Risk Factors Comparison 2024-03-29 to 2023-03-29 Form: 10-K

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You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10- K and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price **and value** of our **securities** ~~common stock~~ would likely decline. Risks Related to Our Financial Position and Capital Needs We ~~will need substantial~~ **expect to require** additional capital ~~for~~ **in** the **future to** ~~continued~~ **continue** ~~development~~ **to fund our operations and to finance the further advancement** of our product candidates ~~and for our long- term operations. We will need to raise capital to continue product development~~ , **which** ~~including the development of our lead product candidate VTX- 002 for the treatment of NEA. Our capital requirements depend on many factors, including: • The rate and level of patient recruitment into clinical trials, particularly those in Phase 2 and Phase 3 stages of development; • The level of research and development investment required to develop product candidates; • The timing and amount of milestone payments we are required to make under license agreements; • The timing and amount of payments under the Loan Agreement; • Time and costs involved in obtaining regulatory approvals; • Changes in product development plans needed to address any difficulties that may arise in manufacturing, preclinical activities, clinical trials or commercialization; • Revenue from sales of Millipred ®; • The ability and willingness to enter into new agreements with strategic partners, and the terms of these agreements; • The success rate in preclinical and clinical efforts; • The costs of future commercialization activities, including product sales, marketing, manufacturing and distribution; • Proceeds, if any, from sales of any PRV received; • Revenue, if any, received from commercial sales of product candidates, should any of our product candidates receive marketing approval; • The effect of competing product and market developments; • In- licensing and / or acquisition or other transaction costs (if any) for potential product development candidates; and • Costs of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights. We will likely require significant amounts of additional capital in the future, and such capital~~ might not be available **to us** on ~~favorable~~ **acceptable** terms ~~when~~ **, or at all. Failure to obtain any necessary capital could force us to delay, limit or terminate our product development efforts or cease our operations. At December 31, 2023, we had $ 7. 4 million in cash and cash equivalents and $ 4. 6 million in current liabilities. In March 2024, we closed a private placement financing for up to $ 185 million in gross proceeds, including initial upfront gross investment of $ 115. 6 million. Avalo estimates upfront net proceeds of approximately $ 105 million after deducting estimated transaction fees and expenses from both the private placement financing and the acquisition of AlmataBio. The Company could receive an additional $ 69. 4 million of gross proceeds upon the exercise of warrants issued in the financing. Accordingly, as of the date of this Report, we believe we have sufficient funds to finance our continuing operations beyond the short term to further advance our product candidates. We may not have sufficient funds in the intermediate term and will likely** ~~needed~~ -- **need to raise additional** ~~equivalents and $ 22.1 million in current liabilities.Accordingly,we might not currently have sufficient~~ funds **prior** to ~~finance our continuing operations beyond the short term or to further advance~~ any **phase 3 development** of our product candidates.As a research and development company,our operations have consumed substantial amounts of cash since inception.Identifying potential product candidates and conducting preclinical testing and clinical trials is a time - consuming,expensive and uncertain process that takes years to complete,and we expect our research and development expenses to increase substantially in connection with our ongoing activities,particularly as we advance our current product candidates through or into clinical trials.Circumstances may cause us to consume **or require** capital more rapidly than we currently anticipate **.As an example,our cash position in the past has caused us to prioritize product candidates for development,out- license certain product candidates and to defer the development of other candidates** .We will need to raise additional funds or otherwise obtain funding through collaborations to complete the development of any of our product candidates **and to continue** ~~,including the development of~~ our **operations** ~~lead candidate AVTX- 002 for the treatment of NEA~~ .Additional fundraising efforts may divert our management from our day - to - day activities,which may adversely affect our ability to develop and commercialize our product candidates.In addition,we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us ~~,if at~~ , if at all. Furthermore, our ability to raise capital on a timely basis through the issuance and sale of equity securities might be limited by Nasdaq' s listing rules on transactions that do not qualify as " public offerings " (as defined in Nasdaq listing rules), which might require us to obtain stockholder approval prior to the issuance of common stock (or securities convertible into or exercisable for common stock) at a price per share that is less than the ~~"~~ **“** Minimum Price ~~"~~ **”** if the issuance would equal 20 % or more of our common stock outstanding before the issuance. ~~As an example, our cash position in the past has caused us to prioritize product candidates for development, out- license certain product candidates and to defer the development of other candidates.~~ We might never progress to the point where we have commercially successful product sales or other revenue sufficient to sustain operations. Accordingly, we may seek to raise ~~these~~ **needed** funds through public or private equity offerings, debt financings, credit facilities, partnering or other corporate collaborations and licensing arrangements. If adequate funds are not available or are not available on acceptable terms, our ability to fund our operations, take advantage of opportunities, develop products and technologies, and otherwise respond to competitive pressures could be significantly delayed or limited, and we might need to downsize or halt our operations . Our recurring operating losses and negative..... acceptable to us, if at all . If we do not raise additional capital when required or on acceptable terms, we may need to: • Significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or cease operations altogether; • Seek strategic

alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or • Relinquish, or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ~~itself~~ **ourself** . Our future funding requirements, both short and long term, will depend on many factors, including: • The initiation, progress, timing, costs and results of preclinical and clinical studies for our product candidates and any future ~~Product~~ **product** candidates we may develop **; • The level of research and development investment required to develop product candidates; • The rate and level of patient recruitment into clinical trials; • The timing and amount of milestone payments we are required to make under license agreements; • Changes in product development plans needed to address any difficulties that may arise in manufacturing, preclinical activities, clinical trials or commercialization** ; • The outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and other regulatory authorities, including the potential for such authorities to require that we perform more studies than currently expected; • The cost to establish, maintain, expand and defend the scope of our intellectual property portfolio **and patent claims** , including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights; • The effect of competing technological and market developments ~~; • Market acceptance of any approved product candidates~~ ; • The cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial - scale manufacturing; and • The cost of **future commercialization activities including,** developing our sales, marketing **. manufacturing** and distribution capabilities to accommodate any of our product candidates for which we receive marketing approval and that we determine to commercialize ourselves or in collaboration with our partners; **• Market acceptance of any approved product candidates; • The effect of competing product and market developments; • The ability and willingness to enter into new agreements with strategic partners, and the terms of these agreements;** and • The costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies. **We** ~~Under our Loan Agreement, our Lenders~~ have ~~broad discretion~~ **incurred significant net losses in most periods since our inception and we expect to continue to incur net losses in the future.Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate an adequate effect or acceptable safety profile,gain marketing approval and become commercially viable.Historically,we have financed our operations primarily through public and private equity offerings.We incurred a net loss of $ 31.5 million** for the year ended December 31, ~~2022~~ **2023** .As of December 31, ~~2022~~ **2023** ,we had an accumulated deficit of $ ~~303~~ **335** . ~~8~~ **1** million.Substantially all of our operating losses have resulted from costs incurred in connection with our research and development program and from general and administrative costs associated with our operations.We expect to continue to incur losses in the future and we might never achieve profitability on an annual basis.We may also encounter unforeseen expenses,difficulties,complications,delays and other unknown factors that may adversely affect our business.Our future profitability will depend,in part,on the rate of future growth of our expenses ~~and our ability to generate revenues.Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.We have a significant amount of gross net operating losses (" NOLs ") for federal and state purposes.The NOLs accumulated through the end of 2017 will begin to expire in 2031.Unused NOLs for the current~~ as **we develop our product candidates and our ability** to ~~what qualifies as~~ **obtain approval of one or more of our product candidates to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. We face risks associated with short- term liquid investments. In March 2024, we closed** a ~~Material Adverse Change that~~ **private placement financing for up to $ 185 million in gross proceeds, including initial upfront gross investment of $ 115. 6 million. Avalo estimates upfront net proceeds of approximately $ 105 million after deducting estimated transaction fees and expenses from both the private placement financing and the acquisition of AlmataBio. The Company** could **receive an additional $ 69** ~~cause the loan amounts due to be accelerated, thus exposing us to illiquidity . The limitations under our Loan Agreement may also restrict our operations~~ **4 million of gross proceeds upon the exercise of warrants issued in the financing. We historically have invested** ~~or~~ **our cash** ~~produce other adverse results. The Loan Agreement, which we entered into~~ in ~~June 2021, contains~~ **money market funds and intend to invest in** a variety of ~~affirmative and negative covenants~~ **short- term investments** , including ~~required financial reporting~~ **money market funds** , ~~limitations on certain dispositions~~ **that are intended to preserve principal value and maintain a high degree** of ~~assets~~ **liquidity while providing current income. These types of investments are not insured against loss of principal and there is no guarantee that investments in these funds will be redeemable at par value. Once invested** , ~~limitations on~~ **if we cannot liquidate our investments, or redeem** ~~the~~ **them** ~~incurrence of additional debt~~ **at par, we could incur losses** and **experience liquidity issues. A decline in** ~~other~~ -- **the** ~~requirements. The Loan Agreement also gives the Lenders the~~ **value of our investments or a delay or suspension of our** right to **redeem may have** ~~declare an event of default and accelerate the loan amounts due under the Loan Agreement if there has been~~ a material adverse ~~change in~~ **effect on** our ~~business, including a change which~~ results **of operations** ~~in a material impairment in our~~ - **or financial condition** ~~prospect of repayment of any portion of the loan amounts or the value or priority of the Lenders' security interest in the collateral. To secure our performance of our obligations under this Loan Agreement, we granted a security interest in substantially all of our assets, other than certain intellectual property assets, to the Lenders~~ . Our ~~failure~~ **ability** to **use** ~~comply with the covenants in the Loan Agreement, the occurrence of an adverse change as described above or~~ **our** ~~the occurrence of~~ **net operating loss carryforwards and** certain other **tax attributes may** ~~specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, potential foreclosure on our assets and other adverse results. Additionally, we are bound by certain negative covenants setting forth actions that are not permitted to~~ be **limited** ~~taken during the term of the Loan Agreement without consent of the Lenders, including, without limitation, incurring certain additional~~

~~indebtedness, making certain asset dispositions, entering into certain mergers, acquisitions or other business combination transactions or incurring any non- permitted lien or other encumbrance on our assets. The foregoing prohibitions and constraints on our operations could result in our inability to: (i) acquire promising intellectual property or other assets on desired timelines or terms; (ii) reduce costs by disposing of assets or business segments no longer deemed advantageous to retain; (iii) stimulate further corporate growth or development through the assumption of additional debt; or (iv) enter into other arrangements that necessitate the imposition of a lien on corporate assets~~ . We **have** ~~cannot assure you that our business will be able to generate sufficient cash flow or that future borrowings or other financings will be available to us in an amount sufficient to enable us to pay the principal, premium, if any, and interest on our existing or future indebtedness. Servicing our debt requires~~ a significant amount of ~~cash, and we might not have~~ **gross net operating losses (" NOLs ")** ~~or~~ **for federal and state purposes** ~~be able to obtain sufficient cash to pay our substantial debt~~ . ~~As~~ **The NOLs accumulated through the end** of **2017 will begin to expire in 2031. Unused NOLs for the current tax year and prior tax years will carry forward to offset future taxable income, if any, until such unused losses expire. Unused NOLs generated after** December 31, ~~2022~~ **2017** , ~~our remaining aggregate principal payments~~ **will not expire and may be carried forward indefinitely but will be only deductible to the extent of 80 % of current year taxable income in any given year. In addition, both the deductibility of current and future unused NOL carryovers may be subject to limitation** under **Sections 382** ~~our Loan Agreement were $ 21. 2 million. We are required to make our first scheduled principal payment in the amount of $ 0. 6 million in July 2023. Our ability to make this~~ and **383 of the IRC. Sections 382 and 383 of the IRC subject the** future **utilization of NOLs** ~~scheduled payments on our indebtedness depends on our near term~~ and **certain other tax attributes** ~~future performance, which is subject to many factors beyond our control. If we are unable to service our debt, we may be required to adopt one or more alternatives~~ , such as ~~selling assets~~ **research and experimental tax credits** , ~~restructuring debt or obtaining additional~~ **to an annual limitation in the event of certain ownership changes. In general, an " ownership change " is defined as a greater than 50 % change (by value) in** equity ~~capital~~ **ownership over a three- year period. Our operating results fluctuate from quarter to quarter and year to year, making future operating results difficult to predict. Our quarterly and annual operating results historically have fluctuated and are likely to continue to fluctuate depending** on ~~terms~~ **several factors, many of which are beyond our control. Accordingly, our quarterly and annual results are difficult to predict prior to the end of the quarter or year, and we may be unable to confirm or adjust expectations with respect to our operating results for a particular period until** that **period has closed** ~~may be onerous or highly dilutive~~ . In ~~addition,~~ **the event we provide cash projections** ~~our~~ **or** ~~ability to refinance our indebtedness will depend on the~~ **other guidance, any failure to meet** ~~capital markets and our financial condition at~~ such ~~time~~ **targets or failure to meet the expectations of analysts could adversely impact the market price of our securities** . ~~We might~~ **Therefore, you should** not ~~be able to engage in~~ **rely upon the results of** any **quarterly** ~~of these activities or engage in these activities on desirable terms, which could result in a default and acceleration of our~~ **or** ~~debt obligations~~ **annual periods as indications of future operating performance** . Our role as a guarantor of certain obligations assigned to Aytu exposes us to risk of loss or illiquidity. In connection with the Aytu Divestiture, as defined in the Notes to our Consolidated Financial Statements, we assigned payment obligations (" TRIS Obligations ") to Aytu under a supply and distribution agreement (the " Karbinal Agreement ") with TRIS Pharma Inc **.** (" TRIS "), which includes a per- unit royalty make whole payment for each unit sold under an annual minimum sales commitment through 2025. The total future make- whole payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold. As a part of the assignment, we became a guarantor to the TRIS Obligations. If Aytu defaults under the terms of the Karbinal Agreement, we could be liable as a guarantor for unpaid amounts of the TRIS Obligation. Any amount we would be required to pay under the TRIS Obligation would limit the amount of cash available for development of our clinical pipeline and may expose us to significant losses, which would materially and adversely affect our results of operations. We have ~~incurred significant net losses in most periods since~~ **no approved commercial products. Our supply and license agreement for our only commercial pharmaceutical product, Millipred ®, which the Company considered a non- core asset, expired on September 30, 2023. The product revenue from Millipred ® was not sufficient to provide adequate capital for the continued development of our product candidates. With no commercial products, our operations are not expected to produce revenues for the foreseeable future,** ~~our~~ **or** ~~inception~~ **at all, which might harm our ability to obtain additional financing and might require us to reduce or discontinue our operations. Our ability to increase revenue in the future will depend on developing and commercializing our current clinical pipeline of product candidates. Identifying, developing, obtaining regulatory approval and commercializing product candidates are prone to the risks of failure inherent in clinical development. Developing product candidates is expensive,** and we expect to **spend substantial amounts as we fund our** ~~continue to incur net losses in the future. Investment in biopharmaceutical~~ product development ~~is highly speculative because it entails substantial upfront capital expenditures and significant risk~~ **. We cannot provide any assurance that we will be able to successfully advance any product candidate through the development process or successfully commercialize any product candidate, or** that any ~~potential~~ **such** product candidate will ~~fail to demonstrate an adequate~~ **be widely accepted in the marketplace or be more** ~~effect~~ **effective than other** ~~or acceptable safety profile, gain marketing approval and become~~ commercially ~~viable~~ **available alternatives** . **Any failure to develop** ~~Historically, we have financed our~~ **or commercialize a product candidate in our current clinical pipeline could require us to raise additional financing. We might not collect the outstanding money owed to us under the Millipred ® transition service agreement. Aytu Bioscience, Inc. (" Aytu ") managed Millipred ® commercial** operations ~~primarily~~ **until August 31, 2021 pursuant to a transition service agreement with us, which included managing the third - party logistics provider and providing accounting reporting services. Aytu collected cash on behalf of Avalo for revenue generated by sales of Millipred ® from the second quarter of 2020** through ~~public~~ **the third quarter of 2021** and ~~private equity offerings~~ **is obligated to transfer the cash generated by such sales** . ~~We incurred~~ **In the third quarter** of 2021,Avalo finalized its trade and distribution channel to allow it to control third party

distribution and began managing commercial operations at that time.The current transition service agreement allows Aytu to withhold cash of $ ~~2,000,000 until September 30,2022 and $~~ 1,000,000 until December 1,2024 ~~. The~~ **,at which point,the** full amount is due to Avalo ~~on December 1,2024~~ .Adverse economic conditions or financial difficulties of Aytu could impair its ability to remit such payments or could cause Aytu to delay such payments.If Aytu were unable to meet its obligations,it could consider restructuring under the bankruptcy laws,which might **make it difficult for us to collect all or** a ~~net loss~~ **significant portion** of **the cash owed to us by Aytu. Our inability to collect the accounts receivable to our revenues generated by Millipred ® from Aytu could adversely affect our cash flows, financial condition, and results of operations. As of December 31, 2023, Aytu owed us approximately** $ ~~41~~ **0** . 7 million for the year ended December 31,..... and financial condition and our stock price . Risks Related to the Discovery and Development of Our Product Candidates **If we fail to completely and successfully integrate the anti- Il- 1β mAb asset that we recently acquired, we may not realize the anticipated benefits from that acquisition, and our results of operations would be materially and adversely affected. Further, our near- term focus on AVTX- 009 may negatively impact the planned development of our other product candidates. In March 2024, we acquired a Phase 2- ready anti- Il- 1β mAb, which we refer to as AVTX- 009, through the acquisition of AlmataBio, Inc. (" AlmataBio "). We intend for AVTX- 009 to be the Company' s lead asset. In the near- term, we plan to progress the asset for the treatment of hidradenitis suppurativa, however we could explore additional autoimmune indications. While we have experience with anti- inflammatory product candidates and AVTX- 009 is an anti- inflammatory product candidate, AVTX- 009 is a new product candidate for us for which we have no prior experience. Our ability to successfully integrate AVTX- 009 into our operations may be more difficult, costly or time- consuming than we anticipate, or we may not otherwise realize any of the anticipated benefits of this acquisition. Any of the foregoing could adversely affect our future results of operations or could cause our stock price to decline.** If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Before obtaining required approvals from regulatory authorities for the sale of ~~future~~ product candidates, we alone, or with a partner, must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials might not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Our product candidates will require additional clinical and preclinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply on our own or from a third party, expansion of our commercial organization, and substantial investment and significant marketing efforts before we **could** generate any revenues from sales of any of those product candidates approved for marketing. We do not know whether the clinical trials we or our partners may conduct will demonstrate adequate efficacy and safety data resulting in regulatory approval enabling us to market any of our product candidates in any particular country. If later stage clinical trials do not produce favorable results, ~~including reaching favorable results in our Phase 2 PEAK Trial of AVTX- 002,~~ our ability to achieve regulatory approval for any of our product candidates would be adversely impacted, which could cause a sharp decline in our stock price and / or lead to insolvency of the Company. Our product candidates that we intend to commercialize are in early **to mid-** stages of development. If we do not successfully complete ~~preclinical~~ **nonclinical** testing and clinical development of our product candidates or experience delays in doing so, our business may be materially harmed **. Our near- term focus and reliance on AVTX- 009 increases the risk of such exposure** . We have invested a significant portion of our efforts and financial resources in the identification and preclinical and clinical development of product candidates. Our ability to generate significant product revenues will depend on our ability to advance our clinical product candidates towards approval and our preclinical product candidates into clinical development. The outcome of preclinical studies and earlier clinical trials might not predict the success of future clinical trials. Preclinical data and clinical trial data may be susceptible to varying interpretations and analyses, and many product candidates that performed satisfactorily in preclinical studies and early clinical trials have nonetheless failed in later clinical development. Our inability to successfully complete development of any of our product candidates could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales. If we experience delays in clinical testing, we will be delayed in obtaining regulatory approvals and commercializing our product candidates, our costs may increase and our business may be harmed. We do not know whether any clinical trials will begin as planned, whether the design will be revised prior to or during conduct of the study, completed on schedule or conducted at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects. Events which may result in a delay or unsuccessful completion of clinical development include: • Delays in reaching an agreement with or failure in obtaining authorization from the FDA, other regulatory authorities or institutional review boards (" IRBs ") or ethics committees (" ECs ") to commence or amend a clinical trial; • Delays in reaching agreements with the FDA **or other regulatory authorities** regarding requisite trial design or endpoints sufficient to establish a clinically meaningful benefit of our product candidates given there might not be well- established development paths and outcomes; • Inability to agree with the FDA **or other regulatory authorities** on operationally viable endpoints or trial design; • Imposition of a clinical hold or trial termination following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory

authorities, or due to concerns about trial design, or a decision by the FDA, other regulatory authorities, IRBs, ECs or us, or recommendation by a data safety monitoring board, to place the trial on hold or otherwise suspend or terminate clinical trials at any time for safety issues or for any other reason; • Delays in reaching agreement on acceptable terms with prospective contract research organizations (" CROs ") and clinical trial sites; • Deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements; • Failure of our third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines; • Failure to enter into agreements with third parties to obtain the results of clinical trials; • Delays in the importation and manufacture of clinical supply; • Delays in the testing, validation and delivery of the clinical supply of the product candidates to the clinical sites; • For clinical trials in selected subject populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected subjects; • Delays due to the world- wide shortage of animal testing subjects, including monkeys; • Delays in recruiting suitable subjects to participate in a trial; • Delays in having subjects complete participation in a trial or return for post - treatment follow - up; • Delays caused by subjects dropping out of a trial due to side effects or disease progression; • Delays in adding new investigators and clinical trial sites; • Delays resulting from ~~the ongoing COVID- 19 pandemic~~ **national or global health or geopolitical situations** ; • 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; or • Changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials. Any inability by us or our partners to complete clinical development in a timely manner could result in additional costs to us relating to product development and obtaining marketing approval and impair our ability to generate product revenues and commercialization and sales milestone payments and royalties on product sales. If we are unable to enroll appropriate subjects in clinical trials or retain patients in the clinical trials we perform, we will be unable to complete these trials on a timely basis or at all. Identifying and qualifying subjects to participate in clinical trials of our product candidates, and retaining the subjects once qualified, is critical to our **regulatory** success. The timing of our clinical trials depends on the speed at which we can recruit appropriate subjects to participate in testing our product candidates as well as completion of required follow - up periods. If subjects are unwilling to participate in our trials, the timeline for recruiting subjects, conducting trials and obtaining marketing approval of potential products may be delayed. Difficulty or delays in patient recruitment into our trials could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. Many factors affect subject enrollment, including: • The size and nature of the subject population; • The number and location of clinical sites we enroll; • The proximity of subjects to clinical sites; • Perceived risks and benefits of the product candidate under trial; • Competition with other companies for clinical sites or subjects; • The eligibility and exclusion criteria for the trial; • The design of the clinical trial; • ~~Effectiveness of~~ **Doctor, patient and** ~~publicity~~ ~~--~~ **public** ~~for~~ **awareness of** the clinical trials; • Inability to obtain and maintain subject consent; • Ability to monitor subjects adequately during and after the administration of the product candidate and the ability of subjects to comply with the clinical trial requirements; • Risk that enrolled subjects will drop out or be withdrawn before completion; and • Clinicians' and subjects' 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. 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. If we are unable to enroll sufficient subjects in our clinical trials, if enrollment is slower than we anticipate, or if our clinical trials require more subjects than we anticipate, our clinical trials may be delayed or might not be completed. If we experience delays in our clinical trials, the commercial prospects of our product candidates will be harmed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of any of our product candidates. ~~Furthermore, because AVTX- 803 is focused on the treatment of patients with LAD II, a rare genetic disease, our ability to enroll eligible patients in the ongoing Phase 3 trial may be limited or slower than we anticipate in light of the small patient population involved and the specific age range required for this study. In addition, our potential competitors, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, may seek to develop competing therapies, which would further limit the small patient pool available for our studies. Completion of orphan clinical trials may take considerably more time than other trials, sometimes years, depending on factors such as type, complexity, novelty and intended use of a product candidate. As a result of the uncertainties described above, there can be no assurance that we will meet our established timelines for clinical trials involving rare diseases.~~ We may fail to successfully identify, in - license, acquire, develop or commercialize potential product candidates. The success of our business **has in the past and is expected to continue** ~~depends~~ **depend** in part upon our ability to identify and validate new therapeutic targets and identify, develop and commercialize therapeutics, which we may develop ourselves, in - license or acquire from others. Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research efforts may initially show promise in identifying potential therapeutic targets or candidates, yet fail to yield product candidates for clinical development for a number of reasons, including: • Our methodology, including our screening technology, might not successfully identify medically relevant potential product candidates; • Our competitors may develop alternatives that render our product candidates obsolete; • We may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make the product candidates unmarketable; • Our product candidates may cause adverse effects in subjects, even after successful initial toxicology studies, **or not be tolerable,** which may make the product candidates unmarketable; • Other drugs in the same drug class as our ~~products~~ **product candidates** could develop unforeseen adverse effects that could negatively impact development, approval and / or future sales

of our product **candidates** ; • Our product candidates might not be capable of being produced in commercial quantities at an acceptable cost, or at all; • Our product candidates might not demonstrate a meaningful benefit to subjects; • Our potential collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product **candidates** ; and • Our reliance on third party clinical trials may cause us to be denied access to clinical results that may be significant to further clinical development. Additionally, we may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval. Undesirable side effects caused by our product candidates **in clinical trials** could cause us or regulatory authorities to issue a clinical hold and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Should our clinical ~~studies~~ **trials** of our product candidates reveal undesirable side effects, we could suspend or terminate our trials or the FDA or other regulatory authorities as well as IRBs or ECs could order us to suspend or cease clinical trials. The FDA or ~~comparable~~ **other** regulatory authorities could also deny approval of our product candidates for any or all targeted indications or only for a limited indication or patient population or could require label warnings and / or precautions, contraindications, including black box warnings, additional wording regarding adverse reactions, post - market studies, testing and surveillance programs or other conditions including distribution restrictions or other risk management mechanisms under a risk evaluation and mitigation strategy (" REMS "). Drug - related side effects could affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if one or more of our product candidates receives marketing approval, and we or others (regulatory agencies, consumers, etc.) later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: • We may suspend marketing of, or withdraw or recall, such product; • Regulatory authorities may withdraw approvals of such product; • Regulatory authorities may require additional warnings on the label or other label modifications; • Regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product; • Regulatory authorities may require the establishment or modification of a REMS or other restrictions on marketing and distribution, or may require the establishment or modification of a similar strategy that may, for instance, require us to issue a medication guide outlining the risks of such side effects for distribution to patients or restrict distribution of our products and impose burdensome implementation requirements on us; • Regulatory authorities may require that we conduct post - marketing studies; and • We could be sued and held liable for harm caused to subjects or patients. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects. Changes in product candidate manufacturing or formulation may result in additional costs or delay. As product candidates are developed through preclinical studies to late - stage clinical trials towards regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the optimized materials. Such changes may also require additional testing, FDA or other regulatory authorities **'** notification or approval. Similarly, changes in the location of manufacturing or addition of manufacturing facilities may increase our costs and require additional studies and FDA approval. This may require us to ensure that the new facility meets all applicable regulatory requirements, is adequately validated and qualified, and ~~to~~ conduct additional studies of product candidates manufactured at the new location. Any of the above could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay regulatory approval of our product candidates and jeopardize our ability to commence product sales and generate revenue. Biologic products are highly complex and expensive, and if the third- party manufacturers we contract with are unable to provide quality and timely offerings to our clinical trial sites, our clinical trials might be delayed **. Our product candidates AVTX- 009, AVTX- 002 and AVTX- 008 are biologics** . The process of manufacturing biologics and their components is complex, expensive, highly- regulated and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. Furthermore, the development of biologic products involves a lengthy and expensive process with an uncertain outcome, which might require us to incur additional unforeseen costs to complete our clinical trials. Although we are working with third parties to develop reproducible and commercially viable manufacturing processes for our **biologic** product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale- out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. We may make changes as we continue to evolve the manufacturing processes for our **biologic** product candidates for advanced clinical trials and commercialization, and we cannot be sure that even minor changes in these processes will not cause our product candidates to perform differently and affect the results of our ongoing clinical trials, future clinical trials, or the performance of the product once commercialized. In some circumstances, changes in manufacturing operations, including to our protocols, processes,

materials or facilities used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements might lead to delays in our clinical development and commercialization plans for our **biologic** product candidates ~~,~~ and might increase our development costs substantially ~~. Even if we were able to commercialize our products focused on rare genetic diseases, product sales of these products might not justify the cost of development. Because of the small patient population for a rare genetic disease, if pricing is not approved or accepted in the market at an appropriate level for an approved therapeutic product with orphan drug designation, such drug may not generate enough revenue to offset costs of development, manufacturing, marketing, and commercialization despite any benefits received from the rare orphan drug designation, such as market exclusivity, assistance in clinical trial design, or a reduction in user fees or tax credits related to development expense. Furthermore, our estimates regarding potential market size for any rare genetic indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a therapeutic product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects~~ . We face substantial competition and rapid technological change and the possibility that others may discover, develop or commercialize products before or more successfully than us. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early - stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may obtain marketing approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile and better tolerability than our products and these competitors may also be more successful than us in manufacturing and marketing their products. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. There are now and could be future numerous approved therapies for treating the conditions our ~~products~~ **product candidates** seek to address and, consequently, competition in these markets is intense. Many of these approved drugs are or may become well ~~-~~ established therapies or products and widely accepted by physicians, patients and third - party payors. Some of these drugs are or may become branded and subject to patent protection and non - patent regulatory exclusivity, and others are or may become available on a generic basis. Insurers and other third - party payors may also encourage the use of generic products or specific branded products. We expect that any of our product candidates, if approved, would be priced at a significant premium over competitive generic, including branded generic, products, but, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and ~~to~~ be commercially successful. This may make it difficult for us to differentiate ~~our~~ **any approved** product **candidate** from currently approved therapies, which may adversely impact our business strategy. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer. Our products might not achieve adequate market acceptance among physicians, patients, third - party payors and others in the medical community necessary for commercial success. Even if our product candidates have or receive marketing approval, they might not gain adequate market acceptance among physicians, patients and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third - party payors, including government payors, generally, which may be difficult or time - consuming to obtain, may be limited in scope or might not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including: • The efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties; • Prevalence and severity of any side effects of our product candidates; • Relative convenience and ease of administration of our product candidates; • Cost effectiveness of our product candidates; • The claims we may make for our product candidates based on the approved label or any restrictions placed upon our marketing and distribution of our product candidates; • The time it takes for our product candidates to complete clinical development and receive marketing approval; • How quickly and effectively we alone, or with a partner, can market, launch, and distribute any of our product candidates that receive marketing approval; • The ability to commercialize any of our product candidates that receive marketing approval; • The price of our **approved** ~~products~~ **product candidates** , including in comparison to branded or generic competitors and relative to alternative treatments; • Potential or perceived advantages or disadvantages **of our approved product candidates** over alternative treatments; • The ability to collaborate with others in the development and commercialization of new products; • Whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare; • The ability to establish, maintain and protect intellectual property rights related to our product candidates; • The entry of generic versions of any of our approved products onto the market; • The number of products in the same therapeutic class as our product candidates; • The effect of current and future healthcare laws on our drug candidates; • The ability to secure favorable managed care formulary positions **for our approved product candidates** , including federal healthcare program formularies; • The ability to manufacture commercial quantities of any of our product candidates that receive marketing approval; • Acceptance of any of our product candidates that receive marketing approval by physicians and other healthcare providers; and • Potential post - marketing commitments **and post- marketing requirements** imposed on an approved product **candidate** by regulatory authorities, such as patient registries. If any product candidate is approved but does not achieve an adequate level of acceptance

by physicians, hospitals, third - party payors and patients, we might not generate or derive sufficient revenue from that product candidate and might not become or remain profitable. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. **Our near- term focus and reliance on AVTX- 009 increases the risk of such exposure.** Given our limited resources, we have prioritized certain product candidates over others at our management' s discretion. We have also ~~discontinued~~ **de- prioritized** development of certain product candidates. We continually evaluate our capital allocation for each product candidate, and, in the future, may de- prioritize or cancel the development of certain product candidates ~~that currently appear in our milestone chart~~. If the development of our product candidates is unsuccessful or, if successful but the products do not achieve an adequate level of market acceptance, we may no longer have the ability or resources to further develop other product candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications might not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, 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 product candidate. **Our intended near- term focus and reliance on AVTX- 009 increases the risk of this exposure. Our intended near- term focus and reliance on AVTX- 009 exposes us to risk if AVTX- 009 does not perform in clinical trials or receive FDA approval and market acceptance. We acquired AVTX- 009 in March 2024 and intend to focus our resources in the near- term primarily on AVTX- 009. Consequently, our future financial condition and results of operations will be primarily dependent on AVTX- 009. Any setback for or failure of AVTX- 009 during its planned clinical development could cause material delays in and costs to its further development and commercialization. Any such delays or costs could have a material adverse effect on our financial condition and results of operations and could require us to raise more capital, turn to third- party collaborators to continue the development of AVTX- 009 or cease operations. In addition, our near- term focus on AVTX- 009 may negatively impact the planned development of our other product candidates. While we believe that we have adequately completed our due diligence on AVTX- 009, drug development is unpredictable and we could encounter toxicity, safety, adverse reactions or other concerns with AVTX- 009 as we continue its development. We will need to negotiate clinical trial and clinical supply arrangements with third parties for the development of AVTX- 009. If we experience difficulty in those negotiations, it could delay the development of AVTX- 009 as well as add to the expected cost of that development. We might not be successful in negotiating such arrangements on acceptable terms or at all. The development of AVTX- 009 will be subject to all of the risks inherent in drug development that we face with our current product candidates. There can be no assurances that we will successfully develop AVTX- 009.** Risks Related to Regulatory Approval of Our Product Candidates The marketing approval processes of the FDA and ~~comparable~~ other regulatory authorities are lengthy, time - consuming, costly and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business. The time required to develop and to obtain approval from regulatory authorities to market a new drug is unique to each product. It typically takes many years in nonclinical and clinical development and depends upon numerous factors **. In addition** , **regulatory** guidance ~~from~~ **, laws and regulations as well as interactions with** regulatory authorities **may change the course of development** ~~. In addition, approval policies, regulations or~~ **for a product candidate. Further,** the type and amount of **preclinical and** clinical data necessary to gain approval may change during the course of ~~a~~ product ~~candidate~~ **candidates** ' ~~s clinical~~ development and may vary among countries. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval. ~~Moreover, the submission~~ **Submission** of an NDA or BLA ~~for products that have not been granted ODD requires a payment of a significant application fee under the Prescription Drug User Fee Act upon submission. Any supplemental submission~~ to **the FDA** ~~an NDA or BLA~~ (i. e., for new indications, dosing regimen, etc.) **requires** ~~which contained clinical data include~~ an application fee. The filing of an NDA or BLA for **any of** our product candidates ~~that do not have ODD~~ may be delayed due to our lack of financial resources to pay such user fee. Our product candidates could fail to receive regulatory approval from the FDA or a **other** ~~comparable foreign~~ regulatory ~~authority~~ **authorities** for many reasons, including: • The FDA or **other** ~~comparable foreign~~ regulatory authorities may disagree on the design or conduct of our key Phase 2 and **pivotal phase** 3 clinical trials, including the **overall study design** ~~methodology used in our trial (s)~~, primary and secondary endpoints, number of patients, statistical analysis plan, or our proposed product indication. For instance, the FDA may find that the **study** designs ~~that~~ we are utilizing in a planned clinical trial ~~does~~ **do** not support an adequate and well - controlled study ~~or~~ **supportive of** approval. The FDA also might not agree with the **proposed** ~~various disease or~~ quality of life scales and other evaluation tools that we may use in a clinical trial to assess the efficacy of a product candidate; • The FDA or **other** ~~comparable foreign~~ regulatory authorities may disagree with our development plans, specifically the number of studies and types of studies planned to support approval for each product and indication; • Our failure to demonstrate to the satisfaction of the FDA or ~~comparable~~ **other** regulatory authorities that a product candidate is safe and effective for each proposed indication; • Our clinical trials may fail to meet statistical significance required for a positive study; • We may fail to demonstrate that a product candidate' s benefits outweigh its risks; • The FDA or **other** ~~comparable foreign~~ regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • Data collected from clinical trials of our product candidates may be insufficient to support the submission of a marketing application, other submission or to obtain marketing approval, and the FDA or **other** ~~comparable foreign~~ regulatory authority may require additional studies to show **a** product candidate is safe and / or effective; • We may fail to obtain approval of the manufacturing processes or facilities of third - party manufacturers with whom we contract for clinical and commercial supplies; or • There may be changes in ~~the approval policies or~~ **precedence, regulatory guidance, laws and** regulations that render our

preclinical and clinical data insufficient for approval. The FDA or **other** ~~comparable foreign~~ regulatory authority may require more information, including additional preclinical or clinical studies to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain approval to market our product 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 or all of our product candidates for fewer or more limited indications than we request, may require that contraindications, warnings or precautions be included in the product labeling, including a black - box warning, may grant approval with a requirement of post - marketing clinical trials or other post - market requirements, **or post- marketing commitments** or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain marketing approval to commercialize a product candidate or the approval may be for a narrower indication than we expect. We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in clinical trials, regulatory agencies might not complete their review processes in a timely manner, or we might not be able to obtain marketing approval. Additional delays may result if the FDA **or other regulatory authority** , **or** an FDA Advisory Committee ~~or other regulatory authority~~ recommends non - approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Further, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Regulatory authorities may approve a product candidate for fewer or more limited indications than requested, may impose significant limitations in the form of narrow indications, warnings, including black - box warnings, precautions or contra - indications with respect to conditions of use, additional adverse reactions information or may grant approval subject to the performance of post - marketing clinical trials or other post - marketing requirements, including a REMS. Our drugs, if approved, may be required to carry warnings comparable to this and other class - wide warnings. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Even if ~~we were to obtain approval for our product candidates with the Rare Pediatric Disease Designation, the Rare Pediatric Disease Priority Review Voucher Program may no longer be in effect at the time of such approval or we might not be able to capture the value of the Rare Pediatric Disease Priority Review Voucher Program. Rare pediatric disease designation (" RPDD ") is granted by the FDA in the case of serious or life - threatening diseases affecting fewer than 200, 000 people in the United States in which the serious or life - threatening manifestations are primarily in individuals 18 years of age and younger. Upon request, the FDA has the authority to grant a Rare Pediatric Disease PRV for drug and biologic applications approved to prevent or treat a rare pediatric disease and deemed eligible for priority review, among other criteria. The Consolidated Appropriations Act, 2021 was signed into law on December 27, 2020. As part of this legislation, the FDA Rare Pediatric Disease Designation Program has been extended through 2024, permitting the issuance of PRVs through September 30, 2024 for drugs and biologics receiving FDA approval before September 30, 2026. AVTX- 006, AVTX- 801, AVTX- 802 and AVTX- 803 are each potentially eligible for a Rare Pediatric Disease PRV upon FDA approval of each drug, but there is no guarantee that PRVs will be granted. Moreover, any PRV may be sold or transferred an unlimited number of times. Although PRVs may be sold or transferred to third parties, there is no guarantee that we will be able to realize any value if we receive and were to sell a PRV. We may pursue government funding for products we are developing, including those we are developing for the treatment of COVID- 19 ARDS. If we do not apply for or are unable to obtain such government funding, we might be unable to develop certain product candidates. While we have not yet received U. S. government funding, we may apply to receive funding from the U. S. government for products we are developing, including those we are developing for the treatment of COVID- 19 ARDS. If applied for and granted, the government funding could be instrumental to certain product developments. However, there can be no assurances that we will apply for such government funding, or that if we do apply, we will receive such government funding. If we do not receive government funding, we might not be able to develop certain products, which could adversely impact our business, financial condition and results of operations. Even if~~ our product candidates receive marketing approval, we will still be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to administrative sanctions or penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products. Even if we obtain marketing approval for a product candidate, we would be subject to ongoing requirements by the FDA and other regulatory authorities governing the ~~manufacture~~ **manufacturing** , quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and annual reporting of safety and other post - market information. The FDA and other regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or other regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product' s indicated uses or marketing, or impose ongoing requirements for potentially costly post - approval studies or post - market surveillance. In addition, any marketing approvals that we obtain for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for potentially costly post - marketing testing and other requirements, including Phase 4 clinical trials, imposition of a REMS and surveillance to monitor the safety and efficacy of the product candidate. In addition, manufacturers of drug products and their facilities, including contracted facilities, are subject to periodic inspections by the FDA and other regulatory authorities for compliance

with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with the facility where the product is manufactured, we may be subject to reporting obligations and a regulatory agency may impose restrictions on that product, the manufacturing facility, us, or our suppliers, including requesting recalls or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, our contractors, the manufacturing facilities for our product candidates or others working on our behalf fail to comply with applicable regulatory requirements, either before or after marketing approval, a regulatory agency may: • Issue Warning Letters, Untitled Letters, or **FDA** Form 483s, all of which document compliance issues identified by **the** FDA; • Mandate modifications to promotional materials or labeling, or require us to provide corrective information to healthcare practitioners; • Require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; • Seek an injunction or impose civil or criminal penalties or monetary fines, restitution or disgorgement, as well as imprisonment; • Suspend or withdraw marketing approval; • Suspend or terminate any ongoing clinical studies; • Refuse to approve pending applications or supplements to applications filed by us; • Debar us from submitting marketing applications, exclude us from participation in federal healthcare programs, require a corporate integrity agreement or deferred prosecution agreements, debar us from government contracts and refuse future orders under existing contracts; • Suspend or impose restrictions on operations, including restrictions on marketing, distribution or manufacturing of the product, or the imposition of costly new manufacturing requirements or use of alternative suppliers; or • Seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall. The occurrence of any event or penalty described above may inhibit our ability to continue our development programs, commercialize our products and generate revenue. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA ~~,~~ **and** ~~the~~ **other federal agencies** ~~Department of Justice, the Department of Health and Human Services' Office of Inspector General~~ , state attorneys general ~~, members of Congress~~ and the public. While the FDA does not restrict physicians from prescribing approved drugs for uses outside of the drugs' approved labeling, known as off - label use, pharmaceutical manufacturers are strictly prohibited from promoting and marketing their products for such uses. Violations, including promotion of products for off - label uses, are subject to enforcement letters, inquiries, investigations, civil and criminal sanctions by the government, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and refusal of future orders under existing contracts, and exclusion from participation in federal healthcare programs. Additionally, other regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States. In the United States, engaging in the impermissible promotion of ~~our~~ **any** products for off - label uses can also subject ~~us~~ **a company** to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, debarment from government contracts and refusal of future orders under existing contracts, deferred prosecution agreements, and corporate integrity agreements with governmental authorities that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in any fines or settlement funds. If the government does not intervene, the individual may proceed on his or her own. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, such as settlements regarding certain sales practices promoting off - label drug uses involving significant fines. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects. The FDA' s **or other regulatory authorities** policies may change, and additional government **guidance, laws and** regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion of our product 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. If we are unable to obtain, or are delayed in obtaining, state regulatory licenses for the distribution of our products, we would not be able to sell our product candidates in such states. **Most** ~~The majority of~~ states require manufacturer and / or wholesaler licenses for the sale and distribution of drugs into that state. The application process is complicated, time consuming, costly and requires dedicated personnel or a third party to oversee and manage. If we are delayed in obtaining these state licenses, or denied the licenses, even with FDA approval, we would not be able to sell or ship product into that state which would adversely affect our sales and revenues. We **intend** ~~may in the future choose~~ to conduct clinical trials for certain of our product candidates at sites outside the United States, and the FDA might not accept data from trials conducted in such locations. **We intend** ~~Currently all of our clinical trials are conducted in the United States, however in the future, we may in the future choose~~ to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States and the data must be applicable to the U. S. population and medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U. S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not

accept the data from any of our clinical trials that we ~~determine~~ **decide** to conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time - consuming and delay or permanently halt our development of the product candidate. ~~Any~~ **In addition, any** clinical trials outside of the United States might ~~also~~ be subject to delays and risks surrounding geopolitical events. Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States, which would limit our market opportunities and adversely affect our business. In order to market and sell our products in other jurisdictions, we must be granted approval and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country might not be accepted by regulatory authorities in other countries. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We might not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Also, regulatory approval for any of our product candidates may be withdrawn. The failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline. Risks Related to the Commercialization of Our Product Candidates We might not be successful in our efforts to develop and commercialize our product candidates. Our continued development of our product candidates will be dependent on receiving positive data that, in our judgment, merits advancing such programs. Even if we are successful in continuing to build and expand our pipeline, the ~~potential~~ product candidates that we identify might not be suitable for clinical development and commercialization, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to ~~be products that will~~ receive marketing approval and achieve market acceptance. Similarly, even if the FDA accepts our INDs, there is no guarantee that we will be successful in our efforts to advance our product candidates **through development** ~~. Once commercialized~~ , ~~some of our~~ **or** ~~products may face significant competition from non - prescription competition and consumer substitution, and our operating results will suffer~~ if ~~we fail to compete effectively. We may be subject to non - prescription competition and consumer substitution for certain of our non- core pipeline assets. For example, AVTX- 803, our rare genetic disease product candidate, is an ultra - pure formulation of L- fucose. This formulation is a naturally occurring substance contained in various foods, including dairy products and fruit. If~~ approved ~~by the FDA and commercially available~~ , ~~we cannot be sure physicians will view the pharmaceutical grade purity and tested safety of AVTX- 803 as made under eGMP conditions as opposed~~ to **commercialization** ~~the naturally occurring formulations and dietary supplements. In addition, to the extent the net price of AVTX- 803, after insurance and offered discounts, is significantly higher than the prices of commercially available formulations marketed by other companies as dietary supplements (through that lack of coverage by insurers or otherwise), physicians and pharmacists may recommend these commercial alternatives instead of writing or filling prescriptions for AVTX- 803, or patients may elect on their own to take commercially available supplements. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we might receive from the sale of AVTX- 803 due to reduced market acceptance~~ . If we obtain approval to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we would be subject to additional risks related to entering into international business relationships, including: • Different regulatory requirements for approval **, advertising and promotion** of drugs in foreign countries; • Challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • Foreign reimbursement, pricing and insurance regimes; • Unexpected changes in tariffs, trade barriers and regulatory requirements; • Economic weakness, including inflation, or political instability in particular foreign economies and markets; • Compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • Foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; • Foreign taxes; • Difficulties staffing and managing foreign operations; • Workforce uncertainty in countries where labor unrest is more common than in the United States; • Potential liability under the FCPA or comparable foreign regulations; • Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • Business interruptions resulting from geopolitical actions, including war and terrorism, ~~or~~ natural disasters **,** including earthquakes, typhoons, floods and fires **, or pandemics** . These and other risks associated with any future international operations could materially adversely affect our ability to attain or maintain profitable operations. Even if we commercialize any of our product candidates, these products may become subject to unfavorable third - party coverage and reimbursement policies, healthcare reform initiatives, or pricing regulations, any of which could negatively impact our business. Our ability to commercialize any ~~products~~ **product candidates** successfully will depend in part on the extent to which coverage and adequate reimbursement for these ~~products~~ **product candidates** will be available from government authorities, private health insurers, health maintenance organizations and other entities. These third - party payors

determine which medications they will cover and establish reimbursement levels, and increasingly attempt to control costs by limiting coverage and the amount of reimbursement for particular medications. Several third - party payors ~~are requiring~~ **require** ~~that~~ drug companies **to** provide them with predetermined discounts from list prices, ~~are using~~ **and use** preferred drug lists to leverage greater discounts in competitive classes ~~and are challenging the prices charged for drugs~~. In addition, federal programs impose penalties on drug manufacturers in certain instances, in the form of mandatory additional rebates and / or discounts, which can be substantial, and could impact our ability to raise commercial prices. We cannot be sure that coverage and reimbursement will be available for any product **candidate** that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or available only to limited levels, we might not successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates for a drug may vary according to the clinical setting in which it is used and may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls and private entities obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors, and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government - funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition. Moreover, the regulations that govern pricing, coverage and reimbursement for new drug products abroad vary widely from country to country. Current and future U. S. or foreign legislation may significantly change the pricing, coverage and reimbursement in ways that could involve additional costs and cause delays in obtaining approvals. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval. Product liability lawsuits against us could cause us to incur substantial liabilities and ~~to~~ limit commercialization of any product candidates that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and related to the commercial sale of any approved products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our ~~products or~~ product candidates **or any approved product**. For example, we may be sued if any product **candidate** we **test or, if approved,** sell 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 claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • Decreased demand for any product candidates or approved products; • Termination of clinical trial sites or entire trial programs; • Injury to our reputation and significant negative media attention; • Withdrawal of clinical trial participants; • Significant costs to defend the related litigation; • Substantial monetary awards to trial subjects or patients; • Loss of revenue; • Product recalls, withdrawals or labeling, marketing or promotional restrictions; • Diversion of management and scientific resources from our business operations; • The inability to commercialize any ~~products~~ **product candidates** that we may develop; and • A decline in our stock price. We currently hold product and clinical trial liability insurance coverage, but it might not adequately cover all liabilities that we incur. We might not be able to maintain clinical trial insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We also maintain insurance coverage for our commercially available products, which might not adequately cover all liabilities that we may incur. We might not be able to maintain insurance coverage for our product candidates and our approved products at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A product liability claim or series of claims brought against us, whether or not successful, but particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our reputation and business. If, in the future, we are unable to **establish** ~~grow our own~~ sales, ~~or establish~~ marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we might not be successful in commercializing our product candidates. We do not currently have a ~~robust~~ sales or marketing infrastructure. To develop our internal sales, distribution and marketing capabilities for ~~new~~ product candidates, we will have to invest significant ~~amounts of~~ financial and management resources, some of which will be committed prior to any confirmation that any ~~new~~ product candidates will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including: • Our inability to recruit and retain adequate numbers of effective sales and marketing personnel; • Inability of marketing personnel to develop effective marketing materials; • The inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the clinical benefits of our products to achieve market acceptance; • The lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; • The costs associated with training sales personnel on legal compliance matters and monitoring their actions; • Liability for sales personnel failing to comply with applicable legal requirements; and • Unforeseen costs and expenses associated with creating an

independent sales and marketing organization. Where and when appropriate, we may elect to utilize contract sales forces or strategic partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we might not be successful in entering into arrangements with third parties to sell, market and distribute our product 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 these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. Such third parties may also not comply with the applicable regulatory requirements, which could potentially expose us to regulatory and legal enforcement actions. Risks Related to Our Dependence on Third Parties We rely on third parties to conduct ~~, supervise~~ and monitor our clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we might not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. We rely upon third - party CROs to monitor and manage data for our clinical programs. We rely on these parties for execution of our clinical trials and, while we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is 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, our clinical trial sites, and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA **that govern clinical trials. Similar requirements are imposed by** ~~, the Competent Authorities of the Member States of the European Economic Area and~~ comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we, any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or **other** ~~comparable foreign~~ regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, if at all. In addition, we are required to report certain financial interests of our third - party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by principal investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests, or significant payments of other sorts. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, we must conduct our clinical trials with product produced under applicable cGMP requirements **for drug manufacturing** . Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the marketing approval process. Our CROs and clinical trial ~~sites~~ **site personnel** are not our employees, and, except for remedies available to us under our agreements with such CROs and clinical trial sites, we cannot control whether ~~or not~~ they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. These CROs and clinical trial sites may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If CROs or clinical trial sites do not successfully carry out their contractual duties or obligations or 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, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we might not be able to obtain marketing approval for or successfully commercialize our product candidates or we may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third - party service providers in the future, our business may be adversely affected. Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations. We use third parties to manufacture all of our product candidates. This may increase the risk that we will not have sufficient **clinical or commercial** quantities of our product candidates ~~to conduct our clinical trials~~ or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates. We do not own or operate, and have no plans to establish, any manufacturing facilities for our product candidates. We have limited personnel with experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently outsource all manufacturing of our product candidates to third parties typically without any guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Any delays in obtaining adequate supplies with respect to our product candidates may delay the development or commercialization of our other product candidates. In addition, we do not currently have agreements with all third - party manufacturers for the long - term commercial supply of our product candidates. We may be unable to enter agreements for commercial supply with third - party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements, the various manufacturers of each product candidate will likely be single source suppliers to us for a significant period of time. The facilities used by our contract manufacturers to manufacture our product candidates ~~must~~ **may** be inspected by the FDA after we submit an NDA or BLA **and prior to approval thereof** . While we are ultimately responsible

for the manufacture of our product candidates, other than through our contractual arrangements, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for manufacture of both active drug substances and finished drug products for clinical supply and eventually for commercial supply, if we receive regulatory approval. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. Failure of our contract manufacturers to comply with the applicable regulatory requirements may also subject us to regulatory enforcement actions. In addition, other than through our contractual agreements, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or other regulatory authorities do not approve these facilities for the manufacture of our product candidates or if ~~it withdraws any such~~ approval **is withdrawn** in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Reliance on third - party manufacturers subjects us to risks that would not affect us if we manufactured the product candidates ourselves, including: • Reliance on the third parties for regulatory compliance and quality assurance; • The possible breach of the manufacturing agreements by the third parties because of factors beyond our control; • The possible misappropriation of our proprietary information, including trade secrets and know - how; • The possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on our own business priorities; • The disruption and costs associated with changing suppliers, including additional regulatory filings. • Failure to satisfy our contractual duties or obligations; • Inability to meet our product specifications and quality requirements consistently; • Delay or inability to procure or expand sufficient manufacturing capacity; • Manufacturing and / or product quality issues related to manufacturing development and scale - up; • Costs and validation of new equipment and facilities required for scale - up; • Failure to comply with applicable laws, regulations, **guidance** and standards, including cGMP and similar foreign standards; • Deficient or improper record - keeping; • Contractual restrictions on our ability to engage additional or alternative manufacturers; • 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; • Reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we would be unable to manufacture and sell our product candidates or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms; • Lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier; • Lack of access or licenses to proprietary manufacturing methods used by third - party manufacturers to make our product candidates; • Operations of our third - party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or regulatory sanctions related to the manufacturer; • Carrier **and import** disruptions or increased costs that are beyond our control; and • Failure to deliver our products under specified storage conditions and in a timely manner. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. In addition, the manufacture of biologics requires significant expertise, including the development of advanced manufacturing techniques and process controls. The process is highly complex and we may encounter difficulties in production. These issues may include difficulties with production costs, production yields and quality control, including stability of the product candidate. Further, our product candidates may require new or specialized manufacturing with limited third- party manufacturers available to provide these services. The occurrence of any of these problems could significantly delay our clinical trials or the commercial availability of our product candidates. If our existing third - party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to advance our clinical trials or to meet commercial demand while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop **and commercialize** our product candidates and compete effectively. Our suppliers are subject to regulatory requirements covering manufacturing, testing, quality control, manufacturing, and record keeping relating to our product 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 to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions. **National** ~~The COVID- 19 pandemic has limited in the past,~~ and ~~in the future~~ **global health or geopolitical situations** could **have** ~~again limit, the available capacity of these manufacturers for~~ a **negative adverse impact** ~~variety of reasons. These same risks apply to any future pandemic were one~~ - **on** ~~to emerge~~ **our suppliers, which could impede the development or commercialization of our product candidates** . We might not succeed in establishing and maintaining development collaborations, which could adversely affect our ability to develop and commercialize product candidates. A part of our strategy is to enter into product development collaborations in the future, including collaborations with major biotechnology or pharmaceutical companies for the development or commercialization of our current and future product candidates. We also face significant competition in seeking appropriate development partners and the negotiation process is time - consuming and complex. We might not succeed in our efforts to establish development collaborations or other alternative arrangements for any of our existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and / or third parties might not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Furthermore, any collaborations that we enter into might not be successful. The success of our development

collaborations will depend heavily on the efforts and activities of our collaborators. Our relationship with any future collaborations may pose several risks, including the following: • Collaborators have significant discretion in determining the amount and timing of the efforts and resources that they will apply to these collaborations; • Collaborators might not perform their obligations as expected; • The nonclinical studies and clinical trials conducted as part of these collaborations might not be successful; • Collaborators might not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on nonclinical study or clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities; • Collaborators may delay nonclinical studies and clinical trials, provide insufficient funding for nonclinical studies and clinical trials, stop a nonclinical study or clinical trial or abandon a product candidate, repeat or conduct new nonclinical studies or clinical trials or require a new formulation of a product candidate for nonclinical studies or clinical trials; • Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • Product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; • A collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval might not commit sufficient resources to the marketing and distribution of any such product candidate; • Disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time consuming and expensive; • Collaborators might not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • Disputes may arise with respect to the ownership or inventorship of intellectual property developed pursuant to our collaborations; • Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • The terms of our collaboration agreement may restrict us from entering into certain relationships with other third parties, thereby limiting our ~~options~~ **opportunities** ; and • Collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. Even if we are successful in our efforts to establish development collaborations, the terms that we agree upon might not be favorable to us and we might not be able to maintain such development collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into development collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market. Additionally, collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation. If we fail to establish and maintain additional development collaborations related to our product candidates: • The development of certain of our ~~current or future~~ product candidates may be terminated or delayed; • Our cash expenditures related to development of certain of our ~~current or future~~ product candidates would increase significantly and we may need to seek additional financing, which might not be available on favorable terms, or at all; • We may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for ~~Which~~ **which** we have not budgeted; • We would bear all of the risk related to the development of any such product candidates; • We may have to expend unexpected efforts and funds if we are unable to obtain the results of third - party clinical trials; and • The competitiveness of any product candidate that is commercialized could be reduced. Risks Related to Intellectual Property As appropriate, we intend to seek all available periods of regulatory exclusivity for our product candidates. However, there is no guarantee that we will be granted these periods of regulatory exclusivity or that we will be able to maintain these periods of exclusivity. The FDA grants product sponsors certain periods of regulatory exclusivity, during which the agency might not approve, and in certain instances, might not accept, certain marketing applications for competing drugs. For example, product sponsors may be eligible for five years of exclusivity from the date of approval of a new chemical entity, twelve years of exclusivity from the date of approval of a biologic, seven years of exclusivity for drugs that are designated to be orphan drugs, and / or a six - month period of exclusivity added to any existing exclusivity period or patent life for the submission of FDA requested pediatric data. While we intend to apply for all periods of market exclusivity that we may be eligible for, there is no guarantee that we will receive all such periods of market exclusivity. Additionally, under certain circumstances, the FDA may revoke the period of market exclusivity. As a result, there is no guarantee that we will be able to maintain a period of market exclusivity, even if granted ~~. In the case of ODD, other benefits, such as tax credits and exemption from user fees may be available. If we are not able to obtain or maintain orphan drug designation or any period of market exclusivity to which we may be entitled, we will be materially harmed, as we will potentially be subject to greater market competition and may lose the benefits associated with programs~~ . If we are unable to obtain or maintain intellectual property rights, or if the scope of patent protection is not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and we might not be able to compete effectively in our market. Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties' rights to patent portfolios. The patent prosecution process is expensive and time - consuming, and we and our current or future

licensors, licensees or collaborators might 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 licensors, licensees or collaborators 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. Moreover, in some circumstances, we might 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 and are reliant on our licensors, licensees or collaborators. Therefore, these patents and applications might not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators 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. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications might not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Furthermore, 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 owned and licensed patent portfolio might not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, might not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If we breach the license and development agreements related to our product candidates, we could lose the ability to develop and commercialize our product candidates. Our commercial success depends upon our ability, and the ability of our licensors and collaborators, to develop, manufacture, market and sell our product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates or face other penalties under these agreements. We are party to the following agreements for our ~~core~~ programs: **• The Lilly License Agreement (related to AVTX- 009); • The Leap Agreement (related to AVTX- 009);** • The KKC License Agreement (related to AVTX- 002); • The Children' s Hospital of Philadelphia License Agreement (related to AVTX- 002); and • The SBP License Agreement (related to AVTX- 008). If we fail to comply with the obligations under these agreements, including payment terms, our licensors may have the right to terminate any of these agreements, in which event we might not be able to develop, market or sell the relevant product candidate. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements, which might not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs. Any of these occurrences may harm our business, financial condition and prospects significantly. We may be required to make significant payments in connection with our license and development agreements. We are party to license and development agreements with various third parties. For example, for our ~~core~~ programs we are party to the **Lilly License Agreement, Leap Agreement,** KKC License Agreement and the SBP License Agreement. We may be required to make significant payments in connection with our license and development agreements including (but not limited to): **• Under the Lilly License Agreement, we will incur development costs for AVTX-009 and are required to make significant payments in connection with the achievement of specified development and regulatory milestones. Additionally, upon commercialization, we are obligated to pay Lilly sales- based milestones and royalties; • For AVTX- 009, we are subject to additional sales- based milestones payable to Leap Therapeutics, Inc.; • For AVTX- 009, we are subject to additional contingent development milestones payable to the former AlmataBio stockholders;** • Under the KKC License Agreement, we will incur development costs for AVTX- 002 and are required to make significant payments in connection with the achievement of specified development and regulatory milestones. Additionally, upon commercialization, we are obligated to pay KKC sales- based milestones and royalties; • In addition to the KKC License Agreement, for AVTX- 002 we are subject to additional royalties upon commercialization of up to an amount of less than 10 % of net sales; and • Under the SBP License Agreement, we will incur development costs for AVTX- 008 and are required to make significant payments in connection with the achievement of specific development and regulatory milestones. Additionally, upon commercialization, we are obligated to pay Sanford Burnham Prebys sales- based milestone payments and royalties. If the obligations become due under the terms any of these agreements, we might not have sufficient funds available to meet our

obligations and our development efforts may be negatively impacted. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non - compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the ~~USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The~~ U. S. Patent and Trademark Office (" USPTO ") **, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO** and various foreign governmental patent agencies require compliance with ~~a number of~~ procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can **often** ~~in many cases~~ be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non - compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non - payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time - consuming and unsuccessful and have a material adverse effect on the success of our business. Third parties may infringe on our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors or collaborators to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time - consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Accordingly, despite our or our licensors' or collaborators' efforts, we or our licensors or collaborators might not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws might not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that we or our licensors' or collaborators' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly. Third party pre - issuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other pre - issuance or post - grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non - exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. 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 during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our warrants or shares of our common stock. Our inability to protect our confidential information and trade secrets would harm our business and competitive position. In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know - how, technology and other proprietary information, to maintain our competitive position. Though we seek to protect these trade secrets, in part, by entering into non - disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, as well as by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we might 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 both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully and without breach of a confidentiality obligation obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal

complexity, and obtaining and enforcing biopharmaceutical patents is costly, time - consuming, and inherently uncertain. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' 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 decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. In addition, the America Invents Act includes the first - to - file provisions, which increases the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. Future changes in patent law could have a material adverse effect on our business and financial condition. We might not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or collaborators might not be able to prevent third parties from practicing our and our licensors' or collaborators' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' or collaborators' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' or collaborators' technologies in jurisdictions where we or our licensors or collaborators have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we and our licensors or collaborators have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' or collaborators' patents or other intellectual property rights might not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or marketing of competing products in violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators might not prevail in any lawsuits that we or our licensors or collaborators initiate and the damages or other remedies awarded, if any, might not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. Certain countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Risks Related to Legal Compliance Ongoing changes to healthcare laws and regulations may increase the difficulty **of** and ~~cost~~ **costs** associated with commercializing our products and may affect the prices we are paid for those products. The Healthcare sector is heavily regulated in the United States and abroad **. New** ~~, and new~~ laws, regulations, judicial decisions and / or payment and coverage policies — or new interpretations of such laws, regulations, decisions or policies — could negatively impact our business, operations, and financial condition. The United States federal government, state governments, and foreign governments have shown significant and increasing interest in cost- containment initiatives intended to limit the growth of healthcare costs, including without limitation price controls, restrictions on reimbursement, requirements for substitution of generic products for branded prescription drugs, prior authorization requirements, and increased copays and cost shares for beneficiaries. The Patient Protection and Affordable Care Act increased federal oversight of private health insurance plans and included a number of provisions designed to reduce Medicare expenditures and the cost of health care generally, to reduce fraud, waste, abuse and to provide access to increased health coverage. Since its enactment, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the Affordable Care Act that have resulted in profound changes to the law, and efforts to reform the ACA and healthcare sector are ongoing. For example, the Affordable Care Act' s " individual mandate " was repealed in 2019. ~~The~~ **In addition, the former president** Trump **' s** administration took executive actions to delay implementation of portions of the Affordable Care Act. The Biden administration has ~~signaled that it plans to build~~ **built** on the Affordable Care Act and **has worked** to expand the number of people who are ~~presently~~ eligible for subsidies under the law.

Also, on January 28, 2021, President Biden issued an Executive Order directing federal agencies to reconsider rules and other policies that limit Americans' access to health care and to consider actions that will protect and strengthen that access. **The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules limiting access to healthcare, including without limitation reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. The implementation of the ACA is ongoing, and the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.** We expect further reform to the Affordable Care Act, to the Medicare and Medicaid programs and other state and federal healthcare programs, and to the regulation of the healthcare sector generally. Some of these changes could have a material adverse effect on our business and operations. Ongoing and future healthcare reform measures may result, for instance, in more rigorous clinical coverage criteria limiting when our product (s) may be covered and in additional downward pressure on the price that we receive for our product and product candidates, if approved, and could harm our future revenues. **Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products approved for marketing in the United States by the FDA will depend, in part, on the extent to which products are covered by third- party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations.** The **process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third- party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U. S. government, state legislatures and foreign governments have shown significant interest in implementing cost- containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of the product, which are separate and apart from the costs required to obtain FDA or other comparable regulatory approvals based on the product' s safety and effectiveness. A payor' s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third- party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development. In Europe and other countries outside of the United States, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed to. Some countries may require the completion of additional studies that compare the cost- effectiveness of a particular product candidate to currently available therapies. In some countries, cross- border imports from low- priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements. As stated above, the** prices of prescription drugs have been the subject of considerable debate and regulation in the United States and abroad. Recent years have seen several U. S. congressional inquiries into prescription drug pricing, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drugs and related products. Legislative efforts at cost containment in healthcare programs are ongoing. For example, **President Biden signed an Executive Order on July 9, 2021, affirming the administration' s policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower- cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA' s implementing regulations. In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. On August 16, 2022** the Inflation Reduction Act of 2022 ~~includes several provisions~~ **was passed, which among other things, allows CMS** to ~~lower prescription~~ **negotiate prices for certain single- source drugs and biologics reimbursed under Medicare Part B and Part D, beginning in 2026 with ten high- cost drugs paid for by Medicare Part D, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects** drug ~~costs~~ **manufacturers to civil monetary penalties and a potential excise tax** for **failing to comply with the legislation by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The legislation also caps** Medicare ~~patients and reduce~~ **beneficiaries' annual out- of- pocket** drug ~~spending by~~ **expenses at $ 2, 000. The effect of Inflation Reduction Act of 2022 on our business and** the ~~federal government~~ **healthcare industry in**

general is not yet known . Future legislation and regulation may result in further changes in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug formularies and other health care programs. These measures could reduce the ultimate demand for our product **candidates** ~~and potential products~~ , if approved, and / or may constrain the prices that we are able to charge for such products. We expect that state and federal healthcare program reform measures will be ongoing, any of which could limit the amounts that we receive for our ~~products~~ **product candidates** ~~and services or~~ , result in reduced demand for our product ~~or product~~ candidates **, if approved** . Our relationships with commercial and government customers, healthcare providers, third- party payors, and others are subject to applicable anti- kickback, fraud and abuse, transparency and other healthcare related laws, regulations and requirements, which could expose us to criminal and civil liability, exclusion from participation in federal healthcare programs, contractual damages and consequences, reputational harm, administrative burdens, and diminished profits and future earnings. ~~Our business and our relationships with customers, physicians, and third- party payors are subject, directly and indirectly, to federal~~ **Federal** and state health care fraud and abuse laws and regulations ~~. These laws also~~ apply to the healthcare providers and third- party payors who play a primary role in the recommendation and prescription of **drug** ~~our commercially- available~~ products. These laws constrain the business or financial arrangements and relationships through which we **would** market, sell, and distribute our ~~products~~ **product candidates** and will impact, among other things, **any of** our ~~proposed~~ **future** sales, marketing and educational programs. There are also laws, regulations, and requirements applicable to the award and performance of federal grants and contracts **. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti- kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below** . Actions resulting in violations of these laws regulations and requirements may result in civil and criminal liability, damages and restitution, as well as exclusion from participation in federal healthcare programs, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts or contractual damages, reputational damage, and other consequences. Restrictions under applicable federal and state healthcare related laws and regulations include but are not limited to the following: • The federal Anti- Kickback Statute, which prohibits any person from, among other things, knowingly and willfully soliciting, offering, receiving or providing anything of value, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program; • The Veterans Health Care Act, which requires manufacturers of covered drugs to offer them for sale on the Federal Supply Schedule and requires compliance with applicable federal procurement laws and regulations; • 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 false claims act, which imposes liability and significant civil penalties on any person who submits or causes to be submitted a claim to the federal government that he or she knows (or should know) is false; • Federal transparency laws, including the federal Physician Sunshine Act (PSA), which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services (CMS), information related to payments or other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members; and • Analogous or similar state, federal, and foreign laws, regulations, and requirements 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 and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the applicable 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; laws, regulations, and requirements applicable to the award and performance of federal contracts and grants and state, federal and foreign laws that govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts. ~~Efforts~~ **The laws and regulations applicable** to ~~ensure that~~ our business ~~arrangements~~ **are complex, changing and often subject to varying interpretations. As a result, we may not be able to adhere to all applicable laws**

and regulations. Any violation or alleged violation of any of these laws or regulations by us could have a material adverse effect on our business, financial condition, cash flows and results of operations. We may be a party to various lawsuits, demands, claims, qui tam suits, third- party complaints to the FDA, government investigations and audits, of which any could result in, among other things, substantial financial penalties or awards against us, reputational harm, termination of relationships or contracts related to our business, mandated refunds, substantial payments made by us, required changes to our business practices, exclusion from future participation in Medicare and other healthcare programs and possible criminal penalties. Compliance with **these** ~~third parties will comply with applicable~~ healthcare laws and regulations ~~involve~~ **involves** substantial costs. **If a company** ~~Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it~~ is ~~possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are~~ found to be in violation of any of these laws or any other laws, regulations or other requirements ~~that may apply to us~~, ~~we it~~ may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, restitution exclusion from government funded healthcare programs, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts, contractual damages, the curtailment or restructuring of our operations and other consequences. ~~If any of the physicians or other healthcare providers or entities with whom we expect to do business are found in violation of applicable laws, including but not limited to those discussed above, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.~~ The availability of any federal grant funds which we may receive or for which we may apply is subject to federal appropriations law. Such grant funding may also be withdrawn or denied due to a violation of the above laws and / or for other reasons. Failure to obtain or maintain orphan product..... the trading price of our stock. Risks Related to Employee Matters and Managing Our Growth If we fail to attract and keep management and other key personnel, as well as our board members, we may be unable to develop our product candidates or otherwise implement our business plan. Our success will depend on the retention of our directors and members of our management and leadership team including Dr. Garry A. Neil, Chief Executive Officer and Chairman of the Board, Christopher Sullivan, Chief Financial Officer, Lisa Hegg Ph. D., Senior Vice President of Program Management, Corporate Infrastructure, and Clinical Operations, Colleen Matkowski, Senior Vice President of Global Regulatory Affairs and Quality Assurance, and Dino Miano, Senior Vice President, CMC and Technical Operations, and on our ability to continue to attract and retain highly skilled and qualified personnel. **We might face challenges to employee retention and attraction due to our reliance and intended focus on AVTX- 009. In addition,** ~~From~~ **from** time to time, there may be changes to our executive management team resulting from the hiring or departure of other executives, which could disrupt our business. For example ~~:~~**, our executive management changed** in February 2022 ~~, our then- current Chief Scientific Officer, Garry A. Neil, replaced Michael Cola as our Chief Executive Officer. Additionally, in February 2022, our then- current Chief Accounting Officer, Christopher Sullivan, replaced Schond Greenway as our Chief Financial Officer~~ . The loss of one or more of our executive officers or key associates could have a serious adverse effect on our business. To continue to execute our business strategy, we must be able to attract and retain highly skilled personnel. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our **intended reliance on AVTX- 009 might make the attraction of personnel who may be concerned with employment exposure due to one principal product candidate more difficult. Additionally, our lack of experience with indications in dermatology might also make the attraction of personnel more difficult. Our** industry has experienced a high rate of turnover of management personnel in recent years. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts **. In addition, our limited financial resources may hinder our ability to attract and retain competent personnel** . Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we have. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly our ability to implement our business strategy and achieve our business objectives. There can be no assurance that we will retain the services of any of our directors, officers or employees, or attract or retain additional senior managers or skilled employees when and as needed. Furthermore, we do not intend to carry key man insurance with respect to any of such individuals. We may encounter difficulties in managing our growth **, including the focus on AVTX- 009 and the resources necessary for its development,** and expanding our operations successfully **. In March 2024, we acquired AVTX- 009 and intend to focus our business primarily on AVTX- 009 in the near future at least. While we have experience with anti- inflammatory product candidates and AVTX- 009 is an anti-inflammatory product candidate, we only have recently begun incorporating it into our operations. This could pose challenges to us in developing AVTX- 009. In addition, our focus on AVTX- 009 could negatively impact the planned development of our other product candidates** . As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, administrative, marketing and sales capabilities or contract with third parties to provide these capabilities for us **. Considering the recent acquisition of AVTX- 009 and our intended focus in at least the near- term on the progression of a phase 2 trial of AVTX- 009 in hidradenitis suppurativa and potentially other autoimmune indications, we will need to increase our research and development infrastructure** . As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Any future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our

ability to manage any future growth **efficiently and** effectively. To that end, we must be able to manage our product development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. The hiring, training and integration of new employees may be more difficult, costly and / or time - consuming for us because we have fewer resources than a larger organization. We might not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully developing our product candidates and growing our company. Our Chief Executive Officer has interests in the development of AVTX- 006 pursuant to a royalty agreement that may conflict with interests of stockholders. Entities affiliated with Dr. Garry Neil, our Chief Executive Officer, are parties to a Royalty Agreement with us relating to AVTX- 006. The Royalty Agreement was entered into in July 2019 and we assumed the agreement in the Aevi Merger. The Investors will be entitled to an aggregate amount equal to a low- single digit percentage of the aggregate net sales of AVTX- 006 products. At any time beginning three years after the date of the first public launch of AVTX- 006 product, we may exercise, at our sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to the Investors of an aggregate of 75 % of the net present value of the royalty payments. As a result of this arrangement, the interests of Dr. Neil with respect to our development programs may conflict with the interests of our stockholders. Dr. Neil could make substantial profits as a result of opportunities related to AVTX- 006, which may result in him having more interest in advancing programs related to AVTX- 006 as opposed to our other pipeline programs. In addition, there would be a conflict of interest if the Company determines to exercise its buyout rights under the Royalty Agreement, the exercise of which would be subject to certain approvals including by our Audit Committee and a majority of our independent directors. We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non - disclosure and non - competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. In addition, we may be subject to claims that former employees, collaborators, or other third parties **of ours** have an ownership interest in our patents or other intellectual property. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in ~~executing~~ **obtaining or enforcing** such an agreement ~~to~~ **with** each party who in fact develops intellectual property that we regard as our own. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license might not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management. Risks Related to our Stock The market price of our stock is volatile, and you could lose all or part of your investment. The market price of our shares of ~~our~~ common stock has been highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. From our initial public offering in October 2015 through December 31, ~~2022~~ **2023** , the per share **adjusted closing** trading price of our common stock has been as high as $ ~~86~~ **20, 777** . ~~64~~ **81** and as low as $ ~~2~~ **8** . ~~96~~ **32** (adjusted for the 1- for- ~~12~~ **240** reverse stock split that occurred in ~~July~~ **December** ~~2022~~ **2023**). As a result of this volatility, you might not be able to sell your shares of our common stock at a favorable price. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K, these factors that could negatively affect or result in fluctuations in the market price of shares of our common stock include: • Our ability to generate significant product revenues, cash flows and a profit; • The success of competitive products or technologies; • Actual or anticipated changes in our growth rate relative to our competitors; • Announcements by our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments; • Regulatory or legal developments in the United States and other countries; • The results of our efforts to discover, develop, in - license or acquire additional product candidates or products; • Actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • Variations in our financial results or those of companies that are perceived to be similar to us; • Variations in the level of expenses related to our product candidates or preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites; • Fluctuations in the valuation of companies perceived by investors to be comparable to us; • Warrant or stock price and volume fluctuations attributable to inconsistent trading volume levels of our warrants or shares; • Announcement or expectation of ~~additional~~ financing efforts; • Changes in operating performance and stock market valuations of other pharmaceutical companies; • Market conditions in the pharmaceutical and biotechnology sectors; • The public' s response to press releases or other public announcements by us or third parties, including our filings with the U. S. Securities and Exchange Commission (" SEC ") and announcements relating to litigation or other disputes, strategic transactions or intellectual property impacting us or our business; • ~~Announcement~~ **Announcements** related to litigation; • Fluctuations in quarterly operating results, as well as differences between our actual financial and operating results and those expected by investors; • The financial projections we may provide to the public, any changes in these projections or our failure to meet these projections; • Changes in financial estimates by any securities analysts who follow our ~~warrants or~~ shares of common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our ~~warrants or~~ shares of common stock; • Ratings downgrades by any securities analysts who follow our ~~warrants or~~ shares of common stock; • The development and sustainability of an active trading market for our shares of common stock; • Future sales of our shares of common stock by our officers, directors and

significant stockholders; • Other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; • Changes in accounting principles; and • General economic, industry and market conditions. In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of shares of common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a material adverse impact on the market price of our shares of common stock. When the market price of a stock is volatile, security holders may institute class action litigation against the company that issued the stock. If we become involved in this type of litigation, regardless of the **merits or** outcome, we could incur substantial legal costs and our management' s attention could be diverted from the operation of our business, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. **Conversion of the outstanding shares of our preferred stock and the exercise of outstanding warrants will dilute the percentage ownership of the holders of our common stock. Subject to our stockholder approval, the non- voting convertible preferred stock that we issued in March 2024 is automatically convertible upon such approval into an aggregate of approximately 22. 4 million shares of our common stock, subject to certain beneficial ownership limitations. We intend to seek such stockholder approval in the near future. In addition, if exercised, the warrants issued in March 2024 could result in the issuance of up to an aggregate of approximately 12. 0 million shares of Avalo' s common stock or an equivalent amount (as converted to common stock) of non- voting convertible preferred stock. The conversion and / or issuance of those shares will cause the percentage of voting ownership of our existing stockholders to be significantly diluted, although the economic interest will not change because the value of shares issuable upon conversion was reflected in the purchase price of the preferred stock.** Future sales and issuances of shares of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect ~~that~~ **to need to raise** additional capital ~~may be needed~~ in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, and expanded research and development activities. To raise capital, we ~~may~~ **expect to** sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by such sales and new investors could gain rights, preferences and privileges senior to our existing stockholders. We are authorized to grant equity awards, including stock grants and stock options, to our employees, directors and consultants. As of December 31, ~~2022~~ **2023** , there were **450** ~~204, 290~~ shares available for future issuance under the Third Amended and Restated 2016 Equity Incentive Plan (the " 2016 Amended Plan "). During the term of the 2016 Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, by an amount equal to 4 % of the total number of outstanding shares of our common stock on the last trading day in December of the prior calendar year. On January 1, ~~2023~~ **2024** , ~~on~~ **under** ~~the~~ **these** ~~terms~~ **term** ~~of the 2016 Amended Plan~~ , an additional ~~377~~ **32** , ~~221~~ **070** shares were made available for issuance. In addition, as of December 31, ~~2022~~ **2023** , there were **784** ~~170, 035~~ shares available for future issuance under the 2016 Employee Stock Purchase Plan (the " ESPP "). On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP will automatically increase by a number equal to the lesser of (i) 1 % of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, and (ii) **174** ~~41, 667~~ shares of our common stock, or (iii) a number of shares of our common stock as determined by our board of directors or compensation committee. On January 1, ~~2023~~ **2024 , under these terms** , the number of shares available for issuance under the ESPP increased by **174** ~~41, 667~~ shares available for issuance **. In connection with the acquisition of AVTX- 009, we have agreed to increase the shares available for issuance under the 2016 Amended Plan by 5 % as a means to incentivize our management and employees** . Future issuances, as well as the possibility of future issuances, under the 2016 Amended Plan or the ESPP or other equity incentive plans could cause the market price of our common stock to decrease ~~. Armistice is our largest stockholder and has significant influence over us, and its interests may be different from or conflict with those of our other stockholders. As of February 15, 2023, Armistice beneficially owns approximately 35 % of our outstanding common stock. As a result, Armistice continues to be able to exert a significant degree of influence over our management, affairs, and matters requiring stockholder approval, including the election of directors, a merger, consolidation or sale of all or substantially all of our assets, and any other significant transaction. The interests of Armistice might not always coincide with our interests or the interests of our other stockholders. For instance, this concentration of ownership may have the effect of delaying or preventing a change in control of us otherwise favored by our other stockholders and could have an adverse effect on our stock price. Armistice makes investments in companies and may, from time to time, acquire and hold interests in businesses that compete directly or indirectly with us. Armistice may also pursue, for its own account, acquisition opportunities that may be complementary to our business, and as a result, those acquisition opportunities might not be available to us. The interests of Armistice may supersede ours, causing Armistice or their affiliates to compete against us or to pursue opportunities instead of us, for which we have no recourse. Such actions on the part of Armistice and inaction on our part could have a material adverse effect on our business, financial condition, results of operations and cash flows. Steven Boyd, Armistice' s Chief Investment Officer, served on our board of directors from May 2017 until August 8, 2022 and as Chairman of our board of directors from December 14, 2021 until August 8, 2022. Additionally, Keith Maher, Armistice managing director, also served on our board of directors from October 2021 until August 8, 2022. Pursuant to the waiver dated August 11, 2022, Armistice permanently waived its right to appoint up to two directors to our board of directors and right to replace such directors in certain circumstances, including upon resignation or removal of such directors. The level of Armistice' s ownership of our common stock would result in a limited amount of shares being available to be traded in the market, resulting in reduced liquidity. Certain of the shares owned by Armistice have been registered for resale under the~~

~~Securities Act. Sales of substantial amounts of shares of our common stock by Armistice in the public market, or the perception that such sales will occur, for any reason, could adversely affect the market price of shares of our common stock and make it difficult for it to raise funds through securities offerings in the future~~ . If we are not able to comply with the applicable continued listing requirements or standards of The Nasdaq Stock Market, Nasdaq could delist our common stock. Our common stock is currently listed on The Nasdaq Stock Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, a minimum closing bid price of $ 1. 00 per share, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards. For example, on ~~March 17~~ **August 8** , ~~2022~~ **2023** , Nasdaq notified us that we failed the $ 1. 00 minimum bid price requirement **and the $ 35 million minimum Market Value of Listed Securities (" MVLS ") requirement. The Company affected a 1- for- 240 reverse stock split on December 28, 2023, which has allowed its common stock to trade above $ 1. 00 since December 29, 2023** . On ~~July 22~~ **January 30** , ~~2022~~ **2024** ~~we~~ **, the Company** received written notification from Nasdaq confirming that ~~our common stock had a closing price of $ 1. 00 or greater for~~ the **Company** ~~ten consecutive trading dates from July 8 to July 21, 2022 and that as a result we~~ had regained compliance with the **Bid** ~~minimum bid price~~ **Price** ~~requirement~~ **Rule** . ~~However~~ **Nasdaq also notified the Company that it is subject to a mandatory panel monitor for a period of one year from January 30** , **2024. If, within the one- year monitoring period, Nasdaq finds the Company again out of compliance with the Bid Price Rule, then notwithstanding Nasdaq Rule 5810 (c) (2), the Company will not be permitted to provide Nasdaq with a plan of compliance with respect to that deficiency and Nasdaq will not be permitted to grant additional time for the Company to regain compliance with respect to that deficiency, nor will the Company be afforded an applicable cure or compliance period pursuant to Nasdaq Rule 5810 (c) (3). Instead, Nasdaq will issue a Delist Determination Letter and the Company will have an opportunity to request a new hearing with the initial Nasdaq panel assigned to the Company for its recent noncompliance or newly convened hearings panel if the initial panel is unavailable. The Company will have the opportunity to respond to the hearings panel as provided by Nasdaq Rule 5815 (d) (4) (C). If the Company fails to satisfy the Nasdaq panel, its securities would be delisted from Nasdaq.** ~~there~~ **There** can be no assurance that we will continue to maintain such requirement **or remain in compliance with any other Nasdaq listing requirements** . In the event that our common stock is delisted from The Nasdaq Stock Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over - the - counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on **an** ~~a major~~ exchange. **A** ~~Such a de - listing~~ **delisting** would also likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a ~~de - listing~~ **delisting** , we may take actions to restore our compliance with The Nasdaq Stock Market' s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq Stock Market minimum bid price requirement or prevent ~~future~~ non - compliance with The Nasdaq Stock Market' s listing requirements. Low trading volume of our common stock on the Nasdaq Capital Market may increase price volatility. Our common stock may be subject to price volatility, low trading volume and large spreads in bid and ask prices quoted by market makers. **Low** ~~Due to the low volume of shares traded on any~~ trading **means that trading** ~~day, persons buying or selling~~ in relatively small quantities may easily influence prices of our common stock. **Low** ~~This low~~ trading volume could also cause the price of our stock to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our common stock may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low trading volume. If large spreads between the bid and ask prices of our common stock exist at the time of a purchase, the stock would have to appreciate substantially on a relative percentage basis for an investor to recoup their investment. No assurance can be given that a higher volume active market in our common stock will develop or be sustained. If a higher volume active market does not develop, holders of our common stock may be unable to readily sell the shares they hold or may not be able to sell their shares at all. Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock. **We expect to need to raise capital to fund our operations in the future and may do so through the sale of common stock or securities convertible into shares of common stock.** Sales of a substantial number of shares of our common stock in the public markets could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. ~~As~~ **Sales of shares of common stock or common stock equivalents also may be offered in private placements, and these sales also may have a depressive effect on the market for our shares of common stock due to the delayed issuance of these shares into the public market. Further, as** additional shares of our common stock become available for resale in the public market, and otherwise, the supply of our common stock will increase, which could decrease its price. **We** ~~In addition, some or all of the shares of common stock may be offered from time to time in the open market pursuant to Rule 144, and these sales may have a depressive effect on the market for our shares of common stock. Therefore, we~~ cannot predict the effect that future sales of our common stock **or common stock or common stock equivalents** would have on the market price of our common stock **. Subject to our stockholder approval, the non- voting convertible preferred stock that we issued in March 2024 is automatically convertible upon such approval into an aggregate of approximately 22. 4 million shares of our common stock, subject to certain beneficial ownership limitations. We intend to seek such stockholder approval in the near future. In addition, if exercised, the warrants issued in March 2024 could result in the issuance of up to an aggregate of approximately 12. 0 million shares of Avalo' s common stock or**

an equivalent amount (as converted to common stock) of non- voting convertible preferred stock. We have agreed to register the shares of common stock underlying the non- voting convertible preferred stock and warrants for resale by the investors holding the non- voting convertible preferred stock and warrants. When the registration is effective, the pending sale and the actual sale of those shares of common stock on the open market could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities . If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our securities prices and trading volume could decline. The trading market for our securities ~~will depend~~ **depends** in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited, and might not sustain, research coverage by securities and industry analysts. If we do not sustain coverage of ourselves, the trading price for our securities would be negatively impacted. If the securities and industry analysts are unable to predict accurately the cost of advancing our pipeline, that could result in our reported costs being different than expectations, which could negatively affect our stock price. If ~~we do obtain securities or industry analyst coverage and if~~ one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, our securities prices would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our securities could decrease, which could cause our securities prices and trading volume to decline. We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future. The continued operation and expansion of our business will require substantial funding. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Consequently, currently stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any ~~future~~ gains on their investment. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. We incur increased costs and obligations as a result of being a public company. As a public company, we are required to comply with certain additional corporate governance and financial reporting practices and policies. As a result, due to compliance requirements of the Exchange Act, the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Protection Act, the listing requirements of the Nasdaq, and other applicable securities rules and regulations, we have and will continue to incur significant legal, accounting, and other expenses. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results with the SEC. We are also required to ensure that we have the ability to prepare financial statements and other disclosures that are fully compliant with all SEC reporting requirements on a timely basis. Compliance with these rules and regulations has increased and may continue to increase our legal and financial compliance costs, make some activities more difficult, time- consuming, or costly, and increase demand on our systems and resources. Our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. ~~This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.~~ Any person or entity purchasing or otherwise acquiring any interest in any of our securities will be deemed to have notice of and consented to these provisions. These exclusive - forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees **. This choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations** . Some provisions of our charter documents and Delaware law may have anti - takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation and third amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include: • Authorizing the issuance of " blank check " preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval; • Prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates; • Prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; •

Eliminating the ability of stockholders to call a special meeting of stockholders; and • Establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation ~~might~~ **may** not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors **has** approved the transaction. Any provision of our amended and restated certificate of incorporation or third amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our securities. General Risk Factors **Our business and operations could suffer in the event of computer system failures, cyber- attacks or deficiencies in our cyber- security.** In **the** ordinary course of our business,we collect and store sensitive data,including intellectual property,research data,our proprietary business information and that of our suppliers,technical information about our ~~products~~ **product candidates** ,clinical trial plans and employee records.Similarly,our third- party providers possess certain of our sensitive data and confidential information.The secure maintenance of this information is critical to our operations and business strategy.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,ransomware,cyber fraud,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.Any such breach could compromise our networks and the information stored there could be accessed,publicly disclosed,encrypted,lost or stolen.Any such access,inappropriate disclosure of confidential or proprietary information or other loss of information,including our data being breached at third- party providers,could result in legal claims or proceedings,liability or financial loss under laws that protect the privacy of personal information,disruption of our operations or the development of our pipeline assets and damage to our reputation,which could adversely affect our business.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.Furthermore,as a result of cyber- attacks we may inadvertently misappropriate assets that we may not be able to fully recover.We may be subject to future litigation against us,which could be costly and time - consuming to defend.We may become subject,from time to time,to legal proceedings and claims that arise in the ordinary course of business such as claims brought by our ~~clients~~ **collaborators** in ~~connection with~~ connection with ~~the reporting of~~ **commercial disputes,** ~~our~~ **or employment claims made by our current or former employees. Litigation might result in substantial costs and may divert management' s attention and resources, which might seriously harm our business, overall** financial condition **,** and **operating** results ~~of~~ **. Insurance might not cover such claims, might not provide sufficient payments to cover all the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby reducing our** ~~operations~~ - **operating results** ~~, we are required to make estimates~~ and ~~judgments~~ **leading analysts or potential investors to reduce their expectations of our performance,** which ~~involve uncertainties, and any significant differences between our estimates and actual results~~ could **reduce** ~~have an adverse impact on our financial position, results of operations and cash flows. Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in~~ the ~~United States,~~ **trading price of** ~~or~~ **our stock** ~~GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and revenues and related disclosure of contingent assets and liabilities. For example, we estimate returns, wholesaler fees, prompt payment discounts, chargebacks and government rebates. We also estimate clinical trial costs incurred using subject data and information from our CROs. If we underestimate or overestimate these expenses, adjustments to expenses may be necessary in future periods. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows~~ . We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage. We maintain a large quantity of sensitive information, including confidential business information and information associated with clinical trials. Because of the sensitivity of this information, our privacy and security measures related to such information are very important. Although we have privacy and security measures in place designed to protect sensitive data and our systems, techniques used to obtain unauthorized access or to sabotage systems and data change frequently and often are not recognized until launched against a target. It is also possible that, due to the surreptitious nature of certain data breaches and other incidents, they may remain undetected for an extended period, which may exacerbate harm to the company. We cannot ensure that our privacy and security measures will not be breached or otherwise fail to protect sensitive information or prevent disruption of our operations, including as a result of inadvertent disclosures through technological or human error (including employee or service provider error), malfeasance, hacking, ransomware, social engineering (including phishing schemes), computer viruses, malware, or otherwise. Unauthorized individuals may acquire or obtain unauthorized access to sensitive information. Data breaches, failures of our privacy or security measures, inadvertent disclosures, disruptions of our services, and other incidents could result in serious harm to our reputation, our business might suffer, and we could incur serious liability and other expenses related to litigation (such as damages associated with breach- of- contract claims), penalties for violation of applicable laws or

regulations, costly litigation or government investigations, and significant costs for remediation and remediation efforts to prevent future occurrences. The harm associated with these negative results is likely to be exacerbated if the affected information is personally identifiable. Like others in our industry, we experience cyber- attacks and other attempts to disrupt or gain unauthorized access to our systems on a regular basis. When we become aware of privacy or security incidents, we work diligently to address them, including by working to terminate unauthorized or inappropriate access and implementing additional measures, training, and providing guidance to end users in order to avoid the reoccurrence and future incidents. Although to date, privacy and security incidents have not been material, they could expose us to significant expense, legal liability, and harm to our reputation, which might result in an adverse impact our operating results. We are subject to certain laws and regulations governing the privacy and security of personal information, including regulations pertaining to health information. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues that may affect our business. In the United States, there are numerous federal and state privacy and data security laws and regulations that govern the collection, use, disclosure, and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject to lawsuits, penalties, or sanctions. The HHS Office for Civil Rights, which enforces HIPAA, remains active in its enforcement of the law. Additionally, state attorneys general may bring civil actions seeking either injunctions or damages in response to violations of HIPAA that threaten the privacy of state residents. Privacy and data security has become an area of emphasis for some state legislatures. For example, the California Privacy Rights Act, the Colorado Privacy Act, and the Virginia Consumer Data Protection Act were all enacted recently and ~~will become~~ **became** operative in 2023. ~~(Some provisions are already operative.)~~ State legislatures may pass additional privacy and data security laws with inconsistent requirements. In addition to the risk associated with enforcement, compliance with and implementation of these evolving laws, rules, and regulations regarding the privacy, security and protection of personal information could result in higher compliance and technology costs for us and present challenges for our business model. There are numerous federal and state laws that generally require notice to affected individuals, regulators, and sometimes the media or credit reporting agencies in the event of a data breach impacting personal information. For example, at the federal level, HIPAA Breach Notification Rule mandates notification of breaches affecting protected health information to affected individuals and regulators under conditions set forth in the Rule. Covered entities must report breaches of unsecured protected health information to affected individuals without unreasonable delay, but not to exceed 60 days of discovery of the breach by a covered entity or its agents. Notification must also be made to HHS and, in certain circumstances involving large breaches, to the media. Business Associates must report breaches of unsecured protected health information to covered entities. All states, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands have enacted data breach notification laws. These laws may impose notification obligations in addition to, or inconsistent with, the HIPAA Breach Notification Rule when a data breach implicates protected health information. In that event that we fail to detect or timely report a data breach it may be subject to significant penalties under federal and state law. In the event that we report a data breach as required by federal or state law, federal or state regulators may initiate an investigation into, and / or litigation related to, our privacy or data security practices. Private plaintiffs may also initiate costly class action litigation following a data breach. Numerous other countries have, or are developing, laws governing the collection, use, and transmission of personal information. These laws often impose significant compliance obligations. For example, the General Data Protection Regulation (" GDPR ") has imposed stringent obligations and restrictions on the ability to collect, analyze, and transfer personal information, including health data from clinical trials and substantial fines for breaches of the data protection rules in the European Economic Area (" EEA "). To the extent that our activities are or become subject to the GDPR, we may need to devote significant effort and resources to complying with those legal regimes. Any failure to comply with the rules arising from the GDPR could lead to government enforcement actions and significant penalties against us and adversely impact our operating results. If our operations are found to violate GDPR requirements, we may incur substantial fines, have to change our business practices, and face reputational harm, any of which could have an adverse effect on our business. In particular, serious breaches of the GDPR can result in administrative fines of up to 4 % of annual worldwide revenues. Fines of up to 2 % of annual worldwide revenues can be levied for other specified violations. The validity of data transfer mechanisms remains subject to legal, regulatory, and political developments in both Europe and the United States, such as recent recommendations from the European Data Protection Board, the invalidation of the EU- U. S. Privacy Shield, and potential invalidation of other data transfer mechanisms, which could have a significant adverse impact on our ability to process and transfer personal data outside of the EEA. These developments create some uncertainty, and compliance obligations could cause us to incur costs or harm the operations of our products and services in ways that harm our business. ~~Our disclosure controls and procedures might not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act, the Sarbanes - Oxley Act and The Nasdaq Stock Market rules and regulations. The Sarbanes - Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well - conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We cannot assure, in the future, a material weakness or significant deficiency will not exist or otherwise be discovered. If that were to happen, it could harm our operating results and cause stockholders to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our securities. These inherent limitations include the realities that judgments in decision - making can be faulty, and that~~

~~breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. 47~~