Risk Factors Comparison 2024-03-13 to 2023-03-06 Form: 10-K

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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 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 **cadisegliatin (** 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 litigation and government investigations, including 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 • our ability to maintain listing of our Class A common stock on Nasdaq • 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. 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 $ **20. 3 million, $** 19. 2 million ~~,~~ **and** $ 13. 0 ~~million and $ 8. 5~~ million for the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ , respectively. As of December 31, ~~2022~~ **2023** , we had a total accumulated deficit of approximately $ ~~265~~ **281** . ~~5~~ **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~~ **cadisegliatin** . 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 **cadisegliatin (** TTP399 **)** and our other drug ~~candidates~~ **candidate** ~~, 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~~ **cadisegliatin** and our other drug candidates and continue to work on our other research programs. ~~Our~~ **Although we anticipate that the proceeds from the Private Placement will enable us to conduct a Phase 3 clinical trial for cadisegliatin, 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 OfferingSM Sales~~ **sales** ~~Agreement~~ **agreement** (the " **TD Cowen** Sales Agreement ") with **Cowen** ~~Cantor Fitzgerald~~ & ~~Co.~~ **Company, LLC** (" ~~Cantor Fitzgerald~~ **TD Cowen** ") (the " **TD Cowen** ATM Offering ") ~~and our purchase agreement with Lincoln Park Capital Fund, LLC (" Lincoln Park ") (the " LPC Purchase Agreement ")~~ . Under **this** ~~both of these arrangements~~ **arrangement** , 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~~ **agreement** . As of March ~~6~~ **13** , ~~2023~~ **2024** , there remains $ ~~37~~ **50** . ~~3~~ **0** million of availability under the **TD Cowen** ATM ~~offering~~ **Offering** ~~. While the LPC Purchase Agreement allows for sales of up to $ 47. 0 million~~ , **although** ~~we have issued 5, 331, 306 of these~~ -- **the amount** ~~shares for~~

~~gross proceeds~~ of **our Class A common stock that** ~~approximately $ 11. 1 million. Though~~ we **may offer and sell** ~~can register additional shares for sale~~ under ~~this agreement, such sales may be~~ **the TD Cowen ATM Offering during any 12 calendar month period is currently** limited **to one- third of the aggregate market value of our voting and non- voting common equity held** by ~~the conditions set forth in the LPC Purchase Agreement~~ **non- affiliates pursuant to General Instruction I. B. 6 of Form S- 3** . In addition, our ability to use ~~these~~ **this** ~~sources~~ - **source** of capital is dependent on a number of factors, including the prevailing market price of and the volume of trading in our Class A common stock. We also will need to raise substantial additional capital in the future to conduct further clinical trials of ~~TTP399~~ **cadisegliatin** and to continue developing our other drug candidates. Although we ~~are seeking~~ **continue to seek** financing, partnering and licensing transactions for the further development of ~~TTP399~~ **cadisegliatin** , these efforts may not be successful. 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~~ **cadisegliatin** as a potential adjunctive therapy to insulin for the treatment of type 1 diabetes; • the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals; • the number and characteristics of drug candidates that we pursue, including our drug candidates in preclinical development; • the ability of our drug candidates to progress through clinical development successfully; • our need to expand our research and development activities; • the costs associated with securing, establishing and maintaining commercialization capabilities; • the costs of acquiring, licensing or investing in businesses, products, drug candidates and technologies; • our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights; • our need and ability to hire additional management and scientific and medical personnel; • the effect of competing technological and market developments; • our need to implement additional internal systems and infrastructure, including financial and reporting systems; • the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future; and • the amount of any payments we are required to make to M & F TTP Holdings Two LLC in the future under the Tax Receivable Agreement. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates. Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds other than those available to us under the **TD Cowen** 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~~ **cadisegliatin** 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 Our development efforts are focused on the continued development of **cadisegliatin (** TTP399 **)** . There can be no assurance that we will be able to implement our business strategy successfully. Our development focus is on the continued development of ~~TTP399~~ **cadisegliatin**

as a potential adjunctive treatment for patients with type 1 diabetes and supporting our currently partnered programs. If we are not able to successfully execute our business strategy and do not achieve the anticipated benefits, our business, results of operations and financial condition could suffer. 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. 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. 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 risk evaluation and mitigation strategies (" 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. 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 contract research organizations (CRO) 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 Data and Safety Monitoring Board (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; or • changes in the regulatory requirement and guidance. 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 **cadisegliatin (** 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, a 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~~ **cadisegliatin** 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 **, and somatostatin type 2 receptor blockers such as Zucara' s ZT- 01** . Some of these SGLT- 1 and SGLT- 2 inhibitors ~~have~~ **had** been approved for certain sub- groups of type 1 diabetics in Europe and Japan, but **are no longer marketed** ~~these~~ **there**

~~therapies~~ **, and** 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 **the** 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 (" FCPA") 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; • the Health Insurance Portability and Accountability Act of 1996 (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 Health Information Technology for Economic and Clinical Health Act (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, biological products 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 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~~ **cadisegliatin** . 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 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 **cadisegliatin (** 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~~ **cadisegliatin** or our other drug candidates. If we obtain regulatory approval for ~~TTP399~~ **cadisegliatin** 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. **Our success depends on our ability to protect our intellectual property and our proprietary technologies.** If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our commercial success may be adversely affected. 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 **generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies, and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in- licensing relevant issued patents or pending applications from third parties. We** will be able to protect our proprietary ~~technology~~ **technologies** 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 determination of inventorship. If we or our current licensors or licensees, or any future licensors or licensees, fail to 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. **Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.** The patent applications that we **own, co-** 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. **In addition, given the amount of time required for the development, testing and regulatory review of our therapeutic programs and eventual product candidates, patents protecting the product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following: • the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; • patent applications may not result in any patents being issued; • patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage; • our competitors, many of whom may have substantially greater resources than we do and many of whom may have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and • countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.** 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 **. In addition, although we enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third- party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection** . 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. **Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U. S. and non- U. S. patent agencies. The USPTO and various non- U. S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.** 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 candidates and future** 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 **.**

Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act (the " America Invents Act ") enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application would be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors are the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications. The America Invents Act also included several significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO- administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our owned and in- licensed patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. The U. S. law relating the patentability of certain inventions in the life sciences is uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future. The U. S. Supreme Court and federal courts have ruled on several patent cases in recent years that impact the scope of patentability of certain inventions or discoveries related to the life, including both narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our products, and could jeopardize or otherwise reduce patent term, reduce the scope of, or invalidate or render unenforceable our patent rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions and / or decisions by the U. S. Congress, the U. S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. As an example, beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (the " UPC "). Also, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. In 2012, the European Union Patent Package (the " EU Patent Package ") regulations were passed with the goal of providing a single pan- European Unitary Patent and a new European UPC for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC' s existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt- out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan- European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates dues to increased competition and, resultantly, on our business, financial condition, prospects and results of operations. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would

be adversely affected. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our future licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in- license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in- license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our future licensors by developing similar or alternative technologies or products in a non- infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our current or future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third- party pre- issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post- grant review (" PGR ") and inter partes review (" IPR "), or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, our patents or the patents of our current or future licensors may become subject to post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our current or future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technologies or product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our current or future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates . 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. **Our patent rights may prove to be an inadequate barrier to competition. The lifespan of any one patent is limited, and each of these patents will ultimately expire and we cannot be sure that pending applications will be granted, or that we will discover new inventions which we can successfully patent. Moreover, any of our granted patents may be held invalid by a court of competent jurisdiction, and any of these patents may also be construed narrowly by a court of competent jurisdiction in such a way that it is held to not directly cover our product candidates. Furthermore, even if our patents are held to be valid and broadly interpreted, third parties may find legitimate ways to compete with our product candidates by inventing around our patent. Finally, the process of obtaining new patents is lengthy and expensive, as is the process for enforcing patent rights against an alleged infringer. Any such litigation could take years, cost large sums of money, and pose a significant distraction to management. Indeed, certain jurisdictions outside of the U. S. and European Union (" E. U. "), where we hope to commercialize our product candidates, have a history of inconsistent, relatively lax or ineffective enforcement of patent rights. In such jurisdictions, even a valid patent may have limited value. Our failure to effectively enforce our patents would have a harmful impact on our ability to commercialize our product candidates in these jurisdictions.** We may not be able to enforce all of 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. **Beginning June** ~~No earlier that October~~ 1, ~~2022~~ **2023** , European **patent** applications ~~will soon~~ have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (" UPC). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. ~~Geo-~~ **In addition,** ~~political~~ **geopolitical** actions in the United States and in foreign countries **(such as the Russia and Ukraine conflict)** could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any ~~current or~~ future licensors and the maintenance, enforcement or defense of our issued patents **which** ~~or those of any current or future licensors. For example, the United States and foreign government~~

~~actions related to Russia' s invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions~~ could **impair** ~~result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly,~~ our competitive **intellectual property** position ~~may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected~~ . 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 **. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations, and prospects will be adversely affected** . 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 **. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position. In addition, we rely on the protection of our trade secrets, including unpatented know- how, technology and other proprietary information to maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. Although we have taken steps to protect our trade secrets and unpatented know- how, including entering into confidentiality agreements with third parties, and confidential information and inventions assignment agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose**

protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. We may be subject to claims that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets. We have entered into and may enter in the future into non- disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third- party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they may have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industry, we employ individuals and engage the service of consultants, who were previously employed at, may have previously provided, or may be currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these individuals, including members of our senior management, executed proprietary rights, non- disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we use reasonable efforts to ensure that our employees, independent contractors, and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such former employers, clients, or third parties. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. The patent protection and patent prosecution for some of our product candidates may be dependent on third parties. While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution . 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. 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. 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. An 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.~~ 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 **cadisegliatin (** 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. We may be subject to litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation or otherwise negatively impact our business. We may be subject to litigation or government investigations. The outcome of any litigation or government investigation, regardless of its merits, is inherently uncertain. Any lawsuits or government investigations, and the disposition of such lawsuits and government investigations, could be time- consuming and expensive to resolve and divert management attention and resources. Any adverse determination related to litigation or government investigations could adversely affect our financial performance, harm our reputation or otherwise negatively impact our business. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter or government investigation could materially affect our future operating results, our cash flows or both. 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. If we are unable to maintain listing of our Class A common stock on the Nasdaq Capital Market or another national stock exchange, it may be more difficult for our stockholders to sell their Class A common stock. Nasdaq requires issuers to comply with certain standards in order to remain listed on its exchange. ~~We have~~ **On December 13, 2023, we** received a **letter** ~~delisting notice~~ from Nasdaq **notifying us that the Company** ~~as~~ **was** ~~result of~~ **not in compliance with** the **requirement** ~~closing bid price~~ of **Nasdaq Listing Rule 5550 (b) (2) because** our Class A common stock ~~being~~ **was** below **the required market value of listed securities (" MVLS ") of** $ **35 million** ~~1. 00 per share~~ for **the prior** 30 consecutive business days. **In accordance with** ~~Our Class A common stock may be involuntarily delisted from~~ Nasdaq ~~if~~ **Listing Rule 5810 (c) (3) (C),** we ~~fail~~ **have 180 calendar days, or until June 10, 2024,** to regain compliance with ~~the~~ **Nasdaq Listing Rule 5550 (b) (2). Compliance can be achieved without further action if our MVLS closes at $ 35 million or more for a** minimum ~~closing bid price requirement~~ of ~~$ 1~~ **10 consecutive business days at any time during the 180- day compliance period** . ~~00 per share~~ **If we do not regain compliance during such period, subject to an appeals process, our Class A Common Stock will be subject to delisting and may be removed from The Nasdaq Capital Market** . If we are unable to maintain our listing on Nasdaq, it may become more difficult for our stockholders to sell our Class A common stock in the public market, and the price of our Class A common stock may be adversely affected due to the likelihood of decreased liquidity resulting from delisting. In addition, it may inhibit or preclude our ability to raise additional financing. Affiliates of MacAndrews & Forbes Incorporated (together with its affiliates " 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~~ **significant percentage** 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 **substantial influence over** ~~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 **and the investors that participated in the Private Placement (the " Private Placement Investors ")** may have conflicts of interest with respect to matters involving our company. One of our directors is affiliated with MacAndrews ~~. This~~ **and two of our** ~~director~~ **directors are associated with the Private Placement Investors. These directors** will have fiduciary duties to us and in addition will have duties to MacAndrews **and the Private Placement Investors, as applicable** . 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 **or the Private Placement Investors** , whose interests, in some circumstances, may be adverse to ours. In addition, as a result of MacAndrews **' and the Private Placement Investors** ' indirect ownership interest, conflicts of interest could arise with respect to transactions involving business dealings between us and MacAndrews **, the Private Placement Investors** or **any of** their **respective** 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 **. Additionally, the Private Placement Investors have certain participation rights giving them the right to purchase their proportionate share of certain future financing transactions. Such participation rights could impact our ability to raise money and deter new investors who may not be able to acquire a large enough stake in the Company. Conversely, if the Private Placement Investors decline to exercise their participation rights it may adversely affect the way the market and potential investors view the Company** . 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, ~~2022~~ **2023** , MacAndrews and its affiliates ~~hold~~ **held** ~~23~~ **577** , **108** ~~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~~ **912** , **982** ~~519, 212~~ shares of our Class A common stock. As a result, MacAndrews and its affiliates ~~hold~~ **held** shares representing approximately ~~57~~ **56** . 0 % 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 **MacAndrews to** purchase ~~1~~ **45** , **595** ~~823, 917~~ shares of our Class A common stock ~~to MacAndrews~~ . ~~Further~~ **On February 27** , **2024** ~~as part of our Loan Agreement~~ , we issued ~~warrants to purchase 190~~ **an aggregate of 464** , ~~586~~ **377** shares of our Class A common stock to **the Private Placement Investors. As a result, the Private Placement Investors hold shares representing approximately 14. 9 % of the combined voting power of our outstanding common stock. We also issued pre- funded warrants to purchase up to an aggregate of 3, 853, 997 shares of Class A common stock. Such pre- funded warrants provide that each Private Placement Investor will not have the right to exercise any portion of its pre- funded warrant if, together with its affiliates, such Private Placement Investor would beneficially own in excess of 4. 99 %** ~~our~~ **or** ~~lenders~~ **9. 99 %, as applicable, of the number of shares of our common stock outstanding immediately after giving effect to such exercise (the " Beneficial Ownership Limitation "); provided, however, that each Private Placement Investor may increase the Beneficial Ownership Limitation by giving 61 days' notice to us, but not to any percentage in excess of 19. 99 %. On March 5, 2024, we entered into an exchange agreement pursuant to which the Private Placement Investors exchanged an aggregate of 116, 493 shares for pre- funded warrants. As a result, following the exchange, the Private Placement Investors hold shares representing approximately 11. 6 % of the combined voting power of our outstanding common stock** . 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. **The investor rights agreement was amended on February 27, 2024 to alter MacAndrews' governance rights. Additionally, we entered into a securities purchase agreement and a registration rights agreement with the Private Placement Investors providing certain governance and registration rights. On February 23, 2024, the Board of Directors approved the adoption of an equity incentive plan (the" 2024 Plan") to replace the existing 2015 Plan. The 2024 Plan, if approved by the shareholders at the 2024 annual meeting of shareholders, will authorize us to issue equity awards relating to an additional 750, 000 shares of our Class A Common Stock.** 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 **TD Cowen** ~~LPC Purchase Agreement, the~~ ATM Offering, or pursuant to warrants issued to ~~M & F Group and our~~ previous **investors and** 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 investor agreements,** 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 anti- takeover 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. **Further, the Private Placement Investors are also not deemed to be " interested stockholders, " regardless of the percentage of our stock owned by them, and accordingly will not be subject to the restrictions set forth in Section 203 of the Delaware General Corporation Law** 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 **. Additionally, pursuant to the investor rights agreement with an affiliate of MacAndrews, MacAndrews has the right to designate two members of our Board of Directors, and as part of the Private Placement, the Private Placement Investors have rights to designate three members of our Board of Directors, making it more difficult for a third party to acquire control of our Board. The agreement with the Private Placement Investors also provides that five of our directors must approve certain actions including any acquisition by a third party, which makes it more difficult for our Board of Directors to approve such a transaction** . 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.