluate *TTP399* as a potential treatment of type 1 diabetes and planned studies of *HPP737* as a potential treatment of psoriasis;
- 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 ATM Offering and LPC Purchase Agreement. However, we are evaluating several financing strategies to fund the on-going and future clinical trials of *TTP399* and *HPP737*, 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

As of December 31, 2020, we do not currently have outstanding any off-balance sheet arrangements as defined under SEC rules. However, during the periods presented we had Letter Agreements under which we had received funding of $59.0 million and, in exchange, had issued a total of 33,790,546 shares of our Class A Common Stock.

Discussion of Critical Accounting Policies and Estimates

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

While our significant accounting policies are more fully described in Note 2, "Summary of Significant Accounting Policies," to our audited financial statements, 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.

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 was fully repaid as of December 31, 2020. As a result, we no longer have any material 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, 2020. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2020, 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, 2020. 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, 2020, 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.

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 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

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 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

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 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The following documents are included on pages F-1 through F-30 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)).
4.3*	Description of Capital Stock.
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)).

Exhibit Number	Description
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)).
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)).
10.13††	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)).
10.14††	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)).
10.15	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)).
10.16††	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)).
10.17††	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)).
10.18††	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)).
10.19†	Employment Agreement, dated as of March 7, 2019, by and between vTv Therapeutics LLC and Stephen L. Holcombe, and for certain limited purposes specified therein, vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.1 to the Company's Form 8-K, filed March 11, 2019 (File No. 001-37524)).
10.20†	Employment Agreement, dated as of March 7, 2019, by and between vTv Therapeutics LLC and Rudy C. Howard, and for certain limited purposes specified therein, vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.2 to the Company's Form 8-K filed March 11, 2019 (File No. 001-37524)).
10.21	Form of Securities Purchase Agreement to Purchase Class A Common Stock, under the Company's Form S-3 (incorporated by reference from Exhibit 10.1 to the Company's Form 8-K, filed March 20, 2019 (File No. 001-37524)).
10.22	Letter Agreement, dated as of March 18, 2019, by and between MacAndrews & Forbes Group LLC and vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.2 to the Company's Form 8-K, filed March 20, 2019 (File No. 001-37524)).
10.23	Letter Agreement, dated as of September 26, 2019, 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 October 30, 2019 (File No. 001-37524)).
10.24	Form of Securities Purchase Agreement to Purchase Class A Common Stock, under the September 26, 2019 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 October 30, 2019 (File No. 001-37524)).

Exhibit Number	Description
10.25	Letter Agreement, dated as of December 23, 2019, by and between MacAndrews & Forbes Group LLC and vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.25 to the Company's Form 10-K, filed February 21, 2020 (File No. 001-37524)).
10.26	Form of Securities Purchase Agreement to Purchase Class A Common Stock, under the December 23, 2019 Letter Agreement, by and between MacAndrews & Forbes Group LLC and vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.26 to the Company's Form 10-K, filed February 21, 2020 (File No. 001-37524)).
10.27	Controlled Equity OfferingSM Sales Agreement, dated as of April 24, 2020, by and between vTv Therapeutics Inc. and Cantor Fitzgerald & Co. (incorporated by reference from Exhibit 1.1 to the Company's Form 8-K, filed on April 24, 2020 (File No. 001-37524)).
10.28	Second Amendment of Venture Loan and Security Agreement and Consent, dated as of April 1, 2020, by and among the Company, vTv Therapeutics LLC, Horizon Funding Trust 2019-1 and Silicon Valley Bank (incorporated by reference from Exhibit 10.1 to the Company's Form 10-Q, filed on August 3, 2020 (File No. 001-37524)).
10.29	Third Amendment of Venture Loan and Security Agreement and Consent, dated as of July 29, 2020, by and among the Company, vTv Therapeutics LLC, Horizon Funding Trust 2019-1 and Silicon Valley Bank (incorporated by reference from Exhibit 10.1 to the Company's Form 10-Q, filed on May 7, 2020 (File No. 001-37524)).
10.30	First Amendment to vTv Therapeutics Inc. 2015 Omnibus Equity Incentive Plan (incorporated by reference from Exhibit 3.5 to the Company's Form S-8, filed August 3, 2020 (File No. 333-240304)).
10.31	Purchase Agreement, dated November 24, 2020, by and between vTv Therapeutics Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference from Exhibit 10.1 to the Company's Form 8-K, filed on November 24, 2020 (File No. 001-37524)).
10.32	Registration Rights Agreement, dated November 24, 2020, by and between vTv Therapeutics Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference from Exhibit 10.2 to the Company's Form 8-K, filed on November 24, 2020 (File No. 001-37524)).
10.33†	Employment Agreement, dated as of December 10, 2020, by and between vTv Therapeutics LLC and Stephen L. Holcombe, and for certain limited purposes specified therein, vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.1 to the Company's Form 8-K, filed December 10, 2020 (File No. 001-37524)).
10.34†	Employment Agreement, dated as of December 10, 2020, by and between vTv Therapeutics LLC and Rudy C. Howard, and for certain limited purposes specified therein, vTv Therapeutics Inc. (incorporated by reference from Exhibit 10.2 to the Company's Form 8-K filed December 10, 2020 (File No. 001-37524)).
10.35*††	License Agreement, dated December 11, 2020, by and between Anteris Bio, Inc. and vTv Therapeutics LLC.
10.36*††	First Amendment to License Agreement, dated as of December 21, 2020 by and between Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. And vTv Therapeutics LLC.
10.37†	Executive Chairperson Agreement, dated as of December 30, 2020, by and between vTv Therapeutics Inc. and Robin E. Abrams (incorporated by reference from Exhibit 10.1 to the Company's Form 8-K filed December 30, 2020 (File No. 001-37524)).
21.1*	Subsidiaries of vTv Therapeutics Inc.
23.1*	Consent of Ernst & Young LLP, Independent Registered Public 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.
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

Exhibit Number	Description
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

ITEM 16. FORM 10-K SUMMARY

None.

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 24, 2021

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/ Robin E. Abrams Robin E. Abrams	Chairwoman	February 24, 2021
/s/ Stephen L. Holcombe Stephen L. Holcombe	President and Chief Executive Officer (Principal Executive Officer)	February 24, 2021
/s/ Rudy C. Howard Rudy C. Howard	Chief Financial Officer (Principal Financial and Accounting Officer)	February 24, 2021
/s/ John A. Fry John A. Fry	Director	February 24, 2021
/s/ Hersh Kozlov Hersh Kozlov	Director	February 24, 2021
/s/ Richard S. Nelson Richard S. Nelson	Director	February 24, 2021
/s/ Noel J. Spiegel Noel J. Spiegel	Director	February 24, 2021
/s/ Howard L. Weiner Howard L. Weiner	Director	February 24, 2021

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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Accrued Development Costs

Description of the Matter	As discussed in Notes 2 and 7 to the consolidated financial statements, the Company has recorded \$2.6 million of accrued expenses at December 31, 2020, which includes costs for clinical trial and contract manufacturing activities (together, clinical related activities) based upon estimates of expenses incurred through the balance sheet date that have yet to be invoiced by the contract research organizations (CROs), clinical study sites, contract manufacturing organizations, or other vendors (together, clinical vendors). This accrual process involves identifying services that have been performed and estimating the level of service performed and the associated cost when the Company has not yet been invoiced or otherwise notified of actual cost incurred. Auditing the Company's accruals for clinical vendor costs associated with in-process clinical related activities is judgmental because the timing and pattern of vendor invoicing may not correspond to the level of services provided and the estimate can incorporate significant assumptions such as expected patient enrollment, site activation, and estimated project duration.

How We Addressed the Matter in Our Audit	To evaluate the clinical vendors accrued costs, our audit procedures included, among others, reading the Company’s contracts with clinical vendors (including pending change orders), testing the completeness and accuracy of the underlying data used in the estimate of the level of service provided including evaluating the significant assumptions as discussed above for the applicable in process contracts with clinical vendors. To assess the significant assumptions, we corroborated the progress of clinical related activities through inquiry with the Company’s operations personnel that oversee the clinical trials contract manufacturing activities and with information obtained directly from third party clinical vendors, as well as tested invoices received from clinical vendors subsequent to the balance sheet date.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2000.
Raleigh, North Carolina
February 24, 2021

vTv Therapeutics Inc.
Consolidated Balance Sheets
(dollars in thousands, except per share and share data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 5,747	$ 1,777
Accounts receivable, net	158	5
Prepaid expenses and other current assets	939	806
Current deposits	371	250
Total current assets	7,215	2,838
Restricted cash and cash equivalents, long-term	—	2,500
Property and equipment, net	367	461
Operating lease right-of-use assets	482	543
Long-term investments	6,725	2,480
Long-term deposits	—	444
Total assets	$ 14,789	$ 9,266
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,120	$ 7,068
Current portion of operating lease liabilities	155	110
Current portion of contract liabilities	31	31
Current portion of notes payable	84	6,172
Total current liabilities	6,390	13,381
Contract liabilities, net of current portion	1,009	1,033
Operating lease liabilities, net of current portion	676	831
Warrant liability, related party	2,871	2,601
Other liabilities	50	260
Total liabilities	10,996	18,106
Commitments and contingencies		
Redeemable noncontrolling interest	83,895	40,183
Stockholders' deficit:		
Class A Common Stock, $0.01 par value; 100,000,000 shares authorized, 54,050,710 and 40,918,522 shares outstanding as of December 31, 2020 and December 31, 2019, respectively	541	409
Class B Common Stock, $0.01 par value; 100,000,000 shares authorized, and 23,094,221 outstanding as of December 31, 2020 and December 31, 2019	232	232
Additional paid-in capital	209,161	183,858
Accumulated deficit	(290,036)	(233,522)
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(80,102)	(49,023)
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	$ 14,789	$ 9,266

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, 2020	2019	2018
Revenue	$ 6,414	$ 2,764	$ 12,434
Operating expenses:			
Research and development	11,015	15,119	23,035
General and administrative	7,251	8,537	9,223
Total operating expenses	18,266	23,656	32,258
Operating loss	(11,852)	(20,892)	(19,824)
Other income (loss)	—	1	46
Other (expense) income – related party	(270)	827	(638)
Interest income	12	53	61
Interest expense	(692)	(1,827)	(3,290)
Loss before income taxes and noncontrolling interest	(12,802)	(21,838)	(23,645)
Income tax provision	—	100	200
Net loss before noncontrolling interest	(12,802)	(21,938)	(23,845)
Less: net loss attributable to noncontrolling interest	(4,303)	(8,894)	(15,934)
Net loss attributable to vTv Therapeutics Inc.	$ (8,499)	$ (13,044)	$ (7,911)
Net loss attributable to vTv Therapeutics Inc. common shareholders	$ (8,499)	$ (17,913)	$ (8,650)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	$ (0.18)	$ (0.59)	$ (0.69)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	47,137,917	30,292,030	12,449,236

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, 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)**
Net loss	(8,894)	—	—	—	—	—	(13,044)	(13,044)
Share-based compensation	—	—	—	—	—	1,518	—	1,518
Issuance of Class A Common Stock under registered direct offering	—	3,636,364	37	—	—	5,406	—	5,443
Issuance of Class A Common Stock to a related party under the Letter Agreements	—	16,923,427	169	—	—	27,331	—	27,500
Issuance of Letter Agreement and warrants to purchase Class A Common Stock - related party	—	—	—	—	—	(992)	—	(992)
Vesting of restricted stock units	—	11,666	—	—	—	—	—	—
Change in redemption value of noncontrolling interest	(13,405)	—	—	—	—	—	13,405	13,405
Balances at December 31, 2019	**40,183**	**40,918,522**	**409**	**23,094,221**	**232**	**183,858**	**(233,522)**	**(49,023)**
Net loss	(4,303)	—	—	—	—	—	(8,499)	(8,499)
Share-based compensation	—	—	—	—	—	1,009	—	1,009
Issuance of Class A Common Stock under ATM offering	—	5,480,941	55	—	—	12,441	—	12,496
Issuance of Class A Common Stock to a related party under the Letter Agreements	—	6,250,000	63	—	—	9,937	—	10,000
Issuance of Class A Common Stock under LPC Agreement	—	1,389,580	14	—	—	1,916	—	1,930
Vesting of restricted stock units	—	11,667	—	—	—	—	—	—
Change in redemption value of noncontrolling interest	48,015	—	—	—	—	—	(48,015)	(48,015)
Balances at December 31, 2020	**$ 83,895**	**54,050,710**	**$ 541**	**23,094,221**	**$ 232**	**$ 209,161**	**$ (290,036)**	**$ (80,102)**

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

vTv Therapeutics Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Twelve Months Ended December 31, 2020	2019	2018
Cash flows from operating activities:			
Net loss before noncontrolling interest	$ (12,802)	$ (21,938)	$ (23,845)
Adjustments to reconcile net loss before noncontrolling interest to net cash used in operating activities:			
Loss (gain) on disposal of property and equipment, net	—	(288)	(12)
Depreciation expense	94	39	218
Share-based compensation expense	1,009	1,518	2,676
Change in fair value of investments	(4,245)	—	—
Change in fair value of warrants, related party	270	(827)	638
Amortization of debt discount	380	532	1,014
Changes in assets and liabilities:			
Accounts receivable	(153)	(5)	8,000
Prepaid expenses and other assets	(254)	732	(1,135)
Long-term deposits	444	(408)	2,256
Accounts payable and accrued expenses	(997)	(618)	(6,199)
Accreted interest on debt	(1,512)	—	—
Contract liabilities	(24)	(1,755)	(10,435)
Other liabilities	(210)	—	(32)
Net cash used in operating activities	(18,000)	(23,018)	(26,856)
Cash flows from investing activities:			
Proceeds from sale of assets	—	312	12
Purchases of property and equipment	—	(70)	(5)
Net cash provided by investing activities	—	242	7
Cash flows from financing activities:			
Proceeds from issuance of Class A Common Stock to a related party under the Letter Agreements	10,000	27,500	21,500
Proceeds from issuance of Class A Common Stock, net of offering costs	14,426	5,443	—
Proceeds from debt issuance	500	500	500
Repayment of notes payable	(5,456)	(10,573)	(5,388)
Net cash provided by financing activities	19,470	22,870	16,612
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	1,470	94	(10,237)
Total cash, cash equivalents and restricted cash and cash equivalents, beginning of year	4,277	4,183	14,420
Total cash, cash equivalents and restricted cash and cash equivalents, end of year	$ 5,747	$ 4,277	$ 4,183
Supplemental cash flow information:			
Cash paid for interest	$ 623	$ 1,295	$ 2,276
Cash paid for income taxes	$ —	$ 100	$ 1,000
Non-cash activities:			
Right-of-use assets obtained in exchange for lease obligations	$ —	$ 548	$ —
Leasehold improvements obtained in exchange for lease obligations	$ —	$ 384	$ —
Change in redemption value of noncontrolling interest	$ 48,015	$ (13,405)	$ (52,873)
Exchange of vTv Therapeutics Inc. Class B Common Stock and vTv Therapeutics, LLC member units for vTv Therapeutics Inc. Class A Common Stock	$ —	$ —	$ 151
Issuance of Letter Agreements and warrants to purchase vTv Therapeutics Inc. Class A Common Stock to a related party	$ —	$ 992	$ 1,308

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

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 is a clinical-stage pharmaceutical company focused on treating metabolic diseases to minimize their long-term complications through end-organ protection.

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 29.9% economic interest in vTv LLC, effectively restricting vTv Therapeutics Inc.'s interest to 70.1% 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, 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, December 2018, March 2019, September 2019 and December 2019 (the "Letter Agreements"), the Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") (the "ATM Offering"), and the purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") (the "LPC Purchase Agreement"). vTv Therapeutics Inc. will not be required to provide financial or other support for vTv LLC. 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. 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, 2020, 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, 2020, the Company had an accumulated deficit of $290.0 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, 2020 of $5.7 million.

As of December 31, 2020, the Company also had the ability to sell an additional 3,941,726 shares of Class A Common Stock under the LPC Purchase Agreement based on the number of shares initially registered. The extent to which the Company utilizes the LPC Purchase Agreement as a source of funding will depend on a number of factors, including the prevailing market price of and the volume of trading in the Company's Class A Common Stock and the extent to which the Company is able to secure funds from other sources. The number of shares that the Company may sell to Lincoln Park under the purchase agreement on any given day and during the term of the agreement is limited. Additionally, the Company and Lincoln Park may not effect any sales of shares of our common stock under the purchase agreement during the continuance of an event of default under the purchase agreement.

On January 14, 2021, the Company also expanded the availability under its ATM Offering, pursuant to which the Company may offer and sell, from time to time, through Cantor, shares of its Class A common stock having an aggregate offering price of $5.5 million. Management believes these sources of liquidity 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, availability under the ATM Offering and amounts raised under the LPC Purchase Agreement through February 24, 2021 will allow the Company to meet its liquidity requirements through the end of the third quarter of 2021. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The Company is evaluating several financing strategies to fund its planned and ongoing clinical trials, 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.

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.

Three customers represented 100% of the revenue earned during the years ended December 31, 2020 and 2018. Four customers represented 100% of the revenue earned during the year ended December 31, 2019.

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, long-term relates to the minimum balance that the Company was required to maintain in a deposit account pledged to secure the Loan Agreement and was subject to an account control agreement pursuant to the Loan Agreement, as amended. The Loan Agreement was amended to remove the minimum cash requirements during 2020 and with its full repayment as of December 31, 2020, the account control agreement has been terminated.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Consolidated Balance Sheets as of December 31, 2020 and 2019 that sum to the total of the same such amounts shown in the Consolidated Statements of Cash Flows (in thousands):

	2020	2019
Cash and cash equivalents	$ 5,747	$ 1,777
Restricted cash and cash equivalents, long-term	—	2,500
Total cash, cash equivalents and restricted cash and cash equivalents shown in the consolidated statement of cash flows	$ 5,747	$ 4,277

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, 2020 or 2019. There were no assets held for sale at December 31, 2020 or 2019.

Investments

The Company holds equity investments without readily determinable market values. The Company has elected to measure these investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment.

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 and manufacturing 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 13.

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.

Leases

The Company determines if an arrangement is a lease at inception. Balances recognized related to operating leases are included in operating lease right-of-use assets and operating lease liabilities in the Consolidated Balance Sheets. Operating lease right-of-use assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Lease terms may include options to extend of terminate the lease if it is reasonably certain that the Company will exercise the option. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of future payments. The operating lease right-of-use asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company has elected a practical expedient to not separate its lease and non-lease components and instead account for them as a single lease component.

Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Lease payments for short-term leases are recorded to operating expense on a straight-line basis and variable lease payments are recorded in the period in which the obligation for those payments is incurred.

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

There have been no recently accounting pronouncements which are expected to have a material impact on the Company's financial statements.

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-δ) 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, 2020, 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. As of December 31, 2020, revenue allocated to this performance obligation has been fully recognized. No revenue was recognized related to the Reneo License Agreement for the year ended December 31, 2020. For the years ended December 31, 2019 and 2018, $1.7 million and $3.7 million of revenue was recognized related to this combined performance obligation, respectively.

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 territories, 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. As discussed further in Note 20, on January 14, 2021, the Company entered into the First Amendment to the Huadong License Agreement (the "First Huadong Amendment"). Under the terms of the Huadong License Agreement, as amended, 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 $22.0 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.

Prior to the First Huadong Amendment, the Company also had the obligation to conduct a Phase 2 multi-region clinical trial (the "Phase 2 MRCT"), should Huadong require it to do so. If conducted, the Phase 2 MRCT was to include 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 and was to 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 was responsible for contributing up to $3.0 million in connection with the Phase 2 MRCT. The First Huadong Amendment eliminated this obligation from the Huadong License Agreement.

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, 2020, 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 year ended December 31, 2018, the Company recognized $6.8 million of revenue related to this combined performance obligation.

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 begun the Phase 2 MRCT trial, the entire amount remains deferred as of December 31, 2020 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, 2020 was $1.0 million. No revenue for this performance obligation has been recognized as of December 31, 2020. As discussed above and further in Note 20, the obligation to conduct the Phase 2 MRCT was removed by the First Huadong Amendment.

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, 2020 and revenue will be recognized using the proportional performance model over the period of the Company's participation on the JDC. The unrecognized amount of the transaction price allocated to this performance obligation as of December 31, 2020 was $0.1 million. An immaterial amount of revenue was recognized for this performance obligation for the years ended December 31, 2020, 2019 and 2018.

There have been no adjustments to the transaction price for the performance obligations under the Huadong License Agreement during the years ended December 31, 2020, 2019 and 2018.

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 territories (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. The Newsoara License Agreement was amended in 2020 to change certain future milestone payments and patent rights (the "First Newsoara Amendment"). Under the terms of the Newsoara License Agreement, Newsoara paid the Company an upfront cash payment of $2.0 million. During the year ended December 31, 2019, the Company received an additional payment of $1.0 million related to the satisfaction of a development milestone during the year. As amended, the Company is eligible to receive additional potential development, regulatory and sales-based milestone payments totaling up to $58.5 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, 2020, 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 $2.0 million of the transaction price related to the upfront payment allocated to this performance obligation was recognized during the year ended December 31, 2018.

During the year ended December 31, 2019, the transaction price for this performance obligation was increased by $1.0 million due to the satisfaction of a development milestone under the license agreement. This amount was fully recognized as revenue during the year ended December 31, 2019, as the related performance obligation has been fully satisfied.

Anteris License Agreement

On December 11, 2020, we entered into a license agreement with Anteris Bio, Inc. ("Anteris") (the "Anteris License Agreement"), under which Anteris obtained a worldwide, exclusive and sublicensable license to develop and commercialize the Company's Nrf2 activator, *HPP971*.

Under the terms of the Anteris License Agreement, Anteris paid the Company an initial license fee of $2.0 million. The Company is eligible to receive additional potential development, regulatory, and sales-based milestone payments totaling up to $151.0 million. Anteris is also obligated to pay vTv royalty payments at a double-digit rate based on annual net sales of licensed products. Such royalties will be payable on a licensed product-by-licensed product 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 received preferred stock representing a minority ownership interest in Anteris.

Pursuant to the terms of the Anteris License Agreement, the Company was required to provide technology transfer services for a 30 day period after the effective date. In accordance with ASC Topic 606, the Company identified all of the performance obligations at the inception of the Anteris 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. As of December 31, 2020, the transaction price consists of the $2.0 million initial license payment as well as the fair value of the equity interest received in Anteris of $4.2 million. The remaining milestone payments that the Company is eligible to receive have not been included in the transaction price as of December 31, 2020, as it is not considered probable that such payments will be received. The revenue related to this performance obligation has been fully recognized as of December 31, 2020 as the technology transfer services are considered complete.

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, 2020, the Company had received funding under this agreement of $3.0 million, and research and development costs were offset by $3.0 million.

Contract Liabilities

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

	December 31, 2020	December 31, 2019
Current portion of contract liabilities	$ 31	$ 31
Contract liabilities, net of current portion	1,009	1,033
Total contract liabilities	$ 1,040	$ 1,064

The change in the Company's contract liabilities for the year ended December 31, 2020 of an immaterial amount was due to the recognition of amounts included in the contract liability at the beginning of the period. The Company also recognized an additional $1.0 million of revenue related to changes in the estimated transaction prices for one of its customer contracts during the year ended December 31, 2019 for which the related performance obligation had already been satisfied.

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. Following an amendment to increase the number of shares available under the plan in 2020, 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 7.0 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, 2020, 2019 and 2018, the Company recognized $1.0 million, $1.5 million and $2.7 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, 2020, the Company had total unrecognized stock-based compensation expense of approximately $3.6 million, which is expected to be recognized on a straight-line basis over a weighted average period of 2.6 years. The weighted average grant date fair value for all option grants during the years ended December 31, 2020, 2019 and 2018 was $1.81, $1.91 and $2.28 per option, respectively.

The aggregate intrinsic value of the in-the-money awards outstanding as well as those exercisable as of December 31, 2020 was an insignificant amount.

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, 2020, 2019 and 2018:

	For the Year Ended December 31,		
	2020	**2019**	**2018**
Expected volatility	120.37% - 121.43%	115.29% - 120.15%	71.15% - 99.23%
Expected life of option, in years	5.7 - 6.0	5.3 - 6.0	5.7 - 6.0
Risk-free interest rate	0.39% - 0.53%	1.58% - 2.64%	2.69% - 2.84%
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, 2020 (in thousands, except per share amounts):

	Number of Shares	Weighted-Average Exercise Price
Awards outstanding at December 31, 2019	2,531,143	$ 6.19
Granted	1,975,250	2.10
Forfeited	(53,036)	3.28
Awards outstanding at December 31, 2020	4,453,357	$ 4.41
Options exercisable at December 31, 2020	1,852,721	$ 7.58
Weighted average remaining contractual term	6.0 Years	
Options vested and expected to vest at December 31, 2020	4,166,666	$ 4.57
Weighted average remaining contractual term	7.9 Years	

The following table summarizes the activity related to the awards of RSUs for the year ended December 31, 2020:

	Number of Shares	Weighted-Average Grant Date Fair Value
Awards outstanding at December 31, 2019	11,667	$ 5.81
Vested	(11,667)	5.81
Awards outstanding at December 31, 2020	—	$ —
RSUs expected to vest at December 31, 2020	—	$ —

As of December 31, 2020, the Company had no unrecognized stock-based compensation expense for its outstanding RSU awards.

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

	2020	2019	2018
Research and development	$ 348	$ 522	$ 994
General and administrative	661	996	1,682
Total share-based compensation expense	$ 1,009	$ 1,518	$ 2,676

Note 5: Prepaid Expenses and Other Current Assets

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

	December 31,	
	2020	2019
Prepaid insurance	$ 771	$ 551
Prepaid taxes	129	147
Prepaid - other	39	108
Total	$ 939	$ 806

Note 6: Property and Equipment

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

	December 31,	
	2020	2019
Leasehold improvements	$ 406	$ 405
Computers and hardware	48	48
Software	80	107
Furniture and office equipment	49	49
Total property and equipment	583	609
Less: accumulated depreciation and amortization	(216)	(148)
Property and equipment, net	$ 367	$ 461

Depreciation expense was $0.1 million and $0.2 million for the years ended December 31, 2020 and 2018, respectively and was an insignificant amount for the year ended December 31, 2019.

Note 7: Investments

In connection with the Reneo and Anteris License Agreements, the Company has received equity interests representing a minority equity interest in each investee. In each case, the Company's investment is measured at cost less impairment, adjusted for any changes in observable prices, because the Company owns less than 20% of the voting equity and does not have the ability to exercise significant influence over the investees. The investments were initially recognized at fair value and are classified as long-term investments in the Company's Consolidated Balance Sheets.

As of December 31, 2020, the Company's equity investments without readily determinable fair values assessed under the measurement alternative consist of the following:

	December 31, 2020	December 31, 2019
Reneo common stock	$ 2,480	$ 2,480
Anteris preferred stock	4,245	—
Total	$ 6,725	$ 2,480

The Company received its investment in Anteris preferred stock as consideration under the Anteris License Agreement entered into on December 11, 2020. The fair value of the investment was derived from the transaction prices of other securities sold using a market approach. The investment qualifies as Level 3 under the fair value hierarchy as it was valued using unobservable inputs including volatility and risk-free rate assumptions which were 125.0% and 0.37%, respectively.

No adjustments have been made to the value of the Company's investment in either Reneo or Anteris since their initial measurement either due to impairment or based on observable price changes.

Note 8: Accounts Payable and Accrued Expenses

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

	December 31, 2020	December 31, 2019
Accounts payable	$ 1,925	$ 2,232
Accrued development costs	2,581	3,148
Accrued compensation and related costs	1,594	1,559
Accrued other	20	129
Total	$ 6,120	$ 7,068

Note 9: Leases

The Company leased its former headquarters location under an operating lease that expired in December 2019. In connection with its adoption of ASC Topic 842, the Company recognized a right of use asset and corresponding operating lease liability of $0.3 million related to this lease as of January 1, 2019. The Company elected to use the package of practical expedients in implementing ASC Topic 842 under which the Company did not reassess the operating or finance lease classification of its previously existing leases. Further, the Company did not reassess whether expired or existing contracts include leases.

In August 2019, the Company leased new office space for its headquarters location under an operating lease. This lease commenced in November 2019 after the completion of certain tenant improvements made by the lessor. The lease includes an option to renew for a five-year term as well as an option to terminate after three years, neither of which have been recognized as part of its related right of use assets or lease liabilities as their election is not considered reasonably certain. Further, this lease does not include any material residual value guarantee or restrictive covenants.

At December 31, 2020, the weighted average incremental borrowing rate and remaining lease term for the operating leases held by the Company were 13.1% and 4.1 years, respectively.

Maturities of lease liabilities for the Company's operating leases as of December 31, 2020 were as follows (in thousands):

2021	$ 255
2022	261
2023	268
2024	275
2025	23
Thereafter	—
Total lease payments	1,082
Less: imputed interest	(251)
Present value of lease liabilities	$ 831

Operating lease cost was $0.2 million, $0.4 million and $0.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. During the year ended December 31, 2020, cash paid for operating leases was $0.2 million.

The Company had recognized an asset retirement obligation for an obligation in its old facility lease that required 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. As no amounts were required to be paid upon exit of the lease, the asset retirement obligation was reversed during the year ended December 31, 2020. Asset retirement obligations recorded as a component of other noncurrent liabilities in the Consolidated Balance Sheets were $0.3 million at December 31, 2019. An immaterial amount of accretion and depreciation expense was recognized in the years ended December 31, 2019 and 2018

Note 10: Notes Payable

Notes payable consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Notes payable under the Loan Agreement	$ —	$ 4,896
Short-term financing	84	144
Accreted final payment	—	1,132
Total notes payable	84	6,172
Less: Current portion	(84)	(6,172)
Total notes payable, net of current portion	$ —	$ —

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. On April 1, 2020, the Company entered into an amendment to the Loan Agreement (the “Second Amendment”) and on July 29, 2020, the Company entered into the Third Amendment to the Loan Agreement. These amendments extended the maturity dates of the loans and adjusted the minimum cash balance requirements and their impacts have been incorporated into these disclosures and are more fully described below.

Each loan tranche bore 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 connection with the Third Amendment, the maturity date of the first tranche was extended to September 1, 2020. In addition, a final payment for the first tranche loan equal to $0.8 million originally due on May 1, 2020 was extended to September 1, 2020 as part of the Third Amendment, 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 connection with the Second Amendment, the maturity date of the second tranche was extended to January 1, 2021. In addition, a final payment for the second tranche loan equal to $0.5 million was originally due on October 1, 2020, or such earlier date specified in the Loan Agreement. In connection with the Second Amendment, the due date for this final payment was extended to January 1, 2021, or such earlier date specified in the Loan Agreement. The total amount of the payment was increased to $0.8 million as a result of the Second and Third Amendments. For each of the first and second tranches, the combined Second and Third Amendment required only monthly interest payments on the outstanding principal balance for the amounts due from April 1, 2020, through August 1, 2020. As amended, the remaining principal balance and final interest payment under the first tranche was paid upon maturity. Further, the Second and Third Amendments require equal monthly principal payments plus accrued interest for the second tranche beginning September 1, 2020 through the scheduled maturity on January 1, 2021. The full amount outstanding under both the first and second tranches, including the related final interest payments were paid in accordance with the scheduled maturities, with the final payment made prior to December 31, 2020.

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 were 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 agreed not to pledge or otherwise encumber its intellectual property assets, subject to certain exceptions. Upon full repayment and termination of the Loan Agreement in December 2020, these security interests and pledges have been extinguished.

The Loan Agreement included 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 did not contain any financial maintenance covenants other than a requirement to maintain a minimum cash balance from time-to-time in a deposit account pledged to secure the Loan Agreement and subject to an account control agreement. The Loan Agreement included customary events of default, including payment defaults, covenant defaults, and material adverse change default. Upon full repayment and termination of the Loan Agreement in December 2020, the associated covenants terminated.

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, 2020 and 2019. These costs will be recognized as interest expense over the term of the first tranche using the effective interest method. The Second and Third Amendments were considered modifications to the existing agreement for accounting purposes. As such, the Company determined a new effective interest rate of 21.5% on the debt considering the remaining unamortized cost and the increases to the final payment for the second tranche as a result of these amendments. The related costs were amortized and the final payments for the first and second loan tranches were accrued as additional interest expense, using the effective interest method over the remaining term of the Loan Agreement

The Company recorded interest expense related to the Loan Agreement of $0.7 million, $1.8 million and $3.1 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Note 11: 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 was 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*. This agreement was amended in May 2019 to create milestone payments applicable to certain specific and non-specific areas of therapeutic use. Under the terms of the Novo License Agreement, the Company has additional potential developmental and regulatory milestone payments totaling up to $9.0 million for approval of a product for the treatment of type 1 diabetes, $50.5 million for approval of a product for the treatment of type 2 diabetes, or $115.0 million for approval of a product in any other indication. 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, prior to its amendment in January 2021, vTv LLC was obligated to act as the sponsor of the Phase 2 MRCT should Huadong require it to do so. The Phase 2 MRCT was to include 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 and was to 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 was responsible for contributing up to $3.0 million in connection with the Phase 2 MRCT. In connection with the First Huadong Amendment, discussed further in Note 20, the Company's obligation to sponsor and contribute funding to the Phase 2 MRCT was eliminated from the Huadong License Agreement.

Note 12: 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.

ATM Offering

In April 2020, the Company entered into the Sales Agreement with Cantor as the sales agent, pursuant to which the Company may offer and sell, from time to time, through Cantor, shares of its Class A common stock, par value $0.01 per share, having an aggregate offering price of up to $13.0 million by any method deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act (the "ATM Offering"). The shares are offered and sold pursuant to the Company's shelf registration statement on Form S-3.

During the year ended December 31, 2020, the Company sold 5,480,941 shares of Class A common stock under the ATM Offering at then-market prices for total gross proceeds of approximately $13.0 million, respectively. After offering costs and sales commissions owed in connection with the ATM Offering, the Company's aggregate net proceeds for the year ended December 31, 2020 were approximately $12.5 million.

As discussed further in Note 20, on January 14, 2021, the Company filed a prospectus supplement increasing the aggregate offering price available under the ATM Offering by $5.5 million.

Lincoln Park Capital Transaction

On November 24, 2020, the Company entered into the LPC Purchase Agreement and a registration rights agreement (the "Registration Rights Agreement"), pursuant to which the Company has the right to sell to Lincoln Park shares of the Company's Class A common stock having an aggregate value of up to $47.0 million, subject to certain limitations and conditions set forth in the LPC Purchase Agreement. The Company will control the timing and amount of any sales of shares to Lincoln Park. pursuant to the Purchase Agreement. The Company filed a registration statement to register 5,331,306 shares which became effective on December 8, 2020.

As a result, on November 24, 2020, 425,725 newly issued shares of the Company's common stock, equal to 1.5% percent of the $47.0 million availability, were issued to Lincoln Park as consideration for Lincoln Park's commitment to purchase shares of the Company's Class A common stock under the agreement. Upon effectiveness of the registration statement, 963,855 newly issued shares of Class A common stock, valued at $2.08 per share, were sold to Lincoln Park in an initial purchase for an aggregate gross purchase price of $2.0 million.

Over the 36-month term of the LPC Purchase Agreement, for up to an aggregate amount of $47,000,000 of shares of Class A common stock (subject to certain limitations and conditions), the Company has the right, but not the obligation, from time to time, in its sole discretion, to direct Lincoln Park to purchase up to 250,000 shares per day (the "Regular Purchase Share Limit") of the Class A common stock (each such purchase, a "Regular Purchase"). The Regular Purchase Share Limit will increase to 275,000 shares per day if the closing price of the Class A common stock on the applicable purchase date is not below $4.00 per share and will further increase to 300,000 shares per day if the closing price of the Class A common stock on the applicable purchase date is not below $5.00 per share. In any case, Lincoln Park's maximum obligation under any single Regular Purchase will not exceed $2,000,000. The purchase price for shares of Class A common stock to be purchased by Lincoln Park under a Regular Purchase will be equal to the lower of (in each case, subject to the adjustments described in the LPC Purchase Agreement): (i) the lowest sale price for the Class A common stock on the applicable purchase date and (ii) the arithmetic average of the three lowest closing sales prices for the Class A common stock during the 10 consecutive trading days prior to the purchase date.

If the Company directs Lincoln Park to purchase the maximum number of shares of Class A common stock that the Company may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the LPC Purchase Agreement, the Company may direct Lincoln Park to make an "accelerated purchase" and an "additional accelerated purchase", each of an additional number of shares of Class A common stock which may not exceed the lesser of: (i) 300% of the number of shares purchased pursuant to the corresponding Regular Purchase and (ii) 30% of the total number of shares of the Common Stock traded during a specified period on the applicable purchase date as set forth in the LPC Purchase Agreement. The purchase price for such shares will be the lesser of (i) 97% of the volume weighted average price of the Class A common stock over a certain portion of the date of sale as set forth in the LPC Purchase Agreement and (ii) the closing sale price of the Class A common Stock on the date of sale (an "Accelerated Purchase"). Under certain circumstances and in accordance with the LPC Purchase Agreement, the Company may direct Lincoln Park to purchase shares in multiple Accelerated Purchases on the same trading day.

The LPC Purchase Agreement also prohibits the Company from directing Lincoln Park to purchase any shares of its Class A common stock if those shares, when aggregated with all other shares of Class A common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of Class A common stock as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder.

Under applicable rules of the Nasdaq Global Select Market, the Company may not issue or sell to Lincoln Park under the LPC Purchase Agreement more than 19.99% of the shares of the Class A common stock outstanding immediately prior to the execution of the LPC Purchase Agreement (the "Exchange Cap") (or 14,768,682 shares, based on 73,880,351 shares outstanding immediately prior to the execution of the LPC Purchase Agreement), unless (i) stockholder approval is obtained or (ii) the issuances and sales of Class A common stock pursuant to the LPC Purchase Agreement are not deemed to be "below market" in accordance with the applicable rules of Nasdaq.

The LPC Purchase Agreement does not limit the Company's ability to raise capital from other sources at its sole discretion, except that, subject to certain exceptions, the Company may not enter into another "equity line" or similar transaction.

The LPC Purchase Agreement and Registration Rights Agreement each contain customary representations, warranties, and agreements of the Company and Lincoln Park, indemnification rights and other obligations of the parties. The offering of Class A common stock pursuant to the LPC Purchase Agreement will terminate on the date that all shares offered by the LPC Purchase Agreement have been sold or, if earlier, the expiration or termination of the LPC Purchase Agreement. The Company has the right to terminate the LPC Purchase Agreement at any time, without fee, penalty or cost to the Company.

The net proceeds under the LPC Purchase Agreement to the Company will depend on the frequency and prices at which shares of Class A common stock are sold to Lincoln Park. Actual sales of shares of Class A common stock to Lincoln Park under the LPC Purchase Agreement and the amount of such net proceeds will depend on a variety of factors to be determined by the Company from time to time, including (among others) market conditions, the trading price of the Class A common stock and determinations by the Company as to other available and appropriate sources of funding for the Company. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of Class A common stock.

Letter Agreement Warrants

The Company has entered into the Letter Agreements with MacAndrews. Under the terms of the Letter Agreements, the Company has or had the right to sell to MacAndrews shares of its Class A Common Stock at a specified price per share, and

MacAndrews 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. In addition, in connection with and as a commitment fee for the entrance into certain of these Letter Agreements, the Company also issued MacAndrews 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 14.

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, 2020, 2019 and 2018 the Company recognized income/(expense) of $0.3 million, $0.8 million and $(0.6) million, respectively, related to the change in fair value of the Letter Agreement Warrants. These amounts were recognized as a component of other income (expense), related party in the Consolidated Statements of Operations.

Fair value of the Letter Agreement Warrants was calculated as of their issuance date using the methods described in Note 19 using the following assumptions:

	December 5, 2017	July 30, 2018	December 11, 2018	September 26, 2019	December 23, 2019
Expected volatility	90.00%	95.29%	104.46%	110.35%	110.41%
Expected life of option, in years	7.0	7.0	7.0	7.0	7.0
Risk-free interest rate	2.80%	2.94%	2.77%	1.65%	1.84%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%

Loan Agreement Warrants

On October 28, 2016, the Company entered into the Loan Agreement as discussed in Note 10. 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. The Warrants will expire seven years from their date of issuance.

Note 13: Redeemable Noncontrolling Interest

The Company is subject to the Exchange Agreement with respect to the vTv Units representing the outstanding 29.9% 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, 2020 and 2019, the redeemable noncontrolling interest was recorded based on the redemption value as of the balance sheet date of $83.9 million and $40.2 million, respectively.

Changes in the Company's ownership interest in vTv LLC while the Company retains its controlling interest in vTv LLC are accounted for as equity transactions, and the Company is required to adjust noncontrolling interest and equity for such changes. The following is a summary of net income attributable to vTv Therapeutics Inc. and transfers to noncontrolling interest:

	December 31, 2020	December 31, 2019	December 31, 2018
Net loss attributable to vTv Therapeutics Inc. common shareholders	$ (8,499)	$ (17,913)	$ (8,650)
Increase in vTv Therapeutics Inc. accumulated deficit for purchase of LLC Units as a result of common stock issuances	(8,943)	(17,971)	(19,456)
Change from net loss attributable to vTv Therapeutics Inc. common shareholders and transfers to noncontrolling interest	$ (17,442)	$ (35,884)	$ (28,106)

Note 14: 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, 2020, MacAndrews directly or indirectly holds 36,606,212 shares of the Company's Class A Common Stock. As a result, MacAndrews' holdings represent approximately 77.4% 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 MacAndrews. Under the terms of the Letter Agreements, the Company has the right to sell to MacAndrews shares of its Class A Common Stock at a specified price per share, and MacAndrews has 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. In addition, in connection with and as a commitment fee for the entrance into certain of these Letter Agreements, the Company also issued MacAndrews warrants (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 tables below:

	December 5, 2017 Letter Agreement	July 30, 2018 Letter Agreement	December 11, 2018 Letter Agreement
Aggregate dollar value to be sold under agreement	$10.0 million	$10.0 million	$10.0 million
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, 2020	2,283,105	7,518,797	5,434,783
Remaining shares to be issued as of December 31, 2020	—	—	—

	March 18, 2019 Letter Agreement	September 26, 2019 Letter Agreement	December 23, 2019 Letter Agreement
Aggregate dollar value to be sold under agreement	$9.0 million	$10.0 million	$10.0 million
Specified purchase price per share	$ 1.65	$ 1.46	$ 1.60
Expiration date of letter agreement	March 18, 2020	September 26, 2020	December 23, 2020
Shares available to be issued under related warrants	—	400,990	365,472
Exercise price of related warrants	$ —	$ 1.68	$ 1.84
Expiration date of related warrants		September 26, 2026	December 23, 2026
Total shares issued as of December 31, 2020	5,454,546	6,849,316	6,250,000
Remaining shares to be issued as of December 31, 2020	—	—	—

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, March 18, 2019, September 26, 2019 and December 23, 2019 Letter Agreements 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, 2020, 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, 2020.

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.

Note 15: 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 $0.1 million, $0.1 million and $0.2 million to the plan for the years ended December 31, 2020, 2019 and 2018, respectively.

Note 16: 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 did not record an income tax provision for the year ended December 31, 2020. The Company recorded an income tax provision of $0.1 million and $0.2 million for the years ended December 31, 2019 and 2018, respectively, representing foreign withholding taxes incurred in connection with payments received under license agreements with foreign entities.

As discussed in Note 14, 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, 2020.

In December 2019, the FASB issued ASU 2019-12, which intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in ASC 740 and also clarifies and amends existing guidance to improve consistent application of ASC 740. This guidance is effective for fiscal years beginning after December 15, 2020, including interim periods therein, and early adoption is permitted. Adoption of ASU 2019-12 in 2021 is not expected to have a material effect on the Company's consolidated financial statements.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was enacted in response to COVID-19 pandemic. Under ASC 740, the effects of changes in tax rates and laws are recognized in the period which the new legislation is enacted. The CARES Act made various tax law changes including among other things (i) increased the limitation under IRC Section 163(j) for 2019 and 2020 to permit additional expensing of interest, (ii) enacted a technical correction so that qualified improvement property can be immediately expensed under IRC Section 168(k), (iii) made modifications to the federal net operating loss rules including permitting federal net operating losses incurred in 2018, 2019, and 2020 to be carried back to the five preceding taxable years in order to generate a refund of previously paid income taxes, and (iv) enhanced recoverability of AMT tax credits. Given the Company's full valuation allowance position, the CARES Act did not have a material impact on the financial statements.

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

	December 31,		
	2020	2019	2018
U.S. statutory tax benefit	$ (2,688)	$ (4,586)	$ (4,966)
Partnership income (federal) not subject to tax to the Company	904	1,868	3,346
Foreign withholding tax	—	79	200
State taxes (net of federal benefit)	(13)	134	(224)
Research and development tax credit	(138)	(231)	(1,122)
Other	75	(81)	(168)
Change in valuation allowance	1,860	2,917	3,134
Provision for income taxes	$ —	$ 100	$ 200
Effective income tax rate	0.0%	-0.5%	-0.8%

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

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 17,338	$ 14,540
R&D Tax Credit carryforwards	1,587	1,517
Investment in partnerships	(1,520)	(511)
Charitable contributions	12	11
Total deferred tax assets	17,417	15,557
Valuation allowance	(17,417)	(15,557)
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. Based on the weight of objective evidence, including cumulative pre-tax losses in recent years, 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, 2020, the Company's valuation allowance increased by $1.9 million.

The Company has federal net operating loss carryforwards of $79.1 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 $39.1 million may be carried forward indefinitely but are only available to offset 80% of future taxable income. The Company has federal research and development tax credits of $1.6 million which expire in varying amounts starting in 2035 to 2040.

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, 2020, 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, 2020.

The Company files U.S. federal, 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 2016 to 2019.

Note 17: 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 allowed 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 completed these restructuring activities in the second quarter of 2019.

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. During the year ended December 31, 2019, the Company made cash payments of $0.3 million related to these severance benefits and recognized an immaterial amount of expense related to this plan. 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. There were no accruals recorded for these actions within the Consolidated Balance Sheet as of December 31, 2020 or 2019.

Note 18: 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, 2020, 2019 and 2018 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,		
	2020	2019	2018
Numerator:			
Net loss	$ (12,802)	$ (21,938)	$ (23,845)
Less: Net loss attributable to noncontrolling interests	(4,303)	(8,894)	(15,934)
Net loss attributable to vTv Therapeutics Inc.	(8,499)	(13,044)	(7,911)
Less: Deemed distribution to related party (Note 13)	—	(4,869)	(739)
Net loss attributable to common shareholders of vTv Therapeutics Inc., basic and diluted	$ (8,499)	$ (17,913)	$ (8,650)
Denominator:			
Weighted-average vTv Therapeutics Inc. Class A Common Stock, basic and diluted	47,137,917	30,292,030	12,449,236
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	$ (0.18)	$ (0.59)	$ (0.69)

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

	Year Ended December 31,		
	2020	2019	2018
Class B Common Stock (1)	23,094,221	23,094,221	23,094,221
Common stock options granted under the Plan	4,453,357	2,531,143	1,767,503
Restricted stock units	—	11,667	23,333
Common stock options granted under the Letter Agreement	—	6,250,000	4,619,566
Common stock warrants	2,014,503	2,014,503	1,248,041
Total	29,562,081	33,901,534	30,752,664

(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 19: 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 was considered to approximate its carrying value because it bore interest at a variable interest rate.

The Company measures the value of its investments in Reneo and Anteris 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 and Anteris investments, 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 investments in Reneo and Anteris 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, 2020, 2019 and 2018 (in thousands):

	Balance at December 31, 2020	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)	$ 2,871	$ —	$ —	$ 2,871
Total	$ 2,871	$ —	$ —	$ 2,871

	Balance at December 31, 2019	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)	$ 2,601	$ —	$ —	$ 2,601
Total	$ 2,601	$ —	$ —	$ 2,601

(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.

	Changes in Level 3 Instruments for the years ended December 31, 2020, 2019 and 2018				
	Balance at January 1	Net Change in fair value included in earnings	Purchases / Issuance	Sales / Repurchases	Balance at December 31,
2020					
Warrant liability, related party	$ 2,601	$ 270	$ —	$ —	$ 2,871
Total	$ 2,601	$ 270	$ —	$ —	$ 2,871
2019					
Warrant liability, related party	2,436	(827)	992	—	2,601
Total	$ 2,436	$ (827)	$ 992	$ —	$ 2,601
2018					
Warrant liability, related party	492	638	1,306	—	2,436
Total	$ 492	$ 638	$ 1,306	$ —	$ 2,436

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, 2020, 2019 and 2018. Gains and losses recognized due to the change in fair value of the warrant liability, related party are recognized as a component of other (expense) income, related party in the Consolidated Statements of Operations

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, 2020		December 31, 2019	
	Range	**Weighted Average**	**Range**	**Weighted Average**
Expected volatility	120.53% - 142.07%	128.16%	110.76% - 123.83%	115.20%
Risk-free interest rate	0.26% - 0.50%	0.39%	1.69% - 1.83%	1.74%

The weighted average expected volatility and risk-free interest rate was based on the relative fair values of the warrants.

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 20: Subsequent Events

On January 14, 2021, the Company filed a prospectus supplement in connection with the ATM Offering to increase the size of the at-the-market offering pursuant to which the Company may offer and sell, from time to time, through or to Cantor, as sales agent or principal, shares of the Company's Class A Common Stock, by an aggregate offering price of $5.5 million. No shares of Class A Common Stock have been sold under the ATM Offering subsequent to December 31, 2020.

Subsequent to December 31, 2020, the Company exercised its right under the LPC Purchase Agreement to cause Lincoln Park to purchase 3.5 million shares of its Class A Common Stock for total gross proceeds of $8.0 million.

On January 14, 2021, the Company entered into the First Huadong Amendment which eliminates the Company's obligation to sponsor the Phase 2 MRCT and corresponding obligation to contribute up to $3.0 million in support of such trial. The amendment also reduced the total potential development and regulatory milestone payments by $3.0 million.

Exhibit 4.3

DESCRIPTION OF THE CAPITAL STOCK

Capital Stock

Our authorized capital stock consists of 100,000,000 shares of Class A common stock, par value $0.01 per share, 100,000,000 shares of Class B common stock, par value $0.01 per share, and 50,000,000 shares of preferred stock, par value $0.01 per share. As of February 24, 2021, we have approximately 57,550,710 shares of our Class A common stock outstanding, 23,094,221 shares of our Class B common stock outstanding and no shares of preferred stock outstanding. As of February 24, 2021, there were approximately 22 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.

Common Stock

Voting. Holders of our Class A common stock and Class B common stock are entitled to one vote for each share held on all matters submitted to stockholders for their vote or approval. The holders of our Class A common stock and Class B common stock vote together as a single class on all matters submitted to stockholders for their vote or approval, except with respect to the amendment of certain provisions of our amended and restated certificate of incorporation that would alter or change the powers, preferences or special rights of the Class B common stock so as to affect them adversely, which amendments must be approved by a majority of the votes entitled to be cast by the holders of the shares affected by the amendment, voting as a separate class, or as otherwise required by applicable law.

As of December 31, 2020, subsidiaries and affiliates of MacAndrews & Forbes Incorporated (collectively "MacAndrews") hold 23,084,267 shares of our Class B common stock and 36,606,212 shares of our Class A common stock and therefore control approximately 77.4% of the combined voting power of our outstanding common stock. As a result, MacAndrews is able to control our business policies and affairs and any action requiring the general approval of our stockholders, including the adoption of amendments to our certificate of incorporation and bylaws, the approval of mergers or sales of substantially all of our assets and the removal of members of our Board of Directors with or without cause. MacAndrews also has the power to nominate a majority of the members to our Board of Directors under our investor rights agreement. The concentration of ownership and voting power of MacAndrews may also delay, defer or even prevent an acquisition by a third party or other change of control of our company and may make some transactions more difficult or impossible without the support of MacAndrews, even if such events are in the best interests of minority stockholders.

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

Liquidation or Dissolution. Upon our liquidation or dissolution, the holders of our Class A common stock are entitled to share ratably in those of our assets that are legally available for distribution to stockholders after payment of liabilities and subject to the prior rights of any holders of preferred stock then outstanding. Other than their par value, the holders of our Class B common stock do not have any right to receive a distribution upon a liquidation or dissolution of our company.

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

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

Preferred Stock

We have been authorized to issue up to 50,000,000 shares of preferred stock. Our board of directors has authorized, subject to limitations prescribed by Delaware law and our amended and restated certificate of incorporation, to determine the terms and conditions of the preferred stock, including whether the shares of preferred stock will be issued in one or more series, the number of shares to be included in each series and the powers, designations, preferences and rights of the shares. Our Board of Directors has also been authorized to designate any qualifications, limitations or restrictions on the shares without any further vote or action by the stockholders. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the voting and other rights of the holders of our Class A common stock and Class B common stock, which could have an adverse impact on the market price of our Class A common stock. We have no current plan to issue any shares of preferred stock.

Corporate Opportunities

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the doctrine of “corporate opportunity” will not apply to 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 in a manner that would prohibit them from investing in competing businesses or doing business with our clients or customers. See “Risk Factors—Risks Relating to this Offering and Ownership of Our Class A Common Stock—MacAndrews has substantial influence over our business, and their interests may differ from our interests or those of our other stockholders” in our Annual Report on Form 10-K for the year ended December 31, 2020, which is incorporated herein by reference.

Anti-Takeover Effects of our Certificate of Incorporation and Bylaws

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

These provisions include:

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

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

Vacancies and Newly-Created Directorships on the Board of Directors. Our bylaws provide that the Board of Directors can fill vacancies on the Board of Directors. In addition, the Board of Directors will be permitted to increase the number of directors and fill the vacant positions. These provisions could make it more difficult for shareholders to affect the composition of our Board of Directors.

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

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

Choice of Forum

Our amended and restated certificate of incorporation provides that the Court of Chancery in the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed to us or our stockholders by our directors, officers or other employees, (iii) any action asserting a claim arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation and amended and restated by-laws or (iv) any action asserting a claim that is governed by the internal affairs doctrine. It is possible that a court could rule that this provision is not applicable or is unenforceable. We may consent in writing to alternative forums. Stockholders will be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware and having service of process made on such stockholder's counsel as agent for such stockholder.

Directors' Liability; Indemnification of Directors and Officers

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

Transfer Agent and Registrar

The transfer agent and registrar for our Class A common stock is American Stock Transfer & Trust Company, LLC.

Securities Exchange

Our shares of Class A common stock are listed on The NASDAQ Capital Market under the symbol “VTVT”.

*** Certain information identified by “[***]” has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.**

LICENSE AGREEMENT

This License Agreement (the “**Agreement**”) is entered into as of December 11, 2020 (the “**Effective Date**”), by and between **Anteris Bio, Inc.**, a Delaware corporation having an address at 1111 Broadway, Suite 1300, Oakland, CA, 94607 (“**Anteris**”) and **vTv Therapeutics LLC**, a limited liability company having an address at 3980 Premier Drive, Suite 310, High Point, NC 27265 (“**vTv**”). Anteris and vTv may be referred to herein individually as a “**Party**” or collectively as the “**Parties**”.

Recitals

Whereas, vTv owns certain compounds and patents, know-how, and other intellectual property relating to such compounds;

Whereas, Anteris possesses resources and expertise in the development and commercialization of pharmaceutical products;

Whereas, Anteris desires to obtain an exclusive license to develop, manufacture, commercialize and otherwise exploit the Licensed Compound and Licensed Products in the Field (each as defined below) and vTv desires to grant to Anteris such license.

Agreement

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Anteris and vTv hereby agree as follows:

1. Definitions

1.1 “**Accounting Standards**” means United States Generally Accepted Accounting Principles (GAAP) or International Financial Reporting Standards (IFRS), as consistently applied by Anteris or its Affiliates or Sublicensees, as applicable.

1.2 “**Anteris Indemnitee**” has the meaning set forth in Section 10.2.

1.3 “**Anteris Technology**” means (a) Know-How, including Anteris’ interest in Joint Know-How, that (i) Anteris Controls after the Effective Date, (ii) is developed, discovered, made, conceived, or reduced to practice in the course of Developing or Commercializing any Licensed Compound or Licensed Product under this Agreement, and (iii) is [***] for the research, Development, manufacture, use, Commercialization or other Exploitation of any Licensed Compound or Licensed Product in the Field, and (b) Patents, including Anteris’ interest in Joint Patents, that Anteris Controls after the Effective Date and that (i) Cover Know-How described in subclause (a), or any Licensed Compound, or Licensed Product (or, with respect to Patent applications, would Cover if such Patent applications were to issue as Patents) or (ii) are [***]) for the research, Development, manufacture, use, Commercialization or other Exploitation of any Licensed Compound or Licensed Product in the Field.

1.4 "**Affiliate**" means, with respect to a Party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Party, but for only so long as such control exists. As used in this Section 1.4, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of a Party, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in a Party. Notwithstanding with foregoing, no member of the Sponsor Group shall be considered an Affiliate of vTv.

1.5 "**Applicable Laws**" means applicable laws, statutes, ordinances, rules, regulations, guidances and orders of any Governmental Authority having jurisdiction over or related to the subject item.

1.6 "**Auditor**" has the meaning set forth in Section 7.4.

1.7 "**Backup Compound**" means a small molecule activator of Nrf2 that binds to and inhibits Bach1, in all pharmaceutical forms, that is Controlled by vTv as of the date that Anteris determines to cease Development of the Lead Compound and is designated as a Backup Compound in accordance with Section 4.5.

1.8 "**Calendar Quarter**" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31; provided that (a) the first Calendar Quarter of the Term shall begin on the Effective Date and end on the first to occur of March 31, June 30, September 30, and December 31 thereafter; and (b) the final Calendar Quarter of the Term shall end on the last day of the Term.

1.9 "**Calendar Year**" means each respective period of twelve (12) consecutive months ending on December 31; provided that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on December 31 of the calendar year in which the Effective Date falls, and (b) the final Calendar Year of the Term shall end on the last day of the Term.

1.10 "**Claim**" has the meaning set forth in Section 10.1.

1.11 "**Clinical Trial**" means a clinical study in which a pharmaceutical product is administered to human subjects that is designed to (a) establish that the pharmaceutical product is reasonably safe for continued testing; (b) investigate the safety and efficacy of the pharmaceutical product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the pharmaceutical product in the dosage range to be prescribed; (c) support Regulatory Approval of the pharmaceutical product or label expansion of the pharmaceutical product; or (d) obtain, support or maintain marketing approval, including any and all post-marketing commitments.

1.12 "**Combination Product**" means a Licensed Product that is (a) sold in the form of a combination that contains or comprises a Licensed Compound together with one or more other therapeutically active pharmaceutical agents (whether co-formulated or co-packaged or otherwise sold under one pricing scheme (whether payment of such price is paid to the same or to more than one seller)) that is not a Licensed Compound or (b) [***] such Combination Product (such additional therapeutically active pharmaceutical agent, delivery device or other component an "**Other Product**").

1.13 "**Commercialization**" means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, sales, marketing, and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling, and delivering products to customers) of products, including sales force efforts, detailing, advertising, market research, market access (including price and reimbursement activities), marketing, sales force training, and sales (including receiving, accepting, and filling product orders). In addition, although not involving promotion or sales, medical affairs, including medical education and information services, publication, scientific, advisory and collaborative activities with opinion leaders and professional societies including symposia, and medical support, shall be included within the definition of "Commercialization" for purposes of this Agreement. "**Commercialize**" and "**Commercializing**" have correlative meanings.

1.14 "**Commercially Reasonable Efforts**" means, with respect to Anteris' obligations to Develop, seek MAA Approval, and Commercialize a Licensed Product under this Agreement, those efforts and resources that a reasonably capitalized pharmaceutical company of similar size to Anteris would use in the development, manufacture, and commercialization of a pharmaceutical product owned by such company, which is at a similar stage of research, development, or commercialization, is in a similar therapeutic and disease area, and is of similar market potential, taking into account (a) such product's: (i) profile of efficacy and safety; (ii) proprietary position, including patent and regulatory exclusivity; (iii) regulatory status, including likelihood of obtaining and timing of regulatory approval, anticipated or approved labeling, and anticipated or approved post-approval requirements; and (iv) present and future market and commercial potential, including competitive market conditions and the expected and actual profitability and return on investment, (b) the expected and actual competitiveness of alternative Third Party products (including generic or biosimilar products) under development or sold in the marketplace, (c) issues regarding the ability to manufacture, have manufactured or obtain adequate supply of product, and (d) relative strategic value with respect to other compounds and products in its portfolio of compounds and products.

1.15 "**Competing Product**" means any compound or product, other than the Licensed Compound and Licensed Products, that [***]. For clarity, if [***].

1.16 "**Confidential Information**" means all Know-How and other proprietary scientific, marketing, financial, or commercial information or data that is generated by or on behalf of a Party or its Affiliates or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing, or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs, or formulae in relation to this Agreement. Confidential Information shall include: (a) the terms and conditions of this Agreement, and (b) confidential information disclosed by the Parties or their Affiliates pursuant to any confidentiality agreement entered into by the Parties or their Affiliates prior to the Effective Date.

1.17 "**Control**" or "**Controlled**" means, with respect to any compound, Know-How, Patents, or other intellectual property rights, the legal authority or right (whether by ownership, license, or otherwise, but without taking into account the license granted pursuant to Section 2.1) of a Party to grant access, a license, or a sublicense of, to or under such compound, Know-How, Patents, or other intellectual property rights to the other Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.18 "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent, that, in the absence of ownership of or a license under such Patent, the manufacture, use, sale, offer for sale, or importation of such subject matter would infringe one or more claims of such Patent (or, in the case of a claim of a pending patent application, would infringe such claim if it were to issue as a claim of an issued patent).

1.19 "**Development**" means all development activities for a product (whether alone or for use together, or in combination, with another active agent or pharmaceutical product as a combination product or combination therapy) that are directed to obtaining Regulatory Approval(s) of such product and lifecycle management of such product in any country in the world, including all non-clinical, preclinical, and clinical testing and studies of a product; toxicology, pharmacokinetic, and pharmacological studies; statistical analyses; assay development; protocol design and development; the preparation, filing, and prosecution of any MAA for a product; development activities directed to label expansion and/or obtaining Regulatory Approval for one or more additional indications following initial Regulatory Approval; development activities conducted after receipt of Regulatory Approval; and all regulatory affairs related to any of the foregoing. "**Develop**" and "**Developing**" have correlative meanings.

1.20 "**Digital App**" has the meaning set forth in Section 1.48.

1.21 "**EMA**" means the European Medicines Agency, or any successor agency thereto.

1.22 "**Enforcing Party**" has the meaning set forth in Section 8.3(c).

1.23 "**EU**" means the European Union, as such entity is comprised as of the date of applicability hereunder.

1.24 "**Executive Officers**" means the Chief Executive Officer of Anteris or his/her designee and the Chief Executive Officer of vTv or his/her designee.

1.25 "**Exploit,**" means to research, Develop, make, have made, import, export, use, sell, offer for sale, distribute, promote, market, have sold and otherwise Commercialize, register, modify, enhance, improve, or keep (whether for disposal or otherwise), formulate, optimize, have used, transport or otherwise dispose of. "**Exploitation**" has correlative meaning.

1.26 "**Export Control Laws**" means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International

Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

1.27 "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended.

1.28 "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time.

1.29 "**FDA**" means the U.S. Food and Drug Administration, or any successor agency thereto.

1.30 "**Field**" means any and all uses in humans.

1.31 "**First Commercial Sale**" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the first sale by Anteris or its Affiliate or Sublicensee to a Third Party for end use of such Licensed Product in such country after Regulatory Approval has been granted with respect to such Licensed Product in such country.

1.32 "**Generic Product**" means, on a Licensed Product-by-Licensed Product and country-by-country basis, any pharmaceutical product that (a) contains the same Licensed Compound as such Licensed Product, (b) has been approved through an abbreviated Regulatory Approval pathway that relies in whole or in part on an MAA (or any data included in an MAA) for a Licensed Product, including through the pathway under Section 505(b)(2) of the FFDCA or Section 505(j) of the FFDCA (or similar pathways outside the U.S.), and (c) is sold in such country by a Third Party that is not a Sublicensee and did not purchase such product or Licensed Compound from Anteris or its Affiliates or Sublicensees.

1.33 "**Governmental Authority**" means any national, international, federal, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.34 "**IND**" means an investigational new drug application submitted to the FDA or equivalent application (including any clinical trial application) submitted to the applicable Regulatory Authority in a country outside the U.S., which application is required to commence human clinical trials in the applicable country.

1.35 "**Indemnified Party**" has the meaning set forth in Section 10.3.

1.36 "**Indemnifying Party**" has the meaning set forth in Section 10.3.

1.37 "**Indication**" means a separate and distinct disease, disorder, illness, or health condition and all of its associated signs, symptoms, stages, or progression (including precursor conditions), in each case for which a separate MAA is filed. For clarity, subpopulations or patients with a primary disease or condition, however stratified (including stratification by stages of progression, particular combinations of symptoms associated with the primary disease or condition, prior treatment courses, response to prior treatment, family history, clinical history, genotype, phenotype, or other stratification) shall not be deemed to be separate "Indications" for the purposes of this Agreement.

1.38 "**Initial Prosecuting Party**" has the meaning set forth in Section 8.2(a).

1.39 "**Initiation**" means, with respect to a Clinical Trial, the first dosing of the first (1st) human subject in such Clinical Trial.

1.40 "**Inventions**" means all inventions, whether or not patentable, discovered, made, conceived, or reduced to practice, in the course of activities performed under this Agreement or through the exercise of a license granted in this Agreement, together with all intellectual property rights therein.

1.41 "**Joint Advisory Committee**" or the "**JAC**" has the meaning set forth in Section 3.1.

1.42 "**Joint IP**" has the meaning set forth in Section 8.1(b).

1.43 "**Joint Know-How**" has the meaning set forth in Section 8.1(b).

1.44 "**Joint Patent**" has the meaning set forth in Section 8.1(b).

1.45 "**Know-How**" means (a) any and all know-how or information including trade secrets, inventions (whether patentable or not, and including data or descriptions contained in unpublished patent applications), methods, knowledge, skill, experience, research and development data and results (including medicinal chemistry data, preclinical data, pharmacological, toxicological and clinical test data and results (including investigator reports (both preliminary and final), statistical analyses, expert opinions and reports, safety and other electronic databases), chemical structure, sequences, processes, formulae, techniques, research data, reports, standard operating procedures and batch records), product specifications, study designs and protocols, assays and biological methodology, analytical and quality control data, analytical methods (including applicable reference standards), full batch documentation, packaging records, release, stability, storage and shelf-life data, and manufacturing process information, results or descriptions, (b) databases, practices, techniques, specifications, formulations, formulae, software and algorithms, (c) if applicable, physical materials, reagents and compositions of matter, including chemical or biological materials, in each case, whether patentable or not, and (d) tangible manifestations of any of the foregoing. Know-How shall not include any of the foregoing to the extent it is described or claimed in any published Patent.

1.46 "**Lead Compound**" means all pharmaceutical forms of the compound Controlled by vTv as of the Effective Date known as HPP971, as further described in Schedule 1.46.

1.47 "**Licensed Compound**" means (a) (i) the Lead Compound or (ii) if Anteris elects to discontinue Development of the Lead Compound and substitute a Backup Compound, then the Backup Compound so substituted pursuant to Section 4.5, and (b) any salt, ester, hydrate, solvate, enantiomer, stereoisomer, free acid form, free base form, crystalline form, co-crystalline form, amorphous form, polymorph, metabolite, pro-drug (including ester pro-drug), racemate, chelate, tautomer, or optically active form of a compound described in subclause (a).

1.48 "**Licensed Product**" means any product that contains, comprises or incorporates a Licensed Compound, whether alone or in combination with other active ingredients, in any form, presentation, dosage, or formulation, and for any mode of administration, and including in combination with a digital device or application for patient behavior modification ("**Digital App**").

1.49 "**Licensed Product Infringement**" has the meaning set forth in Section 8.3(a).

1.50 "**Losses**" has the meaning set forth in Section 10.1.

1.51 "**MAA**" means a marketing authorization application or equivalent application (including a "New Drug Application" as defined in the FFDCA), and all amendments and supplements thereto, filed with the applicable Regulatory Authority in the Territory.

1.52 "**MAA Approval**" means approval of an MAA by the applicable Regulatory Authority for marketing and sale of a Licensed Product in the Territory.

1.53 "**Major European Market**" means each of Germany, France, Italy, Spain, and the United Kingdom.

1.54 "**Net Sales**" means, with respect to a Licensed Product, the gross amounts invoiced for sales of such Licensed Product by or on behalf of Anteris or its Affiliates or Sublicensees to Third Parties, less the following deductions recorded by Anteris, its Affiliates or Sublicensees, in each case to the extent taken in accordance with Anteris' or its Affiliates' or Sublicensees' usual accounting practice in compliance with the Accounting Standards:

(a) trade discounts, including trade, cash and quantity discounts or rebates, credits, refunds, or charge backs, or equivalents of any of the foregoing taken or allowed with respect to sales of such Licensed Product;

(b) credits or allowances given or made for claims, rejection or returns of previously sold Licensed Products or for retroactive price reductions and billing errors;

(c) cash and non-cash coupons, co-payment support programs, chargeback payments, rebates, administrative fees (e.g., Federal Supply Schedule-Industrial Funding Fee, administration rebates for all chargeback units sold to Big 4/OGA contracted entities, etc.) and any other similar allowances granted to any non-related party (including to national, state/provincial, local, and other Governmental Authorities, their agencies, purchasers, reimbursers, customers, distributors, wholesalers, group purchasing organizations, pharmacy benefit managers (or equivalents thereof), and managed care organizations (and other similar entities and institutions);

(d) costs of freight, carrier insurance, and other transportation charges related to the distribution of such Licensed Product;

(e) compulsory payments, cash rebates and fees imposed on sales of Licensed Product and paid to or levied by a Governmental Authority (or agent thereof) pursuant to Applicable Law, including that portion of the annual fee on branded prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended), or similar sales-based taxes or fees to the extent allocable to sales of such Licensed Product;

(f) taxes, duties, or other governmental charges (including any tax such as, sales, excise, use, value added or similar tax, other than any taxes based on income) levied on or measured by the billing amount for such Licensed Product or actually paid in connection with the transportation, distribution, use or sale of such Licensed Product;

(g) any invoiced amounts that are not reasonably able to be collected by Anteris or its Affiliates or Sublicensees, including bad debts, that are actually written off as uncollectable amounts; provided that any such amount subsequently collected will be reincluded as Net Sales in the Calendar Quarter in which it is collected; and

(h) customary fee-for-service payments paid to specialty pharmacies or distributors for maintaining agreed inventory levels or providing information consistent with Applicable Laws (e.g., Medicare fraud regulations).

In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Sales of a Licensed Product between Anteris and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Licensed Product to a Third Party shall be included within the computation of Net Sales.

The supply of Licensed Product as samples for charitable or promotional purposes, for use in non-clinical studies or Clinical Trials or any test or other studies, or other instances that are otherwise normal and customary in the industry where Licensed Product is supplied at or below cost shall not be included in the computation of Net Sales.

In the event a Licensed Product is sold as part of a Combination Product in a country, the Net Sales with respect to the Combination Product in such country shall be determined by multiplying the Net Sales amount for the Combination Product during the applicable reporting period, calculated as set forth above, by the fraction A/(A+B), where A is [***], and B is [***]. If the Licensed Product or Other Product(s) in the Combination Product is sold separately in such country, but not at an equivalent dosage or form as contained in the Combination Product, then [***], which dosage is equivalent to that of the Combination Product. If neither the Licensed Product nor the Other Product(s) were sold separately in such country during the applicable reporting period at any dosage strength, then Net Sales will be calculated by multiplying [***], determined by Anteris in its reasonable discretion, that reflects [***] in such Combination Product. In such event, Anteris shall provide vTv with supporting documentation for such determination. If vTv disputes the reasonableness of such determination and wishes to pursue resolution of such dispute, it shall refer such matter for resolution pursuant to Article 13.

1.55 "**Other Product**" has the meaning set forth in Section 1.12.

1.56 "**Patents**" means (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings, and patent applications, and (b) any renewals, divisions, continuations (in whole or in part), or requests for continued examination of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, supplementary protection certificates, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.57 "**Phase 2 Clinical Trial**" means a Clinical Trial of a Licensed Product that satisfies the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations), regardless of where such Clinical Trial is conducted.

1.58 "**Phase 3 Clinical Trial**" means a Clinical Trial of a Licensed Product that satisfies the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations), regardless of where such Clinical Trial is conducted.

1.59 "**Pricing Approval**" means any governmental approval, agreement, determination, or decision establishing prices for a Licensed Product that can be charged or reimbursed in regulatory jurisdictions where the applicable Regulatory Authorities approve or determine the price or reimbursement of pharmaceutical products.

1.60 "**Public Official or Entity**" means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military, or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party, or any official of a political party.

1.61 "**Regulatory Approval**" means any and all approvals (including MAA Approval), licenses, registrations, permits, notifications, and authorizations (or waivers) of any Regulatory Authority that are necessary to commercially distribute, sell, and market a Licensed Product in a country or jurisdiction, including, where applicable, (a) Pricing Approval, (b) pre- and post-approval marketing authorizations, and (c) labeling approvals.

1.62 "**Regulatory Authority**" means any Governmental Authority that has responsibility in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of pharmaceutical products in a given jurisdiction, including the FDA and EMA, or any successor agency of the foregoing having regulatory jurisdiction over the manufacture, distribution, and sale of pharmaceutical products in the Territory, and any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

1.63 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Licensed Product other than Patents, including rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity), or rights similar thereto outside the U.S., such as Directive 2001/83/EC (as amended) in the EU.

1.64 "**Regulatory Filing**" means all applications, filings, submissions, approvals, licenses, registrations, permits, notifications, and authorizations (or waivers) with respect to the testing, Development, manufacture, or Commercialization of any Licensed Product made to or received from any Regulatory Authority in a given country, including any INDs and MAAs.

1.65 "**Reversion Royalty Dispute**" has the meaning set forth in Section 12.4(c).

1.66 "**Royalty Term**" has the meaning set forth in Section 6.6(b).

1.67 "**SEC**" means the U.S. Securities and Exchange Commission, or any successor entity or its foreign equivalent in the Territory, as applicable.

1.68 **"Sponsor Group"** means (a) M&F Worldwide Corp., (b) MacAndrews & Forbes Holdings Inc., (c) each of M&F Worldwide Corp.'s and MacAndrews & Forbes Holdings Inc.'s Affiliates, excluding vTv and its direct and indirect subsidiaries, (d) Ronald O. Perelman, and (e) any of the directors or executive officers of MacAndrews & Forbes Holdings Inc.

1.69 "**Sublicensee**" means a Third Party to whom Anteris grants a sublicense to Develop, use, import, promote, offer for sale, sell, have sold, or otherwise Commercialize any Licensed Product in the Field in the Territory, beyond the mere right to purchase Licensed Products from Anteris and its Affiliates, and excluding contract research organizations, contract manufacturing organizations, and similar service providers, wholesalers, full-service distributors that do not promote the sale of the Licensed Product, and similar physical distributors. In no event shall vTv or any of its Affiliates be deemed a Sublicensee.

1.70 "**Technology Transfer Completion Date**" means the date on which Anteris has received from vTv all vTv Know-How and all Licensed Compound and other materials specified to be provided pursuant to Section 4.2.

1.71 "**Term**" has the meaning set forth in Section 12.1.

1.72 "**Territory**" means worldwide.

1.73 "**Third Party**" means any entity other than Anteris or vTv or an Affiliate of either of them.

1.74 "**Third Party Infringement Claim**" has the meaning set forth in Section 8.4.

1.75 "**U.S.**" means the United States of America, including its territories and possessions.

1.76 "**Valid Claim**" means (a) a claim of an issued and unexpired patent that has not been revoked or held unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer, or otherwise, or (b) a claim of any patent application that has not been cancelled, withdrawn, abandoned, or finally rejected by an administrative agency action from which no appeal can be taken; provided that (i) such patent application is filed in good faith after the Effective Date and is being prosecuted in good faith, and (ii) such patent application is not pending at [***] or more years from the filing date of the earliest patent application from which such claim derives priority; and provided, further, that, if any such claim issues after the end of such [***] year period while the Royalty Term is otherwise ongoing, it will upon such issuance again be a Valid Claim, subject to fulfilling the requirements of clause (a) above.

1.77 "**vTv Indemnitee**" has the meaning set forth in Section 10.1.

1.78 "**vTv Know-How**" means all Know-How, including vTv's interest in Joint Know-How, that vTv Controls as of the Effective Date or during the Term that is necessary or reasonably useful for the research, Development, manufacture, use, Commercialization or other Exploitation of any Licensed Compound or Licensed Product in the Field.

1.79 "**vTv Patents**" means all Patents, including vTv's interest in Joint Patents, that vTv Controls as of the Effective Date or during the Term that (a) Cover any vTv Know-How, Licensed Compound, or Licensed Product (or, with respect to Patent applications, would Cover if such Patent applications were to issue as Patents) or (b) are necessary or reasonably useful (or, with respect to Patent applications, would be necessary or reasonably useful if such Patent applications were to issue as Patents) for the research, Development, manufacture, use, Commercialization or other Exploitation of any Licensed Compound or Licensed Product in the Field. The vTv Patents as of the Effective Date are listed in Schedule 1.79.

1.80 "**vTv Solely Owned Patents**" has the meaning set forth in Section 8.2(a).

1.81 "**vTv Technology**" means vTv Know-How and vTv Patents.

1.82 "**Withholding Amount**" has the meaning set forth in Section 7.3(b).

2. LICENSE GRANT

2.1 **License Granted to Anteris**. vTv hereby grants to Anteris an exclusive (even as to vTv and its Affiliates) license, with the right to grant sublicenses through multiple tiers (subject to Section 2.2), under the vTv Technology to research, Develop, use, make, have made, sell, offer for sale, import, Commercialize and otherwise Exploit the Licensed Compound and Licensed Products in the Field and in the Territory.

2.2 **Sublicenses**. Anteris shall have the right to grant sublicenses under Section 2.1 without the consent of vTv. Anteris shall grant any such sublicense on terms that are consistent with the terms of this Agreement, to the extent applicable based on the scope and purpose of such sublicense, and Anteris shall remain primarily liable to vTv for the performance by the sublicensee of Anteris' obligations under this Agreement that are applicable to such sublicensee.

2.3 **Reserved Rights**. Subject to Section 2.6, vTv hereby reserves the right to practice, and to grant licenses under, the vTv Technology outside of the scope of the license granted in Section 2.1.

2.4 **No Implied Licenses**. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patents, Know-How, or other intellectual property owned or controlled by the other Party.

2.5 **Third Party Licenses**.

(a) **Notice**. vTv shall promptly notify Anteris if it becomes aware of any Third Party Know-How or Patents that are specific to and necessary to Exploit any Licensed Compound or Licensed Product and shall give Anteris the first right to negotiate and obtain a license from such Third Party under such Know-How and Patents.

(b) **vTv Restriction**. Except with the prior written consent of Anteris, vTv shall not obtain a license to any Third Party Patent or Know-How that is specific to and necessary to Exploit any Licensed Compound or Licensed Product. If vTv obtains a license to any Third Party Patents or Know-How that are necessary, but not specific, to Develop, make, have made, use, sell, offer for sale, import, or otherwise Commercialize or Exploit a Licensed Compound or a Licensed Product, vTv shall ensure that such license is sublicensable to Anteris through multiple tiers, and that the Third Party Patents and Know-How so licensed by vTv are Controlled by vTv and included in the vTv Technology licensed to Anteris under Section 2.1.

2.6 **Exclusivity**. During the Term, vTv shall not, directly or indirectly (including with or through a Third Party, pursuant to a license grant or otherwise), research, Develop, make, have made, Commercialize or otherwise Exploit any Competing Product for use in the treatment of any renal disease (i.e., any disease that primarily affects kidney function).

3. Governance

3.1 **Joint Advisory Committee**. Within thirty (30) days after the Effective Date, the Parties shall establish a Joint Advisory Committee (the "**Joint Advisory Committee**" or the "**JAC**"), composed of an equal number of representatives from each Party, to act as a consultative body and provide input with respect to the Development of the Licensed Product. The JAC in particular shall:

(a) discuss objectives and review progress regarding Development of Licensed Products, including discussing input from vTv and reviewing updates from Anteris of activities relating to Development of the Licensed Compound and the Digital App;

(b) facilitate the transfer and disclosure of vTv Know-How, Licensed Compound and materials to Anteris under Section 4.2 and Section 4.5(c); and

(c) perform such other functions as appropriate to further the Development of the Licensed Compound and Licensed Products, as set forth herein or as the Parties may agree upon in writing.

3.2 JAC Membership and Meetings.

(a) JAC Members. Each Party may replace its representatives on the JAC on written notice to the other Party. Anteris shall appoint the chairperson of the JAC. The chairperson shall prepare and circulate agendas to JAC members at least five (5) days before each JAC meeting and shall direct the preparation of reasonably detailed minutes for each JAC meeting, which shall be approved by the chairperson and circulated to JAC members within thirty (30) days after such meeting.

(b) Meetings. The JAC shall hold meetings at such times as it elects to do so, but in no event less frequently than [***] per Calendar Year until [***]. Meetings may be by telephone or video conference or in person. In-person meetings shall be held at locations alternately selected by the Parties. Each Party shall be responsible for its own expenses of participating in any JAC meeting.

(c) Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend the JAC meetings; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide reasonable prior written notice to the other Party and obtain the other Party’s approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld or delayed. Such Party shall ensure that such Third Party is bound by written confidentiality and non-use obligations consistent with the terms of this Agreement.

3.3 Decision-Making; Limitations on Authority. Unless the Parties otherwise agree, the JAC is solely an advisory committee, intended to be a forum for discussion and information exchange between the Parties, and is not a decision-making body. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the JAC unless such delegation or vesting of rights is expressly agreed upon in writing by the Parties. The JAC shall not have the power to amend, interpret, or waive compliance with this Agreement, or take any action in contravention of the terms or conditions of this Agreement.

3.4 Discontinuation of the JAC. The activities of the JAC shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. The JAC shall continue to exist until the first to occur of: (a) the Parties mutually agree to disband the JAC or (b) completion of the first Phase 2 Clinical Trial of the first Licensed Product in the Territory. Upon the first to occur of the foregoing subclause (a) or subclause (b), the JAC shall automatically dissolve and, thereafter, each Party shall designate, to the extent necessary, a contact person for the exchange of information under this Agreement.

3.5 vTv Right Not to Participate in JAC.

(a) Appointment is a right. The appointment of members of the JAC is a right of vTv and not an obligation of vTv and shall not be a “performance obligation” as referenced in any existing authoritative accounting literature. Notwithstanding anything to the contrary herein, vTv shall be free to determine not to appoint members to the JAC.

(b) **Consequences of Non-Appointment**. If vTv does not appoint members of the JAC, it shall not be a breach of this Agreement, nor shall any consideration be required to be returned, and, unless and until such members are appointed by vTv, Anteris may unilaterally discharge the roles of the JAC. If vTv does not appoint members of the JAC, Anteris shall provide directly to vTv the information that Anteris is obligated to provide to the JAC hereunder, including Development updates pursuant to Section 4.4.

4. Development; Technology Transfer

4.1 General. Subject to the terms and conditions of this Agreement, including Section 4.3, Anteris shall have the sole and exclusive right and responsibility, at its own expense and discretion, for the Development of the Licensed Compound and Licensed Products in the Territory, including, for the avoidance of doubt, formulation development, GMP manufacturing, regulatory dossier development, Clinical Trial development and execution, and submission of Regulatory Filings.

4.2 Lead Compound Technology Transfer. Within thirty (30) days following the Effective Date, vTv shall transfer to Anteris (a) complete and accurate copies, in electronic form where possible, of all vTv Know-How in existence as of the Effective Date, including preclinical and clinical data, regulatory data and communications, CMC data, and manufacturing processes and relationships (including Know-How pertaining to ongoing formulation development) relating to the Lead Compound or otherwise necessary for the research, Development, manufacture, Commercialization and other Exploitation of the Licensed Compound and Licensed Products, and (b) [***], in each case, ((a) and (b)), as described in Schedule 4.2. vTv shall reasonably cooperate with Anteris to provide a smooth and prompt transfer of all such vTv Know-How, Lead Compound and other materials. In connection with such transfer, vTv shall reasonably assist Anteris and its designee(s) in the use and understanding of such vTv Know-How and shall provide reasonable technical assistance, and make its technical personnel reasonably available to Anteris. vTv will bear all internal and out-of-pocket costs of providing such technical assistance for [***]hours of assistance, and Anteris will reimburse vTv any internal costs (at an hourly rate of $[***]) and out-of-pocket costs incurred in providing such technical assistance in excess of[***] hours. Following the initial technology transfer, if vTv develops or otherwise comes to Control any Know-How specifically relating to the Lead Compound or necessary for the research, Development, manufacture, Commercialization and other Exploitation of the Licensed Compound and Licensed Products, vTv will, upon Anteris' request (which request Anteris may make no more than once every [***]), provide a summary of such Know-How to Anteris (through the JAC or otherwise) and, at Anteris' request, vTv will transfer or otherwise make available to Anteris all such Know-How requested by Anteris; provided that Anteris reimburses vTv any internal costs (at an hourly rate of $[***]) and out-of-pocket costs incurred in transferring or otherwise making available such Know-How.

4.3 Diligence. Anteris, itself or through its Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Develop and obtain MAA Approval for at least one (1) Licensed Product in (a) the U.S. and (b) at least one of the following: [***].

4.4 Development Updates. In advance of each regularly scheduled JAC meeting, or in writing at least [***] per Calendar Year upon discontinuation of the JAC or in the event vTv does not appoint members to the JAC, Anteris shall provide vTv with a reasonably detailed report (by means of a slide presentation or otherwise) summarizing Anteris' Development activities with respect to the Licensed Compound and Licensed Products, including its Development activities with respect to the Digital App, and the results of such activities. The Parties shall discuss the status, progress, and results of such activities at such JAC meetings, if any.

4.5 **Backup Compounds**. If, at any time prior to obtaining Regulatory Approval for a Licensed Product that contains the Lead Compound, Anteris determines to discontinue all further Development of the Lead Compound based on any technical or scientific reason (such as, by way of example only and not limitation, unsatisfactory results related to formulation, pharmacokinetics, safety, or tolerability or issues relating to length of market exclusivity), Anteris shall have the right to substitute a Backup Compound for the Lead Compound in accordance with this Section 4.5.

(a) If Anteris makes such a determination, it shall give written notice of such determination to vTv (which notice may be given to vTv's JAC members) and the Parties shall meet within thirty (30) days after vTv's receipt of such notice, or such later date as may be agreed by the Parties. If requested by Anteris, the Parties will meet through the JAC at a specially convened meeting of the JAC. Prior to such meeting, vTv shall provide to Anteris information relating to all Backup Compounds that are identified by vTv as Controlled by vTv and not licensed to a Third Party or the subject of an active vTv Development program (and thus available for licensing to Anteris hereunder), including data and reports from non-clinical studies and Clinical Trials (if any), CMC data and other technical data and information relating to such Backup Compounds, that Anteris or vTv considers to be reasonably necessary for Anteris to assess such Backup Compounds and make an informed decision about substituting a Backup Compound for the Lead Compound. All such information provided to Anteris shall be the Confidential Information of vTv and subject to the terms of Article 11. At their meeting, the Parties shall review and discuss such information and the potential Backup Compounds and shall agree upon a Backup Compound to replace the Lead Compound, such agreement not to be unreasonably withheld, conditioned, or delayed.

(b) The Backup Compound that is agreed by the Parties to replace the Lead Compound shall automatically be deemed to be a Licensed Compound under this Agreement and the Lead Compound shall automatically cease to be included as a Licensed Compound under this Agreement. Upon replacement of the Lead Compound with such Backup Compound, Anteris' license under Section 2.1 with respect to the Lead Compound shall terminate without any further action by the Parties and, subject to the terms and conditions of this Agreement, including Section 2.6, all rights to the Lead Compound shall revert to vTv, and Anteris shall transfer and assign to vTv ownership of (i) any data and Regulatory Filings relating to the Lead Compound, and (ii) any quantities of the Lead Compound that Anteris has on hand at such time, in each case ((i) and (ii)) that are owned by Anteris at such time. Notwithstanding the foregoing, Anteris shall retain the right to use, access and reference such data and Regulatory Filings for purposes of and in connection with the Development, manufacture, Commercialization and other Exploitation of the Backup Compound and Licensed Products.

(c) Within thirty (30) days following the Parties' agreement on a Backup Compound, vTv shall (i) conduct a technology transfer to Anteris of complete and accurate copies, in electronic form where possible, of all vTv Know-How in existence at such time, including preclinical and clinical data, regulatory data and communications, CMC data, and manufacturing processes and relationships (including Know-How pertaining to ongoing formulation development) relating to such Backup Compound or otherwise necessary for the research, Development, manufacture, Commercialization and other Exploitation of the Licensed Compound and Licensed Products, and (ii) provide to Anteris [***]. In connection with such transfer, vTv shall reasonably assist Anteris and its designee(s) in the use and understanding of such vTv Know-How and shall provide reasonable technical assistance, and make its technical personnel reasonably available to Anteris. vTv will bear all internal and out-of-pocket costs of providing such technical assistance for up to [***] hours of assistance, and Anteris will reimburse vTv any internal costs (at an hourly rate of $[***]) and out-of-pocket costs incurred in providing such technical assistance in excess of [***] hours. Following the initial technology transfer, if vTv develops or otherwise comes to Control any Know-How specifically relating to such Backup Compound or necessary for the research, Development, manufacture, Commercialization and other Exploitation of the Licensed Compound and Licensed Products, vTv will, upon Anteris' request (which request Anteris may make no more than [***] every twelve (12) months), provide a summary of such Know-How to Anteris (through the JAC or otherwise) and, at Anteris' request, vTv will transfer or otherwise make available to Anteris all such Know-How requested by Anteris; provided that Anteris reimburses vTv any internal costs (at an hourly rate of $[***]) and out-of-pocket costs incurred in transferring or otherwise making available such Know-How.

4.6 **Regulatory Responsibilities**. Subject to the terms and conditions of this Agreement, including Section 4.3, Anteris shall have the sole and exclusive right and responsibility, at its own expense and discretion, to seek to obtain and maintain Regulatory Approvals for the Licensed Products in the Field in the Territory and to conduct all related regulatory affairs, including communications with any Regulatory Authorities relating to the Licensed Compound and Licensed Products. Upon Anteris' reasonable request, vTv shall provide reasonable assistance as necessary for Anteris to file any IND for a Licensed Compound or Licensed Product and to obtain and maintain Regulatory Approvals with respect to Licensed Products. vTv will bear all internal and out-of-pocket costs of providing such assistance for up to [***] hours of assistance, and Anteris will reimburse vTv any internal costs (at an hourly rate of $[***]) and out-of-pocket costs incurred in providing such assistance in excess of [***] hours.

4.7 **Potential Future Agreements**. In addition to vTv's assistance in connection with the technology transfers under Section 4.2 and Section 4.5(c), the Parties may agree to enter into a separate consulting agreement pursuant to which vTv would make available, and would be compensated for, its employees to provide expert opinion in connection with the mechanism of action of the Licensed Compound and other expert opinion, advice and assistance in connection with Anteris' research, Development and manufacture of the Licensed Compound and Licensed Products. The Parties may also agree, pursuant to a separate agreement, to collaborate to conduct preclinical studies, manufacturing, or formulation work for additional small molecule activators of Nrf2 that bind to and inhibit Bach1 from among those compounds identified by vTv as potential Backup Compound candidates. If the Parties enter into such a separate collaboration agreement, the Parties will agree on additional terms and conditions relating to such potential Backup Compound candidate(s) (e.g., economic terms and conditions and, potentially, rights for Anteris to continue to Develop the Lead Compound hereunder while also Developing one or more of such potential Backup Compound candidate(s)).

5. Commercialization

5.1 General. Subject to the terms and conditions of this Agreement, including Section 5.2, Anteris shall have the sole and exclusive right and responsibility, at its own expense and discretion, for the Commercialization of the Licensed Compound and Licensed Products in the Territory. Anteris shall update vTv on an annual basis regarding its significant Commercialization activities with respect to the Licensed Products in the Territory.

5.2 Diligence. Anteris, itself or through its Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Commercialize at least one (1) Licensed Product for which MAA Approval has been obtained in (a) the U.S. and (b) at least one of the following: [***]. For clarity, as between the Parties, Anteris shall at all times retain sole and complete decision-making authority regarding whether to launch any particular Licensed Product in any particular country.

6. Financial Provisions

6.1 Upfront Payment. Anteris shall pay to vTv a one-time, non-refundable, non-creditable upfront payment of two million dollars ($2,000,000) within [***].

6.2 Equity. Anteris and vTv, among other parties, are entering into that certain Series A Preferred Stock Purchase Agreement, dated as of or about the Effective Date, pursuant to which Anteris will issue to vTv [***] shares of [***] Stock of Anteris on the terms and conditions set forth therein.

6.3 Costs of Negotiation. Within [***] days after the Effective Date, vTv shall submit to Anteris an itemized invoice for the reasonable, out-of-pocket expenses incurred by vTv in connection with the preparation and negotiation of this Agreement (excluding costs incurred in connection with the preparation or negotiation of the term sheet for this Agreement) and related arrangements, including the [***] Stock Purchase Agreement described in Section 6.2 and ancillary equity agreements. Anteris shall reimburse vTv for such invoiced amounts, up to a maximum of [***], within [***] days after Anteris' receipt of such invoice.

6.4 Development and Regulatory Milestones Payments.

(a) Development and Regulatory Milestones. Subject to the remainder of this Section 6.4, Anteris shall pay to vTv the one-time, non-refundable, non-creditable milestone payments set forth in the table below upon the first achievement of the applicable milestone event by the first Licensed Product (whether by or on behalf of Anteris or its Affiliates or Sublicensees):

Milestone Event	Milestone Payment
1) [***]	$[***]
2) [***]	$[***]
3) [***]	$[***]

4) [***]	$[***]
5) [***]	$[***]
6) [***]	$[***]
7) [***]	$[***]
8) [***]	$[***]

For clarity, each milestone payment set forth in the table above shall be paid only once upon first achievement of the corresponding milestone event by the first Licensed Product to achieve such event, even if such milestone event is achieved multiple times for a single Licensed Product or is achieved by multiple Licensed Products, and, for the avoidance of doubt, if a Licensed Product containing or comprising the Lead Compound achieves a milestone event, no further milestone payment shall be due if a Licensed Product containing or comprising a Backup Compound subsequently achieves the same milestone event. If any of milestone events 2 through 8 are achieved prior to the achievement of milestone event 1 or if any of milestone events 3 through 8 are achieved prior to the achievement of milestone event 2, then the milestone payment due and payable for milestone event 1 or 2, as applicable, if not previously paid, shall become due and payable simultaneously with the payment for the achieved subsequent milestone event.

(b) **Notice and Payment**. Anteris shall notify vTv in writing and pay to vTv the applicable development milestone payments within [***] days after the achievement of any milestone set forth in this Section 6.4 by Anteris, its Affiliates, or Sublicensee(s).

6.5 **Sales-Based Milestones Payments**.

(a) **Sales Milestones**. Subject to the remainder of this Section 6.5, Anteris shall pay to vTv the one-time, non-refundable, non-creditable milestone payments set forth in the table below within [***] days after the end of the Calendar Quarter in which the corresponding milestone event is first achieved, whether by or on behalf of Anteris or its Affiliates or Sublicensees.

Aggregate Annual Net Sales of all Licensed Products in the Field in the Territory	**Sales Milestone Payments**
Exceed $[***]	$[***]
Exceed $[***]	$[***]
Exceed $[***]	$[***]

(b) **Notice and Payment**. As part of the report in Section 7.1, Anteris shall provide written notice to vTv upon the annual Net Sales of a Licensed Product in the Field in the Territory reaching the values set forth in the table in Section 6.5(a) above. Each milestone payment set forth in the table above shall be paid only once, upon first achievement of the corresponding milestone event, regardless of the number of times such event is achieved. In no event shall Anteris be obligated to pay more than [***] under this Section 6.5. For the avoidance of doubt, from and after the expiration of the Royalty Term for a Licensed Product in a country, Net Sales of such Licensed Product in such country shall be excluded for purposes of calculating the Net Sales thresholds set forth in Section 6.5(a).

6.6 Royalty Payments.

(a) Royalty Rate. Subject to the other terms of this Section 6.6, during the Royalty Term for a Licensed Product, Anteris shall pay to vTv a quarterly, non-refundable, non-creditable [***]% royalty on the annual Net Sales of such Licensed Product sold in the Territory, as calculated by multiplying the foregoing royalty rate by the amount of Net Sales of such Licensed Product in the Territory in the applicable Calendar Quarter.

(b) Royalty Term. Royalties shall be paid on a Licensed Product-by-Licensed Product and country-by-country basis from the First Commercial Sale of such Licensed Product in such country by or on behalf of Anteris, its Affiliates, or Sublicensees, until the last to occur of (i) the expiration of the last-to-expire Valid Claim of the vTv Patents in such country that Covers such Licensed Product or the Licensed Compound contained therein in such country, (ii) the expiration of all Regulatory Exclusivity for such Licensed Product in such country, and (iii) ten (10) years after the First Commercial Sale of such Licensed Product in such country (the "**Royalty Term**").

(c) Royalty Reductions.

(i) Generic Entry. On a Licensed Product-by-Licensed Product and country-by-country basis, and subject to Section 6.6(c)(iv), if one or more applicable Generic Products is sold in such country, and if during the Royalty Term for such Licensed Product in such country such Generic Products gain a market share of at least [***]% of the aggregate market share of such Licensed Product and Generic Products (based on data provided by IQVIA, or if such data is not available, such other reliable data source as reasonably determined by Anteris in consultation with vTv) as measured by unit volume, then commencing the Calendar Quarter in which such Generic Products gain such market share and for the remainder of the applicable Royalty Term, the royalty rate provided in Section 6.6(a) for such Licensed Product shall be reduced in such country by [***]%.

(ii) Expiration of Patents and Regulatory Exclusivity. On a Licensed Product-by-Licensed Product and country-by-country basis, and subject to Section 6.6(c)(iv), if, during any Calendar Quarter during the Royalty Term, there is (A) no vTv Solely-Owned Patent in such country that includes a Valid Claim Covering such Licensed Product or the Licensed Compound contained therein in such country at the time of the sale of such Product, and (B) at such time there is no Regulatory Exclusivity applicable to such Licensed Product in such country, then the royalty rate set forth in Section 6.6(a) for such Licensed Product shall be reduced in such country by [***]% for so long as, during the applicable Royalty Term, the circumstances in subclauses (A) and (B) exist. Notwithstanding the foregoing, if the circumstances in subclauses (A) and (B) exist in a country with respect to a Licensed Product but one or more Joint Patent(s) in such country include(s) a Valid Claim Covering such Licensed Product or the Licensed Compound contained therein in such country at the time of the sale of such Product, then royalties will remain payable but the royalty rate set forth in Section 6.6(a) for such Licensed Product shall be reduced in such country by [***]%.

(iii) Third Party Licenses. On a Licensed Product-by-Licensed Product and country-by-country basis, and subject to Section 6.6(c)(iv), if it is necessary for

Anteris, its Affiliates, or Sublicensees to obtain a license from a Third Party under such Third Party's Patents to use, sell, manufacture, Commercialize or otherwise Exploit such Licensed Product (excluding the Digital App and any Other Products) in such country, then Anteris shall have the right to credit [***]% of the payments made to such Third Party pursuant to such license (including any upfront payment, license fees, milestones and royalty payments) against any royalties owed to vTv with respect to such Licensed Product under Section 6.6(a); provided, however, that in the event such license includes rights that Anteris may Exploit for products other than Licensed Products, Anteris shall only have the right to credit [***]% of the portion of such payments reasonably attributable to such Licensed Product. For clarity, the foregoing reduction shall not apply to any payment made to a Third Party in connection with the grant of a license under such Third Party's Patents that are necessary to use, sell, manufacture, Commercialize or otherwise Exploit the Digital App, but that are not necessary to use, sell, manufacture, Commercialize or otherwise Exploit the Licensed Product (without the Digital App).

(iv) **Royalty Floor**. Notwithstanding the foregoing subclauses (i)-(iii), with respect to any Licensed Product in any Calendar Quarter during the Royalty Term for such Licensed Product, the operation of subclause (i), (ii), and (iii) above, individually or in combination, shall not reduce by more than [***]% the amount that would otherwise have been due under Section 6.6(a) with respect to Net Sales of such Licensed Product during such Calendar Quarter; provided that Anteris may carry forward to subsequent Calendar Quarters any amounts that it was not able to credit under Section 6.6(c)(iii) on account of such royalty floor.

7. Payment; Records; Audits

7.1 **Payment; Reports**. Royalty payments due from Anteris to vTv under Section 6.6 shall be calculated and reported for each Calendar Quarter during the Royalty Term. Royalty payments due under Section 6.6 shall be paid within [***] days after the end of each Calendar Quarter and shall be accompanied by a report setting forth the Net Sales of the Licensed Products by Anteris and its Affiliates and Sublicensees in the Territory, the royalties payable, the exchange rates used, and whether any sales milestone under Section 6.5 has been achieved.

7.2 **Exchange Rate; Manner and Place of Payment**. All references to dollars and "$" herein shall refer to U.S. dollars. All payments hereunder shall be payable in U.S. dollars. Currencies other than the U.S. Dollars shall be converted into U.S. Dollars at the average of the daily foreign exchange rates published in the *Wall Street Journal* (New York Edition), or any other qualified source that is mutually acceptable, for the Calendar Quarter in which such payments accrue, or, for periods less than a Calendar Quarter, the average of the daily rates published in the *Wall Street Journal* (New York Edition) for such period. All payments owed to vTv under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by vTv, unless otherwise specified in writing by vTv.

7.3 **Taxes**.

(a) **Taxes on Income**. Except as otherwise provided in this Section 7.3, each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.

(b) **Tax Cooperation**. Anteris shall use commercially reasonable efforts to inform vTv of any withholding tax obligation imposed by taxing authorities on payments due to vTv under this Agreement. The Parties agree to cooperate in good faith to provide one another with such documents and certifications as are reasonably necessary to enable the Parties to minimize or recover any withholding tax payment. Anteris may withhold and deduct any taxes required to be withheld and deducted from payments payable under this Agreement and any amounts withheld and deducted shall be treated as paid to vTv pursuant to this Agreement. Anteris shall deduct applicable taxes from payments due to vTv and such taxes shall be paid by Anteris to the proper taxing authority on behalf of vTv (evidence of which payment to such taxing authority shall be provided promptly by Anteris to vTv hereunder). Anteris shall be responsible for (i) all sales, use, value added and other transfer taxes (and related tax returns) applicable to payments and transactions under this agreement and (ii) all customs duties, import tariffs, taxes, freight, insurance, inspection costs and the like attributed to or for the transport and importation of any Licensed Product under this Agreement. In the event that a Governmental Authority retroactively determines that a payment made by Anteris to vTv pursuant to this Agreement should have been subject to withholding or similar (or to additional withholding or similar) taxes, and Anteris remits such withholding or similar taxes to the Government Authority, including any interest and penalties that may be imposed thereon (together with the tax paid, the "**Withholding Amount**"), Anteris shall have the right to (a) offset the Withholding Amount against future payment obligations of Anteris under this Agreement, (b) invoice vTv for the Withholding Amount (which shall be payable by vTv within [***] days of its receipt of such invoice) or (c) pursue reimbursement by any other available remedy. Notwithstanding the foregoing, if Anteris takes action that changes the jurisdiction of the payor under this Agreement (including by assigning or transferring some or all of its rights and obligations to an entity in a different jurisdiction or itself changing jurisdictions) and if, solely as a result of such action, the withholding or deduction of tax required by Applicable Laws with respect to payments under this Agreement is increased, then any amount payable under this Agreement shall be increased to take into account such withheld taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), vTv receives an amount equal to the sum it would have received had no such increased withholding been made.

(c) vTv represents and warrants that it is a United States Person as defined in Section 7701(a)(30) of the United States Internal Revenue Code of 1986, as amended and vTv shall provide Anteris with a properly completed IRS Form W-9 upon execution of this Agreement and shall notify Anteris in advance of any payment under this Agreement if such IRS Form W-9 ceases to be valid. Anteris represents and warrants that it is a United States Person as defined in Section 7701(a)(30) of the United States Internal Revenue Code of 1986, as amended.

7.4 **Records; Audit**. Anteris shall keep, and shall require its Affiliates and Sublicensees to keep, complete and accurate records pertaining to the sale or other disposition of Licensed Products in sufficient detail to permit vTv to confirm the accuracy of any sales milestone or royalty payment due hereunder. Anteris will keep such books and records for [***] years following the Calendar Year to which they pertain, or such longer period of time as may be required by Applicable Laws. Upon reasonable prior notice and during regular business hours at such place or places where such records are customarily kept, Anteris' records may be inspected on vTv's behalf by an independent certified public accountant (the "**Auditor**") selected by vTv and reasonably acceptable to Anteris for the sole purpose of verifying for vTv the accuracy of the financial reports furnished by Anteris pursuant to Section 7.1 or of any payments made, or required to be made, to vTv pursuant to Article 6. Before beginning its audit, the Auditor shall execute an undertaking acceptable to each Party by which the Auditor agrees to keep confidential all information reviewed during the audit. Such audits shall be limited to [***] each Calendar Year and [***] with respect to records covering any specific period of time. Such auditor shall not disclose Anteris' Confidential Information to vTv, and shall only report whether the financial reports provided by Anteris and the amount of payments made to vTv are correct or not, and the specific details concerning any discrepancies. If the final result of the inspection reveals an undisputed underpayment, the underpaid amount shall be settled within [***] days after the Auditor's report. If the final result of the inspection reveals an undisputed overpayment, the overpaid amount shall be credited against amounts payable by Anteris in subsequent payment periods, or reimbursed to Anteris by vTv within [***] days after the Auditor's report if there are no subsequent payment periods at that time. vTv shall bear the full cost of such audit unless such audit reveals an underpayment by Anteris of more than [***]% for the audited period, in which case Anteris shall reimburse vTv for the reasonable costs of such audit.

7.5 Late Payments. If any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due at the annual interest rate of [***]% per month; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate.

8. Intellectual Property

8.1 Ownership of Inventions.

(a) Inventorship of all Inventions shall be determined in accordance with U.S. patent laws. Subject to the license grants and other rights herein, as between the Parties, each Party shall own and retain all right, title and interest in and to any and all Inventions that are conceived, discovered, developed or otherwise made solely by or on behalf of such Party (or its Affiliates or its or their (sub)licensees), whether or not patented or patentable, and any and all Patents and other intellectual property rights with respect thereto.

(b) Subject to the license grants and other rights herein, as between the Parties, the Parties shall each own an equal, undivided interest in any and all: (i) Inventions that are conceived, discovered, developed or otherwise made under this Agreement jointly by or on behalf of Anteris or its Affiliates, on the one hand, and vTv or its Affiliates, on the other hand, whether or not patented or patentable (the "**Joint Know-How**"); and (ii) Patents claiming the Joint Know-How (the "**Joint Patents**") and other intellectual property rights with respect to the Inventions described in clause (i) (together with Joint Know-How and Joint Patents, the "**Joint IP**"). Each Party shall promptly disclose to the other Party in writing and shall cause its Affiliates to so disclose, the development, making, conception or reduction to practice of any Joint Know-How or Joint Patents. Subject to the license granted under Section 2.1 and the financial provisions of Article 6, each Party is entitled to practice the Joint IP for all purposes on a worldwide basis and to license such Joint IP through multiple tiers without consent of the other Party (where consent is required by applicable Law, such consent is deemed hereby granted).

8.2 Patent Prosecution and Maintenance.

(a) Prosecution and Maintenance. vTv shall have the first right, but not the obligation, to prosecute and maintain the vTv Patents other than the Joint Patents in the Territory (such vTv Patents, the "**vTv Solely Owned Patents**"), and Anteris shall have the first right, but not the obligation, to prosecute and maintain the Joint Patents in the Territory (the Party with the first right to prosecute and maintain such vTv Solely Owned Patents or Joint Patents, the "**Initial Prosecuting Party**"), in each case at [***]'s expense using counsel of the Initial Prosecuting Party's own choice, and including the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, oppositions, invalidation proceedings and defense of validity or enforceability challenges). The Initial Prosecuting Party shall keep the other Party reasonably informed of the status of filing, prosecution, maintenance, and defense, if any, of the vTv Patents that the Initial Prosecuting Party has the first right to prosecute and maintain. The Initial Prosecuting Party shall also provide the other Party a reasonable opportunity to review and comment on any material filings related to the vTv Patents that the Initial Prosecuting Party has the first right to prosecute and maintain.

(b) Abandonment. If the Initial Prosecuting Party desires to abandon or cease prosecution or maintenance of any vTv Patent that it has the first right to prosecute and maintain, it shall provide reasonable prior written notice to the other Party of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] days prior to the next deadline for any action that must be taken with respect to the applicable vTv Patent in the relevant patent office). In such case, upon the other Party's written election provided no later than [***] days after such notice from the Initial Prosecuting Party, the other Party shall have the right to assume prosecution and maintenance of the applicable vTv Patent at the other Party's expense and with counsel of the other Party's choice. Promptly after such election, the Initial Prosecuting Party will deliver to the other Party copies of all necessary files related to any vTv Patents as requested by the other Party, and will take all actions and execute all documents reasonably necessary for the other Party to assume such patent prosecution activities. If the other Party does not provide such election within [***] days after such notice, the Initial Prosecuting Party may, in its sole discretion, continue prosecution and maintenance of such vTv Patent or discontinue prosecution and maintenance of such vTv Patent.

(c) Patent Term Extensions. As between the Parties, Anteris shall have the authority and responsibility to file for and seek to obtain available patent term extensions or supplemental protection certificates or their equivalents in any country with respect to Patents Covering Licensed Products for which Anteris obtains Regulatory Approval; provided nothing in this Section 8.2(c) shall restrict or otherwise limit vTv from seeking patent term extensions or supplemental protection certificates or their equivalents as to vTv Solely Owned Patents Covering products other than Licensed Products for which vTv obtains regulatory approval.

(d) Cooperation. Each Party shall provide the other Party all reasonable assistance and cooperation in the patent prosecution efforts under this Section 8.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution. Further, Anteris shall notify vTv in writing promptly, but no later than [***], after the filing of any patent application Covering any Licensed Compound or Licensed Product or the manufacture or use of any Licensed Compound or Licensed Product filed by Anteris or any of its Affiliates or Sublicensees (to the extent not previously disclosed to vTv).

8.3 Patent Enforcement.

(a) Notice. Each Party shall notify the other Party within fifteen (15) business days after becoming aware of any alleged or threatened infringement by a Third Party of any of the vTv Patents in the Territory, which infringement adversely affects or is expected to adversely affect any Licensed Product in the Field (collectively, "**Licensed Product Infringement**").

(b) Enforcement Right. Anteris shall have the first right to bring and control any legal action in connection with a Licensed Product Infringement at its own expense as it reasonably determines appropriate. If Anteris (i) elects not to bring such legal action against a Licensed Product Infringement (the decision of which Anteris shall inform vTv promptly) or (ii) Anteris otherwise fails to bring such legal action against a Licensed Product Infringement within [***] days of first becoming aware of such Licensed Product Infringement or such shorter period as would allow vTv a reasonable opportunity to bring a legal action without loss of rights, and does not provide a reasonable business (including strategic) rationale for not doing so, vTv shall have the right to bring and control any legal action in connection with such Licensed Product Infringement at its own expense as it reasonably determines appropriate after consultation with Anteris. Notwithstanding anything to the contrary herein (including in Section 8.2(a)), in the event any declaratory judgment, opposition or similar action or claim alleging invalidity, unenforceability or non-infringement of any of the vTv Patents arises in a legal action in connection with a Licensed Product Infringement, the Party controlling such legal action shall control the response to such action or claim.

(c) Collaboration. Each Party shall provide to the Party enforcing a vTv Patent in a legal action in connection with a Licensed Product Infringement (the "**Enforcing Party**") reasonable assistance in such enforcement, at the Enforcing Party's request and expense, including to be named in such action if required by Applicable Laws to pursue such action. The Enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any such efforts, including determination of litigation strategy and filing of material papers to the competent court. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Enforcing Party.

(d) Expense and Recovery. The Enforcing Party shall be solely responsible for any expenses incurred by such Party as a result of such enforcement of a vTv Patent in a legal action in connection with a Licensed Product Infringement. If the Enforcing Party recovers monetary damages in such enforcement action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Enforcing Party in such enforcement action, second to the reimbursement of any expenses incurred by the other Party in such enforcement action, provided that if such recoveries are not sufficient to reimburse both Parties' expenses incurred in connection with such enforcement action, then such recoveries shall be applied to the aggregate expenses incurred by both Parties on a pro rata basis to reimburse each Party's relative share of such expenses. Following any expenses reimbursement, any remaining amounts shall be retained by the Enforcing Party; provided that, if Anteris is the Enforcing Party, then to the extent that any such remaining amount was awarded in compensation for lost sales or lost profits of Licensed Products, such remaining amount shall be [***].

(e) **Other Infringement**. Except for Licensed Product Infringement as set forth above, each Party shall have the exclusive right to enforce its own Patents against any infringement anywhere in the world.

8.4 **Infringement of Third Party Rights**. If any Licensed Product used or sold by Anteris, its Affiliates, or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of such Third Party's intellectual property rights in a jurisdiction within the Territory ("**Third Party Infringement Claim**"), Anteris shall promptly notify vTv and the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Absent any agreement to the contrary, each Party shall defend itself from any such Third Party Infringement at its own cost and expense, provided, however, that the provisions of Section 8.3 shall govern the right of Anteris to assert a counterclaim of infringement of any vTv Patents.

9. Representations and Warranties

9.1 **Mutual Representations and Warranties**. Each Party represents and warrants to the other that, as of the Effective Date:

(a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action;

(c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it; and

(d) it has the right to grant the licenses granted by it under this Agreement.

9.2 **Covenants**. Each Party covenants as follows:

(a) In the performance of its obligations under this Agreement, such Party shall comply, and shall cause its and its Affiliates' employees and contractors to comply with, all Applicable Laws.

(b) Such Party's and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise, or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including such Party (and such Party represents and warrants that as of the Effective Date, such Party, and to its knowledge, its and its Affiliates' employees and contractors, have not directly or indirectly promised, offered, or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift, or hospitality or other illegal or unethical benefit to a Public Official or Entity or any other person in connection with the performance of such Party's obligations under this Agreement (or, with respect to vTv, in connection with Exploitation of the Lead Compound), and such Party covenants that it and its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing).

(c) Such Party and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not authorize or cause its Indemnitees to be in violation of the FCPA, Export Control Laws, or any other Applicable Laws or otherwise cause any reputational harm to the other Party.

(d) Such Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws in connection with the performance of this Agreement or the Development, manufacture, or Commercialization of any Licensed Product.

(e) In connection with the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with such Party's own anti-corruption and anti-bribery policy.

9.3 Additional vTv Representations and Warranties. vTv represents, warrants, and covenants, as applicable, to Anteris that, as of the Effective Date:

(a) Schedule 1.79 lists all vTv Patents as of the Effective Date and all such Patents listed on Schedule 1.79 are solely and exclusively owned by vTv, free of any encumbrance, lien, or claim of ownership by any Third Party, except for the security interest granted to Horizon Technology Finance Corporation and Silicon Valley Bank under that certain Venture Loan and Security Agreement dated October 28, 2016.

(b) vTv and its Affiliates have complied with all duties of candor required by applicable Governmental Authorities in the prosecution by vTv or any of its Affiliates of the vTv Patents;

(c) To vTv's knowledge as of the Effective Date, (i) all applicable fees for the vTv Patents have been paid on or before the due date for payment or during any extension thereof, and (ii) each of the vTv Patents properly identifies each and every inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such Patent is issued or such application is pending;

(d) vTv has the right to grant all rights and licenses it purports to grant to Anteris with respect to the vTv Technology under this Agreement, free and clear of any rights therein granted to any Third Party;

(e) All vTv Technology is owned by vTv and is not held under license from any other person or entity;

(f) vTv has not granted any liens or security interests on any of the vTv Technology except for the security interest granted to Horizon Technology Finance Corporation and Silicon Valley Bank under that certain Venture Loan and Security Agreement dated October 28, 2016;

(g) The final payment under that certain Venture Loan and Security Agreement dated October 28, 2016 will be made on or around January 1, 2021, and the security interest granted to Horizon Technology Finance Corporation and Silicon Valley Bank thereunder will be released on or around January 1, 2021, but in no event later than January 15, 2021;

(h) vTv has not received as of the Effective Date any written notice from a Third Party that the research or Development of any Licensed Compound or Licensed Product conducted by vTv prior to the Effective Date has infringed any Patents or misappropriated any Know-How of any Third Party;

(i) vTv has not as of the Effective Date, and will not during the Term, grant to any Third Party any right under the vTv Technology that would conflict with the rights granted to Anteris hereunder;

(j) No claim or action has been brought or, to vTv's knowledge as of the Effective Date, threatened, by any Third Party alleging that (i) any of the vTv Patents are invalid or unenforceable, or (ii) the use of the vTv Know-How infringes or misappropriates, or would infringe or misappropriate, any intellectual property right of any Third Party;

(k) There are no pending or, to vTv's knowledge as of the Effective Date, alleged or threatened, (i) inter partes reviews, post-grant reviews, interferences, re-examinations, or oppositions involving the vTv Patents that are in or before any patent authority (or other Governmental Authority performing similar functions) or (ii) inventorship challenges involving the vTv Patents that are in or before any patent or other Governmental Authority;

(l) To vTv's knowledge as of the Effective Date, no Third Party is infringing or misappropriating or has infringed or misappropriated or is threatening to infringe or misappropriate the vTv Technology;

(m) vTv has disclosed to Anteris all non-clinical, pre-clinical, and clinical data in vTv's Control that is material to the evaluation of the safety, efficacy, and manufacturing process of the Lead Compound;

(n) vTv and its Affiliates and, to vTv's knowledge as of the Effective Date, their respective contractors and consultants have conducted, all research and Development of the Lead

Compound, including any and all non-clinical, pre-clinical, and clinical studies of the Lead Compound, in accordance with Applicable Laws in all material respects; and

(o) To vTv's knowledge as of the Effective Date, inventions claimed by the vTv Patents (i) were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof, (ii) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e), and (iii) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. part 401.

9.4 Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE, OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT ANY OF THE DEVELOPMENT, MANUFACTURING, OR COMMERCIALIZATION EFFORTS WITH REGARD TO ANY COMPOUND OR PRODUCT WILL BE SUCCESSFUL.

10. Indemnification

10.1 Indemnification by Anteris. Anteris hereby agrees to defend, indemnify, and hold harmless vTv and its Affiliates and their respective directors, officers, employees, and agents (each, a "**vTv Indemnitee**") from and against any and all liabilities, expenses, and losses, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**"), to which any vTv Indemnitee may become subject as a result of any claim, demand, action, or other proceeding (each, a "**Claim**") by any Third Party to the extent such Losses arise out of:

(a) the Development, use, manufacture, Commercialization, or other Exploitation of any Licensed Compound or Licensed Product by Anteris or its Affiliates or Sublicensees (except to the extent a Claim alleges misappropriation or infringement of any Third Party intellectual property right due to Anteris' or its Affiliates' or Sublicensees' practice of vTv Solely-Owned Patents or vTv Know-How (other than Joint Know-How));

(b) the negligence or willful misconduct of any Anteris Indemnitee; or

(c) the breach by Anteris of any warranty, representation, covenant, or agreement made by Anteris in this Agreement;

except, in each case (a)-(c), to the extent such Losses arise out of any activities set forth in Section 10.2 for which vTv is obligated to indemnify any Anteris Indemnitee under Section 10.2.

10.2 Indemnification by vTv. vTv hereby agrees to defend, indemnify, and hold harmless Anteris, its Affiliates, and Sublicensees and their respective directors, officers, employees, and agents (each, an "**Anteris Indemnitee**") from and against any and all Losses to which any Anteris Indemnitee may become subject as a result of any Claim by any Third Party to the extent such Losses arise out of:

(a) the practice by vTv or its Affiliates or licensees (other than Anteris) of any of vTv's reserved rights under Section 2.3;

(b) the negligence or willful misconduct of any vTv Indemnitee;

(c) the breach by vTv of any warranty, representation, covenant, or agreement made by vTv in this Agreement; or

(d) the Development, use, manufacture, Commercialization, or other Exploitation of any Licensed Compound or Licensed Product by vTv or its Affiliates or licensees after the effective date of termination of this Agreement.

except, in each case (a)-(d), to the extent such Losses arise out of any activities set forth in Section 10.1 for which Anteris is obligated to indemnify any vTv Indemnitee under Section 10.1.

10.3 Indemnification Procedure.

(a) The Party claiming indemnity under this Article 10 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim.

(b) The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choice at its own expense; provided, however, that the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice.

(c) The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, conditioned, or delayed, unless the settlement involves only the payment of money, no admission of wrong-doing or fault by the Indemnified Party, and no restriction on the future actions or activities of the Indemnified Party. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle such Claim without the prior written consent of the Indemnifying Party.

(d) If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (i) the Indemnified Party may defend against and consent to the entry of any judgment, or enter into any settlement with respect to, the Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 10.

10.4 **Insurance**. During the Term and for three (3) years thereafter, each Party, at its own expense, shall maintain commercial general liability insurance and other appropriate insurance in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon the other Party's request.

10.5 **Limitation of Liability**. EXCEPT FOR DAMAGES THAT (A) ARISE IN CONNECTION WITH A PARTY'S (I) WILLFUL MISCONDUCT OR FRAUD OR (II) BREACH OF ITS OBLIGATIONS UNDER ARTICLE 11 OR SECTION 2.6, OR (B) ARE SUBJECT TO INDEMNIFICATION UNDER SECTION 10.1 OR SECTION 10.2, NEITHER PARTY SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE FOR ANY SPECIAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES OR FOR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY (OR ITS AFFILIATES OR (SUB)LICENSEES), REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

11. CONFIDENTIALITY

11.1 **Confidential Information**. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, during the Term and for [***] years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the other Party, and both Parties shall keep confidential and, subject to the remainder of this Article 11, shall not publish or otherwise disclose the terms of this Agreement. Each Party may use the other Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights and performing its obligations under this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors, licensees, sublicensees, and other representatives do not disclose or make any unauthorized use of the other Party's Confidential Information. Each Party will promptly notify the other upon discovery of any loss or unauthorized use or disclosure of the other Party's Confidential Information.

11.2 **Exceptions**. The obligations of confidentiality and restriction on use under Section 11.1 will not apply to any information that the receiving Party can prove by competent written evidence:

(a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available to the public;

(b) is known by the receiving Party at the time of receiving such information, other than by previous disclosure of the disclosing Party, or its Affiliates, employees, agents, consultants, or contractors;

(c) is hereafter furnished to the receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or

(d) is independently discovered or developed by the receiving Party without the use of the disclosing Party's Confidential Information.

11.3 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing, prosecuting, and maintaining Patents as permitted by this Agreement;

(b) filing Regulatory Filings for Licensed Products that such Party has a license or right to Develop, manufacture, and Commercialize under this Agreement in a given country or jurisdiction;

(c) prosecuting or defending litigation as permitted by this Agreement;

(d) complying with Applicable Law (including regulations promulgated by securities exchanges) or court or administrative orders;

(e) disclosure to actual and bona fide potential investors, acquirors, licensees, and other financial or commercial partners for the purpose of evaluating or carrying out an actual or potential investment, acquisition, or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; and

(f) disclosure to its and its Affiliates' employees, consultants, contractors, agents, licensees, and sublicensees, in each case on a need-to-know basis in connection with the Development, manufacture, Commercialization or other Exploitation of the Licensed Compound and Licensed Products in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein.

Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 11.3(c) or Section 11.3(d), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information of a similar nature, but in no event less than reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information. Any information disclosed pursuant to any of the foregoing subsections shall remain Confidential Information and subject to the foregoing provisions of this Article 11.

11.4 Publications. Anteris shall have the sole right, in its sole discretion, to publish or otherwise disclose the results of, and other information regarding, any Development activities performed under this Agreement with respect to any Licensed Compound and Licensed Product.

11.5 Publicity; Public Disclosures. It is understood that each Party may desire or be required to issue press releases relating to this Agreement or activities hereunder. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press releases prior to the issuance thereof, to the extent practicable, provided that a Party may not unreasonably withhold, condition, or delay consent to such releases by more than three

(3) business days, and that either Party may issue such press releases or make such disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, reasonably necessary to comply with Applicable Laws or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it determines, based on the advice of counsel, reasonably necessary to comply with Applicable Laws or for appropriate market disclosure. In addition, once the existence of this Agreement, the identity of the other Party or any terms of this Agreement are publicly disclosed in accordance with this Section 11.5, either Party shall be free to disclose, without the other Party's prior written consent, such information as has already been publicly disclosed in accordance with this Section 11.5.

11.6 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 11. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 11.

12. TERM AND TERMINATION

12.1 Term. This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this Article 12 or by mutual written agreement of the Parties, shall continue, on a Licensed Product-by-Licensed Product and country-by-country basis, until the expiration of the Royalty Term for such Licensed Product in such country (the "**Term**"). Following expiration of this Agreement with respect to a Licensed Product in a country, but not earlier termination, the license granted to Anteris in Section 2.1 shall be deemed to be perpetual, irrevocable, and fully paid-up with respect to such Licensed Product in such country.

12.2 Termination for Cause.

(a) Material Breach. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach to the reasonable satisfaction of the other Party within [***] days after notice of such breach from the non-breaching Party (or within [***] days from the date of such notice in the event such breach is solely based on the breaching Party's failure to pay any amounts or issue any shares due hereunder). If cure of such breach (other than non-payment) cannot reasonably be effected within such [***] day period, the breaching Party shall deliver to the non-breaching Party a plan reasonably calculated to cure such breach within a reasonable timeframe, but in any event within [***] months. So long as the breaching Party is diligently carrying out such plan, the non-breaching Party shall not have the right to terminate this Agreement. If the breaching Party fails to diligently carry out such plan and cure such breach as provided above, then the non-breaching Party may terminate this Agreement upon written notice to the breaching Party.

(b) **Disputed Breach**. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party, and such alleged breaching Party provides the other Party notice of such dispute within [***] days, then the other Party shall not have the right to terminate this Agreement under Section 12.2(a) unless and until a panel of arbitrators, in accordance with Article 13, has determined that the alleged breaching Party has materially breached this Agreement and such Party fails to cure such breach within the applicable cure period set forth in Section 12.2(a) following such determination.

(c) **Bankruptcy**. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee, or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation, or any other similar proceeding for the release of financially distressed debtors or becomes a party to any proceeding or action of the type described above and such proceeding is not dismissed within [***] days after the commencement thereof.

12.3 Termination without Cause by Anteris. Anteris shall have the right to terminate this Agreement in its entirety or on a country-by-country basis, at any time, for any or no reason, upon [***] days' written notice to vTv.

12.4 Effects of Termination. Upon any termination of this Agreement with respect to a country or in its entirety (but not upon expiration of this Agreement pursuant to Section 12.1), the terms of this Section 12.4 will apply. For clarity, during the pendency of any dispute regarding material breach and/or during any termination notice period, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. Further for clarity, if this Agreement is terminated with respect to a country, then the terms of this Section 12.4 (other than Section 12.4(g)) will apply only with respect to such terminated country.

(a) **Licenses**. The license granted by vTv to Anteris will automatically terminate.

(b) **Sublicenses**. At the request of a Sublicensee that is not in default of its obligations under its sublicense agreement within [***] days after the effective date of termination of this Agreement, vTv shall negotiate and enter into a continuing license with such Sublicensee on reasonable terms that do not impose any additional obligations on vTv and fully preserve vTv's rights under this Agreement, including vTv's rights to receive payments under Article 6 (or an appropriate prorated portion of such payments in the case of payments based on a territory larger than the Sublicensee's territory).

(c) **License Grant to vTv**. At vTv's option, to be exercised no later than [***] days after the effective date of termination, as of such termination on a country-by-country basis, Anteris shall grant to vTv an exclusive, royalty-bearing license, with the right to sublicense through multiple tiers, under Anteris Technology, solely to Exploit the Licensed Compound and Licensed Products in the Field and in such country; provided that, on a country-by-country basis, such license shall be subject to vTv's payment to Anteris of commercially reasonable royalties on Net Sales of Licensed Products. If the Parties fail to agree on such commercially reasonable royalties within [***] days following the effective date of termination of this Agreement on a country-by-country basis ("**Reversion Royalty Dispute**"), either Party may submit such Reversion Royalty Dispute for resolution pursuant Section 13.6.

(d) **Assignment of Regulatory Approvals**. Anteris shall promptly (i) assign and transfer (or cause to be assigned and transferred) to vTv or its designee (and, if in Anteris' possession or control, provide copies of) all Regulatory Filings and Regulatory Approvals held in the name of Anteris, or any Affiliate it controls (within the meaning of Section 1.4), relating to the Licensed Compound or any Licensed Products, including related correspondence with Regulatory Authorities and (ii) disclose to vTv, and grant to vTv a Right of Reference or Use (as that term is defined in 21 C.F.R. § 314.3(b) or any non-United States equivalent) with respect to, all pre-clinical and clinical data, including pharmacology and biology data, in Anteris' or its applicable controlled Affiliates' possession and control specifically related to the Licensed Compound or any Licensed Products.

(e) **Assignment of Trademarks**. Anteris shall assign to vTv all of Anteris' and its controlled (within the meaning of Section 1.4) Affiliates' right, title and interest in any product trademark used solely with and for any Licensed Products, along with all associated goodwill, but specifically excluding any corporate trademarks or trade names of Anteris or such controlled Affiliates or any goodwill associated therewith.

(f) **Ongoing Clinical Trials**. Unless expressly prohibited by any Regulatory Authority or Applicable Law, if any clinical studies involving Licensed Products sponsored by Anteris or its Affiliate or Sublicensee are being conducted as of the effective date of termination, at vTv's written request in its sole discretion made within [***] days of the effective date of termination, Anteris shall, and shall cause its Affiliates and Sublicensees to, (i) wind down such clinical studies in accordance with Applicable Law, at [***], or (ii) (x) transfer sponsorship and control of such clinical studies to vTv and (y) continue to conduct such clinical studies for up to [***] months to enable such transfer to be completed without interruption of any such clinical study, in each case ((ii)(x) and (ii)(y)), at [***].

(g) **Manufacturing Matters**.

(i) If this Agreement is terminated in its entirety, to the extent vTv so requests within [***] days after the effective date of such termination, Anteris shall use Commercially Reasonable Efforts to, and to cause any Affiliate it controls (within the meaning of Section 1.4) to, effect the assignment of each manufacturing agreement specific and exclusive to the Licensed Compound or any Licensed Products to vTv, if such agreement is then in effect and such assignment is permitted under such agreement or by the applicable Third Party; *provided* that vTv agrees in writing to assume all obligations under any such manufacturing agreement arising following such assignment, and each Party shall execute such documentation reasonably satisfactory to the other Party to effectuate such assignment and assumption; *provided, further,* that, if any such agreement is specific but not exclusive to the Licensed Compound or any Licensed Products, or is not assignable to vTv for any reason, Anteris and such controlled Affiliates shall use Commercially Reasonable Efforts to provide vTv with the benefits of such agreement to the extent it relates to the Licensed Compound or any Licensed Products.

(ii) If this Agreement is terminated in its entirety, to the extent vTv so requests within [***] days after the effective date of such termination, for a period of up to [***] months following the effective date of such termination, Anteris and any Affiliate it controls (within the meaning of Section 1.4) shall cooperate with vTv in reasonable respects to transfer manufacturing documents and materials that are used (at the time of the termination) by Anteris or any such controlled Affiliate exclusively in the manufacture of the Licensed Compound or any Licensed Products to the extent such manufacturing documents and materials are not obtained by vTv pursuant to the assignment of agreements pursuant to Section 12.4(g)(i) above. If, at the effective date of termination of this Agreement in its entirety, to the extent vTv so requests within [***] days after the effective date of such termination, any Licensed Compound or Licensed Product is held in inventory or is in process of being manufactured by or on behalf of Anteris or its controlled Affiliate, Anteris shall supply to vTv such on-hand Licensed Compound and Licensed Products at a supply price equal to Anteris' or its Affiliate's actual, fully-burdened cost to manufacture or have manufactured, and supply, such Licensed Compound and Licensed Products, as applicable.

12.5 Confidential Information. Upon expiration or termination of this Agreement in its entirety, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that a Party may keep one copy of such materials for legal archival purposes subject to continuing confidentiality obligations.

12.6 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise will be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws outside the U.S., licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws outside the U.S. The Parties agree that a Party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws outside the U.S. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws outside the U.S., the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under subclause (a), following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party.

12.7 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: Sections 7.1 (Payment; Reports) (solely with respect to Net Sales occurring prior to the effective date of termination), 7.2 (Exchange Rate; Manner and Place of Payment) (solely with respect to payments owed as of the effective date of termination), 7.3 (Taxes), 7.4 (Records; Audit), 7.5 (Late Payments), 8.1 (Ownership of Inventions), 8.2 (Patent Prosecution and Maintenance) (to the extent any case for prosecution or administrative action of any Joint Patent is pending or active as of the effective date of termination), 8.3 (Patent Enforcement) (to the extent any legal action in connection with a Licensed Product Infringement is pending or active as of the effective date of termination), 9.4 (Disclaimer), 12.1 (Term), 12.4 (Effects of Termination), 12.5 (Confidential Information), and 12.7 (Survival), and Articles 1 (Definitions) (to the extent used in other surviving provisions), 10 (Indemnification), 11 (Confidentiality), 13 (Dispute Resolution), and 14 (General Provisions) (excluding Section 14.9, Force Majeure).

13. Dispute Resolution

13.1 General. Any dispute between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**") shall be resolved pursuant to this Article 13.

13.2 Executive Officers. Any Dispute shall first be referred to the Executive Officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Executive Officers shall be conclusive and binding on the Parties.

13.3 Intellectual Property Disputes. If the Executive Officers are not able to agree on the resolution of a Dispute within thirty (30) days (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them and such Dispute is with respect to the validity, scope, enforceability, inventorship, or ownership of any Patent, trademark, or other intellectual property right ("**IP Dispute**"), then, if a Party wishes to pursue further resolution of such IP Dispute, such Party may bring an action, claim, or proceeding to resolve such IP Dispute in any court of competent jurisdiction in any country or jurisdiction in which such intellectual property rights apply.

13.4 Arbitration. If the Executive Officers are not able to agree on the resolution of a Dispute within thirty (30) days (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them, then, except as set forth in Section 13.3, if a Party wishes to pursue further resolution of such Dispute, such Dispute shall be finally resolved by binding arbitration in accordance with this Section 13.4. Such Dispute shall be referred to and finally resolved by arbitration under the American Arbitration Association ("**AAA**") rules, as then in effect, by a tribunal of three (3) arbitrators. The seat and legal place of the arbitration shall be San Francisco, California. Within thirty (30) days after such Dispute is referred to the AAA (or such longer time period as may be agreed by the Parties), each Party shall nominate one arbitrator and the third arbitrator shall be nominated by the two Party-nominated arbitrators within fifteen (15) days after the second arbitrator's appointment. If a Party does not nominate its arbitrator within the allotted period, then such arbitrator shall be appointed by the AAA in accordance with its rules. Any arbitrator appointed by the AAA shall have at least ten (10) years' experience in the pharmaceutical industry. The arbitration shall be conducted, and all documents submitted to the arbitrators shall be, in English. Each Party shall bear its own legal costs for its counsel and other expenses, and the Parties shall equally share the costs of the arbitration; provided that the arbitral tribunal shall have the discretion to provide that the losing Party is responsible for all or a portion of such arbitration and legal costs, and in such case the arbitral award will so provide. The arbitrators shall have no power to award damages excluded pursuant to Section 10.5. In no event shall the arbitrators assign a value to any issue greater than the greatest value for such issue claimed by either Party or less than the smallest value for such issue for such item claimed by either Party. The award shall be final and binding upon the Parties and the Parties undertake to carry out any award without delay. Judgment on the award may be entered in any court of competent jurisdiction. Except to the extent necessary to confirm, enforce, or challenge an award of the arbitration, to protect or pursue a legal right, or as otherwise required by Applicable Law or regulation or securities exchange, neither Party nor any arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties. Notwithstanding anything to the contrary in the foregoing, in no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy, or claim would be barred by the applicable Delaware statute of limitations. Any disputes concerning the propriety of the commencement of the arbitration shall be finally settled by the arbitral tribunal.

13.5 **Interim Relief**. Notwithstanding anything herein to the contrary, nothing in this Article 13 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction, or other interim equitable relief concerning a Dispute in any court of competent jurisdiction before or after the initiation of an arbitration as set forth in Section 13.4, if necessary to protect the interests of such Party. This Section 13.5 shall be specifically enforceable.

13.6 **Reversion Royalty Dispute**. Notwithstanding anything herein to the contrary, any Reversion Royalty Dispute shall be submitted to and finally resolved by this Section 13.6 (i.e., “baseball-style” arbitration). The Parties shall promptly designate in writing a single mutually acceptable arbitrator experienced in the licensing, development, and commercialization of pharmaceutical products, who is independent of each Party (i.e., not a current or former employee, consultant, officer, or director or current stockholder of either Party or their respective Affiliates and who does not otherwise have any current or previous business relationship with either Party or their respective Affiliates). If the Parties cannot agree on an arbitrator within fifteen (15) Business Days after referral of the Reversion Royalty Dispute, the arbitrator shall be appointed by the AAA in accordance with its rules. The arbitration shall be conducted in accordance with the AAA rules, as then in effect, to the extent consistent with this Section 13.6. Within fifteen (15) Business Days after the arbitrator’s appointment, each Party shall prepare and deliver to both the arbitrator and the other Party its last, best offer for the unresolved financial terms of the reversion license, and a memorandum in support thereof. The Parties shall also provide the arbitrator with a copy of the relevant provisions of this Agreement. Each Party may submit to the arbitrator (with a copy to the other Party) a rebuttal to the other Party’s support memorandum and will at such time have the opportunity to amend its last such offer based on any new information contained in the other Party’s support memorandum. Within sixty (60) days after the arbitrator’s appointment, the arbitrator will select from the two (2) proposals provided by the Parties the proposal the arbitrator believes is the most fair and reasonable to the Parties under the circumstances. The decision of the arbitrator shall be final and binding on the Parties. The foregoing "baseball-style" arbitration shall be the exclusive remedy of each Party if the Parties cannot agree on a Reversion Royalty Dispute.

14. General Provisions

14.1 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach, or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, without reference to its conflicts of law principles.

14.2 Entire Agreement; Modification. This Agreement, including the exhibits, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

14.3 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture, or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

14.4 Performance by Affiliates. Anteris may discharge any obligations and exercise any right under this Agreement through any of its Affiliates. Anteris shall cause its Affiliates to comply with the provisions of this Agreement in connection with any performance of its obligations under this Agreement.

14.5 Waiver. The waiver by either Party of any right under this Agreement or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. Any waiver by a Party of a particular term or condition will be effective only if set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition.

14.6 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned, or delayed); except that each Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent as follows:

(a) in connection with a sale of all or substantially all of the business or assets of such Party, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets, or otherwise; or

(b) to an Affiliate, provided that if the entity to which this Agreement is assigned ceases to be an Affiliate of the assigning Party, this Agreement shall be automatically assigned back to the assigning Party or its successor.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 14.6. Any assignment not in accordance with this Section 14.6 shall be null and void and of no legal force or effect.

14.7 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. The Parties will in such an instance use their best efforts to replace the invalid, unenforceable, or illegal provision(s) with valid, enforceable, and legal provision(s) that best implement the original intent of the Parties and purposes of this Agreement.

14.8 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, or by registered or certified mail (postage prepaid) requiring return receipt, or by internationally recognized overnight delivery service, in each case to the Party to be notified at its address given below, or at any other address such Party may designate by prior written notice to the other in accordance with this Section 14.8. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) if personally delivered, the date of actual receipt; (b) if delivered by registered or certified mail, five (5) days after the date of postmark; or (c) if delivered by overnight delivery service, the next day the overnight delivery service regularly makes deliveries.

If to vTv, notices must be addressed to:

vTv Therapeutics LLC
3980 Premier Drive, Suite 310
High Point, NC 27265
Attention: Law Department

If to Anteris, notices must be addressed to:

Anteris Bio, c/o Aditum Bio
1111 Broadway, Suite 1300
Oakland, CA, 94607
Attention: Ilan Zipkin

14.9 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control, including fire, flood, explosion, earthquake, pandemic (including quarantine, lockdown or other similar orders imposed by any Governmental Authority in association with such pandemic), or other natural forces or acts of God, war, civil unrest, acts of terrorism, accident, destruction, or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within ten (10) business days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

14.10 **Interpretation**. The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections, and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subjects of the conjunction are, or are intended to be, mutually exclusive. The words "herein", "hereof", and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language.

14.11 **Counterparts; Electronic Signatures**. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same agreement. The Parties agree that execution of this Agreement by industry standard electronic signature software and/or by exchanging executed signature pages in .pdf format via e-mail shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or related to this Agreement, each Party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

{Signature Page Follows}

In Witness Whereof, the Parties hereto have caused this **License Agreement** to be executed and entered into by their duly authorized representatives as of the Effective Date.

Anteris Bio, Inc.

By:/s/ Ilan Zipkin
Name:Ilan D. Zipkin, Ph.D.
Title:CEO

vTv Therapeutics LLC

By: /s/ Stephen L. Holcombe
Name:Stephen L. Holcombe
Title:President and CEO

List of Schedules:

Schedule 1.46
Lead Compound

Structure of HPP971
[***]

Schedule 1.79
vTv Patents

File #	Country	Status	Application No.	Date Filed	Patent No.	Grant Date
[***]	[***]	[***]	[***]	[***]	[***]	[***]

Schedule 4.2

vTv Know-How, Lead Compound and Materials

[***]

*** Certain information identified by "[***]" has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.**

FIRST AMENDMENT

TO

LICENSE AGREEMENT

THIS FIRST AMENDMENT TO LICENSE AGREEMENT (this "Amendment") is entered into this 14th day of January, 2021 (the "Effective Date"), by and between HANGZHOU ZHONGMEI HUADONG PHARMACEUTICAL CO., LTD., a corporation organized under the laws of China, having a business address at No. 866, Moganshan Road, Hangzhou, China ("Huadong"), and VTV THERAPEUTICS LLC, a limited liability company organized under the laws of Delaware, having a business address at 3980 Premier Drive, Suite 310, High Point, NC 27265 ("vTv").

WHEREAS, Huadong and vTv previously entered into the License Agreement on 21st day of December 2017 (the "Agreement") whereby Huadong obtained a license to the vTv Patent Rights and the vTv Know-How for vTv's glucagon-like peptide-1 receptor agonist known as TTP273;

WHEREAS, the Parties desire to amend the Agreement to reflect that the Development Plan no longer contains a Phase II MRCT;

NOW, THEREFORE, based on the foregoing premises and the mutual covenants and obligations set forth below, the parties agree as follows:

1. Amendments

a. Section 1.58. Section 1.58 shall be amended and restated as follows:

"1.58 RESERVED."

b. Section 2.6(e). Section 2.6(e) of the Agreement shall be deleted in its entirety.

c. Section 3.2. Section 3.2 shall be amended and restated as follows:

"3.2 RESERVED."

d. Section 3.3. Section 3.3 shall be amended and restated as follows:

"3.3. Joint Development Committee. The Parties hereby establish a Joint Development Committee (the "JDC") to oversee the Development of Products in the Field in the Territory in accordance with the Development Plan. The Development Plan may be amended from time to time by the JDC."

e. Section 3.3(a). Section 3.3(a) shall be amended and restated as follows:

"(a) Membership; Decision Making. The JDC shall comprise three (3) named representatives of Huadong and three (3) named representatives of vTv. Each Party shall notify the other within [***] days after the Effective Date of the appointment of its representatives to the JDC. Each Party may change its representatives to the JDC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with Development Plan activities as well as sufficient authority to take actions on behalf of a Party to the extent permitted under this Agreement. Subject to Huadong's prior consent not to be unreasonably withheld, vTv may include such Third Party representatives or consultants as non-voting participants in meetings and activities of the JDC, provided that, any such representative or Third Party shall be bound by obligations of confidentiality, non-disclosure and non-use consistent with those set forth herein, and prior to attending such meeting shall execute and deliver a confidentiality and non-disclosure agreement in a form satisfactory to Huadong. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JDC meetings. Each Party shall have collectively one (1) vote in all decisions and the Parties shall attempt to make decisions by consensus. If the JDC cannot reach consensus on any matter within the scope of its oversight, then the dispute shall be referred to the Parties' respective Senior Executives. If the Senior Executives cannot resolve the dispute within [***] Business Days after the dispute has been referred to them, then Huadong shall have the final decision-making authority with respect to such dispute; provided, that (i) Huadong shall not exercise its final decision-making authority in any manner that (A) expands vTv's obligations or reduces vTv's rights under this Agreement or (B) expands Huadong's rights or reduces Huadong's obligations under this Agreement; (ii) any final decision made by Huadong with respect to a proposed clinical trial shall be in compliance with the applicable requirements of FDA, CFDA, or other applicable Regulatory Authority, and (iii) Huadong shall give reasonable consideration to any conclusions timely issued by a special scientific committee, which, at vTv's request from time to time, shall be formed with an equal number of professionals nominated by each Party to consider any science-related matters not otherwise resolved by the JDC or the Senior Executives. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives. A representative from [***] shall act as the chairperson of the JDC meetings. The chairperson shall conduct the following activities: (i) calling meetings of the JDC; (ii) preparing and issuing minutes of each such meeting; and (iii) preparing and circulating an agenda for the upcoming meeting."

f. Section 3.3(c). Section 3.3(c) shall be amended and restated as follows:

"(c) Scope of Joint Development Committee Oversight. The JDC's oversight responsibilities shall be limited to the Development of Compounds and Products in the Field in the Territory. Within such scope the JDC may: (i) confer regarding the status of Development Plan activities; (ii) review and approve amendments to the Development Plan; (iii) address such other matters relating to the Development of Compounds and Products in the Field in the Territory as either Party may bring before the JDC; and (iv) attempt to resolve any dispute within the JDC on an informal basis. The JDC shall have no authority to (x) determine whether any milestone event set forth in Sections 6.3 or 6.4 has been met, (y) make any decision expressly allocated herein to either or both Parties, or (z) amend any provision of this Agreement, other than the Development Plan pursuant to Section 3.1."

g. Section 3.4(b). Section 3.4(b) shall be amended and restated as follows:

"(b) RESERVED."

h. Section 3.6. Section 3.6 shall be amended and restated as follows.

"3.6 RESERVED."

i. Section 3.7. Section 3.7 shall be amended and restated as follows:

"3.7 Huadong Regulatory Filings in the Territory.

(a) Huadong shall be responsible for, and be the owner of all Regulatory Filings in any Region of the Territory, to the extent permitted by applicable Laws, in connection with the Compound or Products;

(b) Huadong shall keep vTv reasonably informed of regulatory developments related to the Products in the Territory and shall promptly notify vTv in writing of any decision by a Regulatory Authority in the Territory regarding any Product; and

(c) Huadong shall notify vTv of any Regulatory Filings submitted to or received from any Regulatory Authority in the Territory and provide vTv electronic copies thereof within [***] days after submission or receipt, provided that at vTv's reasonable request, Huadong shall, at vTv's cost, prepare and provide vTv with English translations of all such Regulatory Filings."

j. Section 5.1. Section 5.1 shall be amended and restated as follows:

"5.1 Diligence. During the Term, Huadong shall, directly or through its Subsidiaries or Sublicensees, use Commercially Reasonable Efforts to (a) [***] and (b) [***]. In addition, Huadong shall dose the first patient in a Phase II Clinical Trial of a Product containing TTP273 on or before March 31, 2021."

k. Section 5.3(a)(i). Section 5.3(a)(i) shall be amended and restated as follows:

"(i) Following the Effective Date, but in no event later than ninety (90) days prior to the initiation of a Phase II Clinical Trial, Huadong and vTv shall develop and agree to the worldwide safety and pharmacovigilance procedures for the Parties with respect to the Products, such as safety data sharing and exchange, Adverse Events reporting and prescription events monitoring in a written agreement (the "Safety Agreement"). Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning Adverse Events or any other safety problem of any significance, and product quality and product complaints involving Adverse Events, sufficient to permit each Party, its Affiliates, licensees or sublicensees to comply with its legal obligations. The Safety Agreement shall be promptly updated if required by changes in legal requirements. Each Party hereby agrees to comply with its respective obligations under the Safety Agreement and to cause its Affiliates, licensees and sublicensees to comply with such obligations. To the extent there is any disagreement between this Section 5.3 or any related definitions and the Safety Agreement, the Safety Agreement shall control with respect to safety matters and this Agreement shall control with respect to all other matters."

l. Section 5.3(b). Section 5.3(b) shall be amended and restated as follows:

"If either Party believes that the other Party is taking or intends to take any action with respect to a Product that could have a material adverse impact upon the regulatory status of any Product in the Territory (in the case of Huadong) or outside the Territory (in the case of vTv), such Party shall have the right to bring the matter to the attention of the JDC and the Parties shall discuss in good faith to resolve such concern. Without limiting the foregoing, unless the Parties otherwise agree: (i) Huadong shall not communicate with any Regulatory Authority having jurisdiction outside the Territory with respect to a Product, unless so ordered by such Regulatory Authority, in which case Huadong shall immediately notify vTv of such order; (ii) Huadong shall not submit any Regulatory Filings or seek regulatory approvals for any Product outside the Territory; (iii) vTv shall not communicate with any Regulatory Authority having jurisdiction in the Territory with respect to a Product, unless so ordered by such Regulatory Authority, in which case vTv shall immediately notify Huadong of such order; (d) vTv shall not submit any Regulatory Filings or seek regulatory approvals for any Product in the Territory. To the extent practicable, vTv shall provide Huadong with any information that reasonably could affect the Development or Commercialization of the Product in the Territory, prior to making such information public."

m. Section 6.3(a)(i). Section 6.3(a)(i) shall be amended and restated as follows:

"(i) [***]. $[***]."

n. Section 6.3(a)(iii). Section 6.3(a)(iii) shall be amended and restated as follows:

"(iii) [***]. [***]."

o. Section 11.2. Section 11.2 shall be amended and restated as follows:

"11.2 Termination for Cause. If either Party (the "Non-Breaching Party") believes that the other Party (the "Breaching Party") has materially breached one or more of its material obligations under this Agreement (a "Material Breach"), then the Non-Breaching Party may give the Breaching Party notice of such Material Breach (a "Material Breach Notice") specifying the nature of the breach. If the Breaching Party does not dispute that it has committed a Material Breach, then, if the Breaching Party fails to cure such breach, or fails to take steps as would be considered reasonable to effectively cure such breach, within [***] days after receipt of the Material Breach Notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. If the Breaching Party disputes that it has committed a Material Breach, the dispute shall be resolved pursuant to Section 12.2. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined to have committed a Material Breach (an "Adverse Ruling"), then, if the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such breach within [***] days after such ruling or such longer period as specified in the Adverse Ruling, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. The right of either Party to terminate this Agreement as set forth in this Section 11.2 shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous default. Notwithstanding the foregoing, the Parties acknowledge and agree that (a) Huadong's failure to make any payment in accordance with ARTICLE VI shall constitute a "Material Breach," and, upon occurrence of such Material Breach and delivery of an applicable Material Breach Notice to Huadong, if Huadong fails to cure such breach within [***] Business Days after receipt of such Material Breach Notice, vTv may terminate this Agreement upon written notice to Huadong, and (b) without limitation in respect of any other obligation under this Agreement, Huadong's obligations pursuant to Sections 2.4(a) and 2.4(b) shall constitute "material obligations" for purposes of the definition of "Material Breach." Notwithstanding anything to the contrary in this Section 11.2, (i) if a Material Breach pertains only to facts relating to one or more Regions other than China Mainland, then, pursuant to this Section 11.2, the Non-Breaching Party shall have a right to terminate this Agreement only with respect to such Regions and (ii) if a Material Breach pertains to facts relating to China Mainland, then, pursuant to this Section 11.2, the Non-Breaching Party shall have a right to terminate this Agreement in its entirety. The Regions or the Territory (as applicable) with respect to which the Non-Breaching Party exercises its termination right pursuant this Section 11.2 is referred to as the "Terminated Region."

p. Section 11.3(a). Section 11.3(a) shall be amended and restated as follows:

"(a) Termination for Convenience. At any time, Huadong may terminate this Agreement in its entirety for any reason or no reason upon [***] days prior written notice to vTv."

q. Section 11.6(b). Section 11.6(b) shall be amended and restated as follows:

"(b) this Agreement shall terminate; provided, that, in the case of termination by Huadong under Section 11.3(b) (Termination for Failure of Manufacturing Technology Transfer), [***]."

r. Section 12.8(b)(vi). Section 12.8(b)(vi) shall be deleted in its entirety.

2. **Defined Terms**. Unless otherwise defined herein, all of the capitalized terms used in this Amendment shall have the respective meanings ascribed to them in the Agreement.

3. **Effect**.Except as expressly amended by this Amendment, the Agreement remains in full force and effect.

4. **Governing Law**. This Amendment shall be governed by and interpreted in accordance with the internal laws of New York, without regard to its conflicts of laws rules.

[S*ignature page follows*]

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the Effective Date.

HANGZHOU ZHONGMEI HUADONG PHARMACEUTICAL CO., LTD.	**vTv THERAPEUTICS LLC**
By: /s/ Jeffrey Liu	By: /s/ Stephen L. Holcombe
Name: Jeffrey Liu	Name: Stephen L. Holcombe
Title: Chief Scientific Officer	Title: President and Chief Executive Officer

Exhibit 21.1

vTv Therapeutics Inc.
Corporate Subsidiaries as of February 24, 2021

Subsidiary	Jurisdiction of Incorporation
vTv Therapeutics LLC	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-206335) pertaining to the vTv Therapeutics Inc. 2015 Omnibus Equity Incentive Plan;

(2) Registration Statement (Form S-3 No. 333-223269) of vTv Therapeutics Inc.;

(3) Registration Statement (Form S-3 No. 333-232571) of vTv Therapeutics Inc.;

(4) Registration Statement (Form S-8 No. 333-240304) of vTv Therapeutics Inc.; and

(5) Registration Statement (Form S-1 No. 333-250934) of vTv Therapeutics Inc.

of our report dated February 20, 2020 with respect to the consolidated financial statements of vTv Therapeutics Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Raleigh, North Carolina
February 24, 2021

EXHIBIT 31.1

SECTION 302 CERTIFICATION

I, Stephen L. Holcombe, certify that:

1. I have reviewed this annual report on Form 10-K of vTv Therapeutics Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Securities Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: February 24, 2021

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

EXHIBIT 31.2

SECTION 302 CERTIFICATION

I, Rudy C. Howard, certify that:

1. I have reviewed this annual report on Form 10-K of vTv Therapeutics Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Securities Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: February 24, 2021

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

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of vTv Therapeutics Inc. (the “Company”) on Form 10-K for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Stephen L. Holcombe, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of the Company that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 24, 2021

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of vTv Therapeutics Inc. (the “Company”) on Form 10-K for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Rudy C. Howard, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of the Company that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 24, 2021

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