Risk Factors Comparison 2025-03-11 to 2024-02-29 Form: 10-K

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You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10- K. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business. ~~Risks~~ **Risk** Factors Summary Our business is subject to a number of risks and uncertainties, including those risks discussed below. These risks include, among others, the following: • Risks Related to Our Financial Position and Capital Needs oWe have incurred significant losses since our inception. We expect to incur losses until revenue from YCANTH (VP- 102) for the treatment of molluscum contagiosum is sufficient to fund our operations, if ever, and we may never achieve or maintain profitability. oWe will need substantial additional funding to meet our financial obligations and to pursue our business objectives, including the continued commercialization of YCANTH (VP- 102) for the treatment of molluscum contagiosum as well as the development of YCANTH **(VP- 102)** for the treatment of ~~additional indications~~ **common warts** and ~~our~~ **VP- 315 for** ~~other~~ -- **the** ~~product candidates~~ **treatment of basal cell carcinoma**. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy, which could have a material adverse impact on our financial results and future operations. oWe may not be able to generate sufficient cash to service our indebtedness ~~or borrow additional funds pursuant to our Loan Facility~~. oWe have a limited operating history and limited history of commercializing products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability **. oGreater than expected returns of YCANTH (VP- 102) may exceed our reserve for returns, which would adversely affect our revenue and operating results. oWhile our financial statements have been prepared assuming that we will continue as a going concern, we do not currently have sufficient working capital to fund our planned operations for the next twelve months and substantial doubt exists as to our ability to continue as a going concern**. • Risks Related to the Development of Our Product Candidates oIf we are unable to successfully develop, receive regulatory approval for and commercialize any product candidates, or experience significant delays in doing so, our business will be harmed. • Risks Related to the Commercialization of Our Product and Other Product Candidates oWe face substantial competition which may result in a smaller than expected commercial opportunity and / or others discovering, developing or commercializing products before or more successfully than we do. oThe success of YCANTH (VP- 102) for the treatment of molluscum contagiosum and our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these procedures. oThe market for YCANTH (VP- 102) for the treatment of molluscum contagiosum and our product candidates may not be as large as we expect. • Risks Related to Our Dependence on Third Parties oWe currently rely on a third party to supply the raw materials and applicator components used for YCANTH (VP- 102) and if we encounter any extended difficulties in procuring, or creating an alternative for those components or our raw material in YCANTH (VP 102) or any of our product candidates, our business operations would be impaired. oWe have entered into, and may seek additional, collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. • Risks Related to Our Intellectual Property oIf we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market. • Risks Related to ~~Employee Matters and Managing Our Growth oWe expect to expand our development and regulatory capabilities and our sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. • Risks Related to~~ Ownership of Our Common Stock and Our Status as a Public Company oThe trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses **. oIf we fail to meet all applicable requirements of Nasdaq and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease**. We have incurred significant losses since our inception. We expect to incur losses until revenue from YCANTH (VP- 102) is sufficient to fund our operations, if ever, and may never achieve or maintain profitability. We are a dermatology therapeutics company developing and selling medications for skin diseases requiring medical intervention. Since inception, we have incurred significant net losses. We incurred net losses of $ **76. 6 million and $** 67. 0 ~~million and $ 24. 5~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of $ ~~230~~ **307**. ~~4~~ **0** million. Since inception, we have financed our operations **primarily through** ~~with $ 123. 2 million in gross proceeds raised in our initial public offering and private placements of convertible debt and convertible preferred stock and $ 85. 3 million in net proceeds from subsequent follow- on offerings, and $ 20. 0 million from~~ the ~~Torii~~ **sale of equity and equity-linked securities and through borrowings under loan** ~~Agreement~~ **agreements** ~~. We borrowed $ 50. 0 million on July 26, 2023, resulting in net proceeds to us of approximately $ 44. 1 million~~. We have devoted substantially all of our financial resources and efforts to the development of our novel topical solution of cantharidin and our product, YCANTH (VP- 102), for the treatment of molluscum contagiosum, including preclinical studies and clinical trials. YCANTH (VP- 102) was approved by the **Food and Drug Administration, or** FDA **,** for the treatment of molluscum contagiosum in July 2023. We are also developing YCANTH (VP- 102) as a treatment for ~~external genital warts and~~ common warts ~~,~~ **and** VP- 315 for the treatment of **basal cell carcinoma, or BCC, and potentially additional** dermatological oncology indications ~~and VP- 103 for the treatment of plantar warts~~. Therefore, we expect to continue to incur significant expenses and operating losses until revenue from

YCANTH (VP- 102) for the treatment of molluscum contagiosum is sufficient to fund our operations. Our net losses may fluctuate significantly from quarter to quarter and year to year. **Our** ~~We anticipate that our~~ expenses ~~will~~ **may** increase ~~substantially~~ **s** as we: **• continue to establish our commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize YCANTH (VP- 102) for the treatment of molluscum contagiosum and product candidates for which we may obtain regulatory approval;** • continue our ongoing clinical programs evaluating VP- 102 for the treatment of ~~external genital warts and~~ common warts and VP- 315 for the treatment of **BCC and potentially additional** dermatological oncology indications ~~, including basal cell carcinoma, as well as initiate and complete additional clinical trials as needed; • initiate clinical trials evaluating VP- 103 for the treatment of plantar warts~~ ; • pursue regulatory approvals for YCANTH (VP- 102) for the treatment of ~~external genital warts and~~ common warts ~~as well as our other current product candidates; • seek to discover~~ and ~~develop additional product candidates; • continue to establish our commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize YCANTH (~~ VP- **315** ~~102)~~ for the treatment of **BCC** ~~molluscum contagiosum and product candidates for which we may obtain regulatory approval~~ ; • seek to in- license or acquire additional product candidates for other dermatological conditions; • adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products; • maintain, expand and protect our intellectual property portfolio; • hire ~~additional~~ **and retain** clinical, manufacturing **, commercialization** and scientific personnel ~~; • add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts~~ ; and • incur additional legal, accounting and other expenses in operating as a public company. To become and remain profitable, we must succeed in commercializing YCANTH (VP- 102) for the treatment of molluscum contagiosum and developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including commercialization of YCANTH (VP- 102) for the treatment of molluscum contagiosum, completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Our revenue will be dependent, in part, upon the size of the markets in the territories for which we have gained or may gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products. Because of the numerous risks and uncertainties associated with commercialization and product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, ~~expand our business,~~ maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. We will need substantial additional funding to meet our financial obligations and to pursue our business objectives **,** including the continued commercialization of YCANTH (VP- 102) for the treatment of molluscum contagiosum as well as the development of YCANTH (VP- 102) for the treatment of ~~additional indications~~ **common warts** and ~~our product candidates~~ **VP- 315 for the treatment of BCC** . If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy which could impact our ability to continue as a going concern. 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 may never generate the necessary data or results required to obtain regulatory approval and achieve product sales of our product candidates. We expect to continue to incur significant expenses over the next several years as we commercialize YCANTH (VP- 102) for the treatment of molluscum contagiosum, pursue clinical trials and marketing approval for YCANTH (VP- 102) for the treatment of common warts ~~, external genital warts,~~ and **potentially** other indications, pursue clinical trials and marketing approval for VP- 315 for the treatment of **BCC and potentially additional** dermatological oncology indications ~~, VP- 103 for the treatment of plantar warts,~~ and advance any of our other product candidates we may develop or otherwise acquire. YCANTH (VP- 102), for the treatment of molluscum contagiosum and our product candidates, if approved, may not achieve commercial success. Although YCANTH (VP- 102) has been approved by the FDA for the treatment of molluscum contagiosum, we do not expect to generate substantial revenue from YCANTH (VP- 102) in the near term. We have incurred, and expect to continue to incur, significant commercialization expenses related to product sales, marketing, distribution and manufacturing of YCANTH (VP- 102) as well as any product candidates for which we receive marketing approval. ~~As~~ **Based on our current business plan and current capital resources, consisting of cash and cash equivalents of $ 46. 3 million as** of December 31, ~~2023~~ **2024** , ~~we had~~ **combined with the uncertainty regarding the availability of additional funding and considering our debt obligations, including a requirement to maintain** cash ~~and~~ **,** cash equivalents **and investments** of **at least** $ ~~69~~ **10** . ~~5~~ **0** million ~~. We believe~~ **at all times, we have concluded** that **there is substantial doubt regarding** our **ability to continue** ~~existing cash and cash equivalents~~ as **a going concern within one year after the date** ~~of December 31, 2023, will be sufficient to support our planned operations into the~~ **these** ~~second quarter of 2025~~ **financial statements are issued** . This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than

the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. In addition, if there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our commercialization activities for YCANTH (VP- 102) for the treatment of molluscum contagiosum, our development activities, acquisitions of additional product candidates, and changes in regulation. Our future capital requirements will depend on many factors, including: • the progress and success of commercializing YCANTH (VP- 102) for the treatment of molluscum contagiosum in the United States; • the costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution, for YCANTH (VP- 102) for the treatment of molluscum contagiosum and any of our product candidates for which we may receive marketing approval; • the scope, progress, costs and results of our development programs evaluating YCANTH (VP- 102) as a potential treatment for ~~external genital warts and~~ common warts, as well as VP- 315 ~~and VP- 103~~ **for the treatment of BCC** ; • the extent to which we develop, in- license or acquire product candidates or technologies; • the number and development requirements of product candidates that we may pursue; • the costs, timing and outcome of regulatory review of our product candidates; • the revenue received from commercial sales of YCANTH (VP- 102) for the treatment of molluscum contagiosum and any of our product candidates for which we receive marketing approval; • our ability to establish collaborations to commercialize YCANTH (VP- 102) for the treatment of molluscum contagiosum or any of our product candidates outside the United States; and • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims. We will require additional capital to continue to commercialize YCANTH (VP- 102) for the treatment of molluscum contagiosum, and to develop YCANTH (VP- 102) for the treatment of ~~external genital warts and~~ common warts, and VP- 315 for the treatment of **BCC and potentially other** dermatological ~~oncology~~ indications ~~and VP- 103 for the treatment of plantar warts~~ . If we receive regulatory approval ~~for YCANTH (VP- 102) for the treatment of common warts and / or external genital warts, or~~ any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long- term business strategy. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy. **For example, we have paused the development of VP- 102 for the treatment of external genital warts and VP- 103 for the treatment of plantar warts due to our cash position.** We have entered into a Credit Agreement with OrbiMed, **or the Credit Agreement,** pursuant to which we ~~may borrow~~ **borrowed** ~~up to~~ $ ~~125~~ **50** . 0 million **in July 2023** . Our obligations under the Credit Agreement are secured by all or substantially all of our assets **. We will not be able to borrow, and do not intend to borrow, any additional funds pursuant to the Credit Agreement** . We are subject to a number of affirmative and restrictive covenants pursuant to the Credit Agreement, which limit or restrict our ability to (subject to certain qualifications and exceptions): create liens and encumbrances; incur additional indebtedness; merge, dissolve, liquidate or consolidate; make acquisitions, investments, advances or loans; dispose of or transfer assets; pay dividends or make other payments in respect of their capital stock; amend certain material documents; redeem or repurchase certain debt; engage in certain transactions with affiliates; and enter into certain restrictive agreements. In addition, ~~we are required to~~ **the Credit Agreement contains a financial covenant that the Company must** maintain **a liquidity of** at least $ 10 **. 0** million ~~of unrestricted cash~~ and ~~cash equivalents at all times~~ **that the Company' s quarterly and annual financial statements not be subject to any qualification or statement which is of a " going concern " or similar nature beginning with our Quarterly Report on Form 10- Q for the quarter ending June 30, 2025** . Our obligations under the Credit Agreement are subject to acceleration upon the occurrence of an event of default (subject to notice and grace periods). We are currently in compliance with the Credit Agreement covenants. ~~If~~ **Based on our net revenue attributable to YCANTH on a trailing 12- month basis not meeting a specified amount set forth in the Credit Agreement as of December 31, 2024,** we **became obligated to start making principal payments starting on January 1, 2025. We** are ~~unable~~ **obligated** to ~~achieve certain milestones, generate sufficient revenue and raise additional capital~~ **repay the principal amount of the loan on the last day of each month in equal monthly installments** through **the maturity date** ~~a combination of equity offerings~~ , **together** ~~debt financings and license and collaboration agreement we will no longer be in compliance~~ with ~~these~~ -- **the applicable repayment premium, exit fee and interest** ~~covenants. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms~~ . Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash ~~reserves~~ **balances** or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay **operating costs and** capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Failure to comply with the conditions of the Credit Agreement could result in an event of default, which could result in an acceleration of amounts due under the Credit Agreement. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and OrbiMed could seek to enforce security interests in the collateral securing such indebtedness, which would harm our business ~~. In addition, the Credit Agreement provides up to $ 25. 0 million will be made available on or prior to June 30, 2024, up to $ 30. 0 million will be made available on or prior to December 31, 2024, up to $ 10. 0 million will be made available on or prior to March 31, 2025, and up to~~

~~$ 10. 0 million will be made available on or prior to June 30, 2025, in each case, subject to certain revenue requirements. If we are unable to achieve the revenue targets by the applicable dates, we would be unable to borrow additional funds pursuant to the Loan Facility, which could negatively impact our ability to fund our operations~~ . Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For instance, under the Loan Agreements as described below, we are restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves **. SEC regulations limit the amount of funds we can raise during any 12- month period pursuant to our shelf registration statement on Form S- 3. SEC regulations limit the amount that companies with a public float of less than $ 75 million may raise during any 12- month period pursuant to a shelf registration statement on Form S- 3, referred to as the baby shelf rules. As of the filing of this Annual Report on Form 10- K, we are subject to such rules. Under these rules, the amount of funds we can raise through primary public offerings of securities in any 12- month period using our registration statement on Form S- 3, including our at- the- market equity offering program, will be limited to one- third of the aggregate market value of the shares of our common stock held by our non- affiliates. Therefore, we will be significantly limited in the amount of proceeds we are able to raise by selling shares of our common stock using our Form S- 3 until such time as our public float exceeds $ 75 million. Furthermore, if we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by the SEC staff** . We commenced operations in 2013, and our operations to date have been largely focused on raising capital and developing YCANTH (VP- 102) for the treatment of molluscum contagiosum and our product candidates, including undertaking preclinical studies and conducting clinical trials. YCANTH (VP- 102), which was approved by the FDA for treatment of molluscum contagiosum in July 2023, is our only approved product and became commercially available in August 2023. We have not yet demonstrated our ability to successfully manufacture a product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization over an extended timeframe. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully commercializing products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. With the approval of YCANTH (VP- 102) for molluscum contagiosum in July 2023, we are transitioning from a company with a development focus to a company with commercial and development activities. We may not be successful in such a transition. **The pharmaceutical wholesalers and distributors to which we sell YCANTH (VP- 102) are permitted to return purchased product under certain circumstances. We estimate expected returns based on our review of similar products in the industry and record discrete reserves if product held by distributors, forecasted sales and expiration of product warrant a reserve. Substantially all returns are due to expiry of the product. For the year ended December 31, 2024, we increased our returns reserve by $ 3. 2 million on previously sold product as a result of lower than forecasted sell- through and expiration of product. Any significant increase in returns that exceeds our reserve could adversely affect our revenue and operating results. While our financial statements have been prepared assuming that we will continue as a going concern, we do not currently have sufficient working capital to fund our planned operations for the next twelve months and substantial doubt exists as to our ability to continue as a going concern. Based on our current business plan and current capital resources, consisting of cash and cash equivalents of $ 46. 3 million as of December 31, 2024, combined with the uncertainty regarding the availability of additional funding and considering our debt obligations, including a requirement to maintain cash, cash equivalents and investments of at least $ 10. 0 million at all times, we have concluded that there is substantial doubt regarding our ability to continue as a going concern within one year after the date these financial statements are issued. Until we can generate sufficient revenue to fund our operations, we will need to finance future cash needs through public or private equity offerings, license agreements, debt financings or restructurings, collaborations, strategic alliances and marketing or distribution arrangements. The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors and employees. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment.** We currently have only one product that is approved for commercial sale. We have invested substantially all of our efforts and financial resources in the development of YCANTH (VP- 102) for the treatment of molluscum contagiosum. We are also developing YCANTH (VP- 102) as a treatment for ~~external genital warts and~~ common warts, **and** VP- 315 for the treatment of **BCC and potentially additional** dermatological oncology indications ~~, including basal cell carcinoma and squamous cell carcinoma, and, VP- 103,~~

~~for the treatment of plantar warts~~ . Our ability to generate substantial revenue from YCANTH **(VP- 102)** for the treatment of molluscum contagiosum or our product candidates will depend heavily on their successful development, regulatory approval and commercialization. The success of YCANTH (VP- 102) for the treatment of molluscum contagiosum and any product candidates that we develop or otherwise may acquire **which receive regulatory approval** will depend on several factors, including: • timely and successful completion of preclinical studies and our clinical trials; • successful development of, or making arrangements with third- party manufacturers for, our commercial manufacturing processes for YCANTH (VP- 102) and any of our product candidates that receive regulatory approval; • receipt of timely marketing approvals from applicable regulatory authorities; • commercial sales of YCANTH (VP- 102) for the treatment of molluscum contagiosum and, if approved, our product candidates • acceptance of YCANTH (VP- 102) for the treatment of molluscum contagiosum and, if approved, our product candidates, by patients, the medical community and third- party payors, for their approved indications; • our success in educating physicians and patients about the benefits, administration and use of YCANTH (VP- 102) for the treatment of molluscum contagiosum and, if approved, our product candidates; • the prevalence and severity of adverse events experienced with YCANTH (VP- 102) for the treatment of molluscum contagiosum and our product candidates; • the availability, perceived advantages, cost, safety and efficacy of alternative treatments for the indications addressed by our product and product candidates; • our ability to produce YCANTH (VP- 102) for the treatment of molluscum contagiosum and, if approved, our product candidates on a commercial scale; • obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product and product candidates and otherwise protecting our rights in our intellectual property portfolio; • maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs; • competing effectively with other procedures; and • maintaining a continued acceptable safety, tolerability and efficacy profile of the products following approval. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Our product candidates' success in clinical trials is not guaranteed, and even if clinical trials are successful, it will not guarantee regulatory approval. Following submission of an NDA, it may not be accepted for substantive review, or even if it is accepted for substantive review, the FDA or other comparable foreign regulatory authorities may require that we conduct additional studies or clinical trials, provide additional data, take additional manufacturing steps, or require other conditions before they will reconsider or approve our application. If the FDA or other comparable foreign regulatory authorities require additional studies, clinical trials or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA or other comparable foreign regulatory authorities may not consider sufficient any additional required studies, clinical trials, data or information that we perform and complete or generate, or we may decide to abandon the program. It is possible that our product candidates will never obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business. Clinical product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. The risk of failure for product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing or at any time during the trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We cannot assure you that any clinical trial that we have conducted, are currently conducting, or may conduct in the future, will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. We may experience delays in ongoing clinical trials for our product candidates, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including: • regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may experience delays in reaching, or failing to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post- treatment follow-up at a higher rate than we anticipate; • our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the

participants are being exposed to unacceptable health risks; • the cost of clinical trials of our product candidates may be greater than we anticipate; and • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate. We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted, by the safety review committee for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. 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. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may: • be delayed in obtaining marketing approval for our product candidates; • not obtain marketing approval at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; • be subject to additional post- marketing testing requirements; or • have the product removed from the market after obtaining marketing approval. Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or 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 and impair our ability to successfully commercialize, or receive approval for, our product candidates. If we experience delays or difficulties in the enrollment and / or maintenance of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including: • the eligibility criteria for the trial in question; • the perceived risks and benefits of the product candidate in the trial; • the availability of products and other treatments to treat the skin disease in the trial; • the willingness of patients to be enrolled in our clinical trials; • the efforts to facilitate timely enrollment in clinical trials; • the patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; and • the proximity and availability of clinical trial sites for prospective patients. Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us or them to abandon one or more clinical trials altogether. For example, parents may be reluctant to enroll their children in our clinical trials that have a relatively high risk of their child being assigned to placebo when in the alternative, they could decline participation, and receive treatment outside of the clinical trial, if available, or pursue other alternative therapies. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on and expect to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large- scale efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. While we succeeded in designing and executing a clinical ~~trials~~ **trial** to support regulatory approval of YCANTH **(VP- 102)** for the treatment of molluscum contagiosum, we may not be similarly successful with respect to the clinical trials for our product candidates, including YCANTH **(VP- 102)** for the treatment of ~~external genital warrants and~~ common warts. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in preclinical testing and earlier- stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of

operations and prospects. Interim " top- line " and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim top- line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates. Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication. If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate. Additionally, if we or others identify undesirable side effects caused by our products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approvals of such product; • regulatory authorities may require additional warnings on the labels; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; • we could be sued and held liable for harm caused to patients; and • our reputation and physician or patient acceptance of our products may suffer. There can be no assurance that we will resolve any issues related to any product- related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of YCANTH (VP- 102) for the treatment of molluscum contagiosum or the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way 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 altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This 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 approval of our product candidates and jeopardize our ability to commence sales and generate revenue. We may not be successful in our efforts to increase our pipeline of product candidates, including by pursuing additional indications for YCANTH (VP- 102) and VP- 315 or in-licensing or acquiring additional product candidates for other dermatological ~~conditions~~ **indications** . A key element of our strategy is to build and expand our pipeline of product candidates, including by developing YCANTH (VP- 102) for the treatment of common warts and ~~external genital warts~~ **VP- 315 for the treatment of BCC** and potentially **additional** ~~other dermatological conditions, VP- 315 for the treatment of~~ dermatological oncology indications ~~, including basal cell carcinoma and squamous cell carcinoma and VP- 103 for the treatment of plantar warts~~ . In addition, we intend to in- license or acquire additional product candidates for other dermatological conditions to build a fully integrated dermatology company. We may not be able to identify or develop product candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify, in- license or acquire may not be suitable for clinical development, 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. 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. Because we have limited financial and management resources, we focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on the commercialization ~~,~~ of YCANTH (VP- 102) for the treatment of molluscum contagiosum, as well as the development of VP- 315 for the potential treatment of basal cell carcinoma. As a result, we may forego pursuit of opportunities with other product candidates, **such as our decision to pause development activities for VP- 102 for the treatment of external genital warts or VP- 103 for the treatment of plantar warts,** or we may delay the development of YCANTH **(VP- 102)** for the treatment of other indications ~~and for VP- 103~~ that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a

particular 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. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. With the exception of YCANTH (VP- 102) for the treatment of molluscum contagiosum, we have not obtained regulatory approval for any product candidate and it is possible that any other product candidates we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any future drug product candidates in the United States until we receive regulatory approval of an NDA **or sNDA as applicable,** from the FDA ~~. To date, we have not met or discussed with the European Medicines Agency or any other comparable foreign authority regarding regulatory approval for YCANTH (VP- 102) or any other product candidate outside of the United States~~ . Prior to obtaining approval to commercialize YCANTH (VP- 102) for any indication other than molluscum contagiosum, or any other potential drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development program. Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects. Even if we eventually complete clinical testing and receive approval of an NDA, sNDA or foreign marketing application for any product candidates, or additional YCANTH **(VP- 102)** indications, the FDA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post- market clinical trials. The FDA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population that we originally request, and the FDA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects. In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future indications or products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Furthermore, even if we obtain regulatory approval for any product candidates, we will still need to establish a commercially viable pricing structure and obtain approval for adequate reimbursement from third- party and government payors. If we are unable to successfully commercialize any future product candidates, we may not be able to generate sufficient revenue to continue our business. Risks Related to the Commercialization of Our Product and Product Candidates YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and any of our product candidates that receive marketing approval, may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and any of our product candidates that receive marketing approval may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If YCANTH **(VP- 102)** for the treatment of molluscum contagiosum or our product candidates, if approved, do not achieve an adequate level of acceptance, we may not generate sufficient revenue and we may not become profitable. The degree of market acceptance of YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and our product candidates, if approved for commercial sale, will depend on a number of factors, including: othe efficacy, safety and potential advantages compared to alternative treatments, including YCANTH **(VP- 102)** compared to compounded cantharidin; oour ability to offer our products for sale at competitive prices; othe convenience and ease of administration compared to alternative treatments, including compounded cantharidin; othe willingness of the target patient population to try new treatments and of physicians to prescribe these treatments; oour ability to hire and retain a sales force in the United States; othe strength of marketing and distribution support; othe availability of third- party coverage and adequate reimbursement for YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and any product candidates that receive marketing approval; othe prevalence and severity of any side effects; and oany restrictions on the use of our products together with other medications. The failure of healthcare professionals or patients to perceive the benefits of using YCANTH **(VP- 102)** for the treatment of molluscum contagiosum instead of compounded cantharidin or other alternative therapies, such as curettage or cryotherapy, would adversely affect the commercial success of YCANTH **(VP- 102)** for the treatment of molluscum contagiosum. If we are unable to maintain sales, marketing and distribution capabilities for YCANTH (VP- 102) for the treatment of molluscum contagiosum or any product candidate that may receive regulatory approval, we may not be successful in commercializing YCANTH (VP- 102) for the treatment of molluscum contagiosum or our product candidates if and when

they are approved. We are in the early stages of commercializing YCANTH (VP- 102) for the treatment of molluscum contagiosum. To achieve commercial success for YCANTH (VP- 102) for the treatment of molluscum contagiosum and any other product candidate for which we may obtain marketing approval, we will need to maintain an effective sales and marketing organization. We have built a focused sales and marketing organization to launch YCANTH (VP- 102) for the treatment of molluscum contagiosum in the United States but expect that we will need to expand upon it if we receive approval of other product candidates. There are inherent risks to maintaining a standalone commercial organization, which is also time-consuming and requires significant financial resources. Factors that create risk and may inhibit our efforts to commercialize our products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products; • challenges in removing unapproved cantharidin products from the market place; • inability to obtain favorable insurance coverage of any approved product; • 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; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we are unable to maintain our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may 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 them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not maintain sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. We face substantial competition, which may result in a smaller than expected commercial opportunity and / or others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical and specialty pharmaceutical companies, compounding facilities, academic institutions and governmental agencies and public and private research institutions. In January 2024, Ligand Pharmaceuticals received FDA approval for Zelsuvmi, a topical treatment for molluscum contagiosum which directly competes with YCANTH (VP- 102). There are also a number of other companies developing products for common warts. In addition, other drugs have been and may continue to be used off label as treatment for molluscum contagiosum **and** ~~, external genital warts,~~ common warts ~~, and plantar warts,~~ and there are other existing alternative therapies such as curettage or cryotherapy. Currently some of the market demand for cantharidin may be satisfied by compounding pharmacies and registered outsourcing facilities regulated under Sections 503A and 503B of the FDCA. Since we received approval for YCANTH (VP- 102) for the treatment of molluscum contagiosum, any compounding by licensed pharmacists or licensed physicians under Section 503A is not legally permitted to include, regularly or in inordinate amounts, the compounding of any drug that is essentially a copy of YCANTH (VP- 102). The FDA has announced that it intends to consider a compounded drug product to be essentially a copy of a commercially available drug under Section 503A if it has the same API, has the same, similar, or an easily substitutable dosage strength, and can be used by the same route of administration. However, a compounded product would not be considered essentially a copy of YCANTH (VP- 102), and could be compounded under Section 503A, if there were a difference between the compounded product and YCANTH (VP-102) that was made for an individual patient, and which the prescribing practitioner determines produces a significant difference for that patient. Similarly, any compounding by outsourcing facilities under Section 503B would not be legally permitted to include the compounding of a drug that is essentially a copy of YCANTH (VP- 102), where the compounded drug would be considered essentially a copy if it were identical or nearly identical to YCANTH (VP- 102) (which the FDA has interpreted to mean that it has the same active ingredient (s), route of administration, dosage form, dosage strength and excipients as the approved drug), or if it contains the active ingredient in YCANTH (VP- 102) (cantharidin), unless there is a change from the approved drug that produces a clinical difference for an individual patient as determined by the prescribing practitioner. Compounding pharmacies and registered outsourcing facilities may therefore be permitted to compound cantharidin drug products, even though we received approval for YCANTH (VP- 102) for the treatment of molluscum contagiosum, if a prescribing practitioner determines that a compounded product prescribed for a specific patient features a change from YCANTH (VP- 102) that produces a significant difference for the patient (under Section 503A), or if a prescribing practitioner determines that a compounded cantharidin product features a change from YCANTH (VP- 102) that produces a clinical difference for the patient (under Section 503B). Physicians may determine that such differences exist for some or all of their patients and may choose to prescribe compounded cantharidin products for such patients. Moreover, under Section 503B, outsourcing facilities are not limited to compounding in response to prescriptions for identified, individual patients, and could compound using bulk cantharidin provided cantharidin appears on a list established by the FDA of bulk drug substances for which there is a clinical need or satisfies certain other limited conditions. Although the FDA has not yet established a list of bulk drug substances for which there is a clinical need, the FDA has announced an interim policy pursuant to which bulk drug substances may be nominated for inclusion on such list and, provided certain conditions are met, outsourcing facilities may compound with such bulk drug substances pending evaluation of the substances for inclusion on the FDA' s list of bulk drug substances for which there is a clinical need. Cantharidin is currently listed among those nominated substances for which bulk drug substance may be used in compounding by outsourcing facilities pending FDA' s evaluation. In December 2023, the FDA issued Guidance for Industry addressing the criteria by which the FDA intends to evaluate whether there exists a clinical need for compounding with a bulk drug substance, including, in the case of a bulk drug substance that is a component of an FDA-approved drug, an evaluation of whether there exists an attribute of the approved drug that makes it medically unsuitable to treat

certain patients; whether the drug product proposed to be compounded is intended to address that attribute; and whether the drug product proposed to be compounded must be compounded from a bulk drug substance rather than from the finished, FDA- approved drug product. If the FDA implements these criteria as in the Guidance for Industry, an outsourcing facility may be permitted to compound a cantharidin product using bulk cantharidin notwithstanding our approval for YCANTH (VP- 102) for the treatment of molluscum contagiosum provided it satisfies these and other criteria set forth in the FDA' s guidance. In addition, the FDA may, in its enforcement discretion, not prioritize enforcement of the restrictions under Sections 503A and 503B on compounding drugs that are essentially copies of YCANTH (VP- 102), if approved, in which case compounded drug product that is essentially a copy of YCANTH (VP- 102) could be made available to physicians and their patients. In the event compounders are authorized to continue to compound cantharidin products following approval of YCANTH (VP- 102), if approved, we could be subject to significant competition. In addition, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than YCANTH (VP- 102) or any other product that we may develop. Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs. **NCE exclusivity for future product candidates may be unsuccessful.** We ~~are seeking~~ **have received** NCE exclusivity for YCANTH (VP- 102) ~~,~~ and **will likely seek** ~~we may be unsuccessful. As part of our business strategy, we are seeking~~ NCE exclusivity ~~for YCANTH (VP- 102) and will likely do so~~ for future product candidates. In the United States, a pharmaceutical manufacturer may obtain five years of non- patent exclusivity upon NDA approval of an NCE which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An " active moiety " is defined as the molecule or ion responsible for the drug substance' s physiological or pharmacologic action. During the five- year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505 (b) (2) NDA for the same active moiety and that relies on the FDA' s findings regarding that drug, except that FDA may accept an application for filing after four years if the follow- on applicant makes a paragraph IV certification. This exclusivity period may be extended by an additional six months if certain requirements are met to qualify the product for pediatric exclusivity, including the receipt of a written request from the FDA that we conduct certain pediatric studies, the submission of study reports from such studies to the FDA after receipt of the written request and satisfaction of the conditions specified in the written request. We believe that ~~cantharidin constitutes an NCE, such that YCANTH (VP- 102) should be eligible for NCE exclusivity and that~~ our planned clinical trials for common warts will qualify ~~YCANTH (VP- 102)~~ for pediatric exclusivity if a written request from the FDA is received. However, there can be no guarantee that we will successfully obtain such exclusivity. ~~If~~ **Even though** we **have** ~~do not obtain~~ **obtained** NCE exclusivity for YCANTH (VP- 102) ~~our ability to generate sustainable revenue may be adversely affected. Moreover, even if we obtain NCE exclusivity for YCANTH (VP- 102)~~ , such exclusivity ~~would~~ **does** not block the sale of compounded cantharidin products in those situations where compounding would be permitted under Sections 503A or 503B of the FDCA. The success of YCANTH (VP- 102) for the treatment of molluscum contagiosum, and our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these procedures. We believe our success depends on continued coverage and adequate reimbursement for procedures using YCANTH **(VP- 102)** for the treatment of molluscum contagiosum as well as coverage and adequate reimbursement for our product candidates, if approved, or, in the absence of coverage and adequate reimbursement, on the extent to which patients will be willing to pay out of pocket for such procedures. A decision by a third- party payor not to cover or separately reimburse for our products could reduce physician utilization of **YCANTH (VP- 102) and** our ~~products~~ **product** ~~once~~ **candidates, if** approved. Additionally, in the United States, there is no uniform policy of coverage and reimbursement among third- party payors. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided is made on a payor- by- payor basis. One payor' s determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement. **The Centers for Medicare & Medicaid Services, or CMS, has issued a permanent Healthcare Common Procedure Coding System, or HCPCS, Level II code, or J- code, (J7354) for YCANTH (VP- 102), as an FDA- approved treatment for molluscum contagiosum. Under the HCPCS process, the J- code for YCANTH (VP- 102) was published April 1, 2024. J- codes are reimbursement codes used by commercial insurance plans, Medicare, Medicare Advantage, and other government payors for physician- administered drugs and are intended to simplify the claims submission and documentation process, facilitating access for patients.** **The Centers for Medicare & Medicaid Services, or CMS, has issued a permanent Healthcare Common Procedure Coding System, or HCPCS, Level II code, or J- code, (J7354) for YCANTH (VP- 102), as an FDA- approved treatment for molluscum contagiosum. Under the HCPCS process, the J- code for YCANTH (VP- 102) was published April 1, 2024. J- codes are reimbursement codes used by commercial insurance plans, Medicare, Medicare Advantage, and other government payors for physician- administered drugs and are intended to simplify the claims submission and documentation process, facilitating access for patients.** Third- party payors determine which medical procedures they will cover and establish reimbursement levels. Even if a third- party payor covers a particular procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in- office for a medical condition generally rely on third- party payors to reimburse all or part of the costs associated with

the procedure and may be unwilling to undergo such procedures for the treatment of molluscum contagiosum ~~, external genital warts~~ or common warts, as applicable, in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for molluscum contagiosum ~~, external genital warts~~ and / or common warts unless coverage is provided, and reimbursement is adequate. Reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost- effective; supported by peer- reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third- party payors. Such updates could impact the demand for our product candidates, to the extent that patients who are prescribed our product candidates, if approved, are not separately reimbursed for the cost of the product candidates. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula and also referred to as the Sustainable Growth Rate, for certain payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs and the Merit- based Incentive Payment System, or MIPS. Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments. Any resulting decrease in payment under the merit- based reimbursement system may adversely affect our revenue and results of operations. In addition, the Medicare physician fee schedule has been adapted by some private payors into their plan- specific physician payment schedule. **Coverage policies and third- party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for YCANTH (VP- 102) for the treatment of molluscum contagiosum or other products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.** We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our product candidates or lowers reimbursement for procedures using our products could harm our business. Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system. There can be no assurance that YCANTH (VP- 102) for the treatment of molluscum contagiosum, or our product candidates, if approved for sale in the United States or in other countries, will **receive** ~~be considered medically reasonable and necessary, that they will be considered cost- effective by third- party payors, that~~ coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale. Molluscum contagiosum ~~, external genital warts~~ and common warts are skin diseases that are currently undertreated with no standard of care. Even with approval of YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and potential approval of any other product candidates, individuals may continue to decline treatment for molluscum contagiosum ~~, external genital warts~~ and common warts as, if left untreated, these skin diseases will eventually be resolved by the body' s immune system. In addition, our estimates of the potential market opportunity for YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and our product candidates include several key assumptions based on our industry knowledge, industry publications, third- party research reports and surveys of dermatologists commissioned by us. These assumptions include the prevalence of molluscum contagiosum, ~~external genital warts,~~ common warts and other skin diseases as well as the estimated reimbursement levels for YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and our product candidates, as applicable. However, there can be no assurance that any of these assumptions are, or will remain, accurate. Furthermore, even if our estimates relating to the prevalence of molluscum contagiosum, ~~external genital warts,~~ common warts and other skin diseases as well as the estimated reimbursement levels for YCANTH **(VP- 102)** for the treatment of molluscum contagiosum or our product candidates, as applicable, are accurate, the degree of market acceptance by the medical community and those infected by such skin diseases following regulatory approval could impact our assumptions and reduce the market size for YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and our product candidates, if approved. Furthermore, the market research study we commissioned surveying payor organizations has no bearing on the payors, and any assumptions or interpretations based on the results of this study, may ultimately be inaccurate. If the actual markets for YCANTH **(VP- 102)** for the treatment of molluscum contagiosum or, if approved, our product candidates are smaller than we expect, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the commercial sale of YCANTH (VP- 102) for the treatment of molluscum contagiosum, as well as the testing of our product candidates in human clinical trials. If we cannot successfully defend ourselves against claims that YCANTH (VP- 102) or our product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for YCANTH (VP- 102) for the treatment of molluscum contagiosum and any product candidates or drugs that we may develop; • injury to our reputation and significant negative media attention; • loss of revenue; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards paid to trial participants or patients; • reduced resources of our management to pursue our business strategy; and • the inability to commercialize any products that we may develop. We currently hold $ 10 million in product liability insurance coverage in the aggregate, with a per incident limit of $ 10 million, which may not be adequate to cover all liabilities that we may incur. We increased our insurance coverage following commencement of our commercialization activities for YCANTH **(VP- 102)** for the

treatment of molluscum contagiosum and may need to further increase our insurance coverage as we ~~expand~~ **continue** our clinical trials or expand commercialization activities for our product candidates that obtain regulatory approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our business activities involve the use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we or our vendors violate these laws, we could be subject to significant fines, liabilities or other adverse consequences. Our business activities involve the controlled use of hazardous materials, including corrosive, explosive and flammable chemicals and other hazardous compounds in addition to certain biological hazardous waste. Ultimately, the activities of our third- party product manufacturers when a product candidate reaches commercialization will also require the use of hazardous materials. Accordingly, we are subject to federal, state and local laws governing the use, handling and disposal of these materials. For example, cantharidin is classified as an extremely hazardous substance in the United States and is subject to strict reporting requirements. Furthermore, the excipients in our product candidate are combustible and flammable. If not handled properly, there is a risk of explosion which could carry liability risk and affect the availability or capacity of the affected vendor. Although we believe that our and our vendors' safety procedures for handling and disposing of these materials comply in all material respects with the standards prescribed by local, state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In addition, our collaborators may not comply with these laws. In the event of an accident or failure to comply with environmental laws, we could be held liable for damages that result, and any such liability could exceed our assets and resources, or we could be subject to limitations or stoppages related to our use of these materials which may lead to an interruption of our business operations or those of our third- party contractors. While we believe that our existing insurance coverage is generally adequate for our normal handling of these hazardous materials, it may not be sufficient to cover pollution conditions or other extraordinary or unanticipated events. Furthermore, an accident could damage or force us to shut down our operations or one of our vendors. Changes in environmental laws may impose costly compliance requirements on us or otherwise subject us to future liabilities and additional laws relating to the management, handling, generation, manufacture, transportation, storage, use and disposal of materials used in or generated by the manufacture of our products or related to our clinical trials. In addition, we cannot predict the effect that these potential requirements may have on us, our suppliers and contractors or our customers. We will rely on third parties to conduct our future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials. We have engaged a CRO historically to conduct our clinical trials and expect to engage a CRO for future clinical trials for YCANTH (VP- 102), for the treatment of ~~external genital warts and~~ common warts, VP- 315 or other product candidates that we may progress to clinical development. We expect to continue to rely on third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced 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 may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for YCANTH (VP- 102) for the treatment of ~~external genital warts and~~ common warts or our other product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly. Switching or adding CROs involves substantial ~~cost~~ **costs** and requires 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 intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, fails to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has

created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of YCANTH (VP- 102) for the treatment of ~~external genital warts or~~ common warts and any other product candidates. We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue. We currently rely on third parties to supply our raw material and applicator components used for YCANTH (VP- 102), and if we encounter any extended difficulties in procuring, or creating an alternative for, our raw material or applicator components for YCANTH (VP- 102) or any of our product candidates we may develop, our business operations would be impaired. To date, we have obtained naturally-sourced cantharidin, which is the raw material used to manufacture the API for YCANTH (VP- 102) and is obtained from blister beetles, directly or indirectly from suppliers based in the People' s Republic of China, or the PRC. We are exposed to a number of environmental risks, including: • risk of contamination being introduced in the beetle population through environmental factors that we cannot control, which would result in unexpected anomalies or new impurities in the cantharidin; • loss of the beetle' s habitat and other similar environmental risks to the beetle population whether due to climate change, over-development, or otherwise; and • risk of disease in the beetles. In addition, any business, public health or economic challenges our existing supplier faces, whether in the ordinary course or not, could impair its ability to meet our cantharidin supply needs. Accordingly, there is a risk that supplies of our product may be significantly delayed by or may become unavailable for an extended period of time as a result of any issues affecting our supplier' s supply and production of naturally- sourced cantharidin. Furthermore, our supplier' s operations may be curtailed or delayed in the event the regulators in the PRC determine that our supplier is not acting in accordance with laws or under appropriate permits or licenses. We may also face additional supply chain risks due to the regulatory and political structure of the PRC, or as a result of the international relationship between the PRC and the United States or any of the other countries in which our products are marketed. For example, any deterioration in the trade relationship between the U. S. and China, which imposes any restrictions, tariffs or limitations on the export of cantharidin from China would impact our ability to meet our raw material needs. We are also exposed to foreign exchange risks, and fluctuations in exchange rates between the U. S. dollar and the Renminbi could negatively impact the commercial viability of importing cantharidin from the PRC. While we have successfully developed a lab scale process for synthesizing the cantharidin molecule, there is risk that we will be unable to scale the process to produce a sufficient quantity of synthetically derived cantharidin to meet our needs and, even if we are ultimately able to scale the proposed process successfully, we cannot predict when we will be able to do so. Intermediate compounds in this proposed synthetic process have been successfully synthesized to a pilot scale. If we are unable to scale the developed process for manufacturing cantharidin synthetically to a satisfactory commercial scale, we may be forced to continue to rely on naturally sourced cantharidin. Any extended difficulties we face in maintaining our supply of cantharidin, or limitations we face in increasing our supply to meet commercial needs for YCANTH (VP- 102) for the treatment of molluscum contagiosum or any of our product candidates, whether such cantharidin is naturally sourced or synthetically derived, would impair our business operations. In addition to the API, the components necessary to build the YCANTH **(VP- 102)** applicator such as the applicator tip, tube and filter are currently sourced from third parties. Any extended difficulty in obtaining those components, or increasing supply to meet commercial needs for YCANTH (VP- 102) would impair our business operations. We contract with third parties for the manufacture of YCANTH (VP- 102) for preclinical, clinical testing and for commercial product. This reliance on third parties increases the risk that we will not have sufficient quantities of YCANTH (VP- 102) or such quantities at an acceptable cost, which could negatively impact our development and / or commercialization efforts. We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacturing of commercial product for YCANTH (VP- 102) for the treatment of molluscum contagiosum, and also rely on third parties for the production of preclinical and clinical material for any other product candidates which we may pursue. This reliance on third parties increases the risk that we will not have sufficient quantities of YCANTH (VP- 102) or be able to obtain quantities at an acceptable cost or quality, which could impact commercialization efforts, or delay, prevent or impair our ability to timely conduct our clinical trials. We also rely on third- party manufacturers or third- party collaborators for the manufacturing of our commercial supply of YCANTH (VP- 102), and will do so for any other product candidates for which we obtain marketing approval. The facilities used by our contract manufacturers to manufacture YCANTH (VP- 102), as well as our other potential product candidates, must be approved by the FDA or other regulatory authorities pursuant to inspections that are routinely conducted prior to the approval of an NDA. In addition, all manufacturers remain subject to periodic FDA inspections post NDA approval ~~.~~. We do not have control over a supplier' s or manufacturer' s compliance with laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. We may be unable to establish any agreements with future third- party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, qualifying and validating such manufacturers may take a significant period of time and reliance on third- party manufacturers entails additional risks, including: • reliance on the third party for regulatory compliance and quality assurance; • the possible

breach of the manufacturing agreement by the third party; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; • the possible increase in costs for the applicator components, raw materials or API in YCANTH (VP- 102); and • the possible termination or nonrenewal of any agreement by any third party at a time that is costly or inconvenient for us. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Our product candidates and any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. To date, all assembly of our single- use precision applicators has been done using manual processes. In order to meet anticipated longer term volume requirements, we may need to transition to an automated or semi- automated assembly process. If our current contract manufacturers cannot successfully transition to automated and / or semi- automated assembly processes, we may be required to replace such manufacturers. We may incur added costs or delays in identifying and qualifying any such replacement. We expect to continue to depend on third- party contract manufacturers for the foreseeable future. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize YCANTH (VP- 102) for the treatment of molluscum contagiosum and any other drugs that receive marketing approval on a timely and competitive basis. If there is any disruption in our supply chain, it could take a significant period of time to qualify and validate a replacement on terms acceptable to us, if we are able to at all. On March 17, 2021, we entered into the Torii Agreement, pursuant to which we granted Torii an exclusive license to develop and commercialize our product candidates that contain a topical formulation of cantharidin for the treatment of molluscum contagiosum and common warts in Japan, including YCANTH (VP- 102). Additionally, we granted Torii a right of first negotiation with respect to additional indications for the licensed products and certain additional products for use in the licensed field, in each case in Japan. We may seek additional third- party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any collaboration arrangements include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Such agreements may provide us limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. For instance, Torii is responsible for all development activities and specified costs in support of obtaining regulatory approval of the licensed products in Japan, provided that Torii' s activities will be overseen by a joint steering committee. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose the following risks to us: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may 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 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 clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • 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 discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, 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 may not commit sufficient resources to the marketing and distribution of such products; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; 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. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. ~~Further~~ **Furthermore , we** cannot guarantee these relationships, including our relationship with Torii, will continue or that we will be able to receive the milestone or transfer price payments pursuant to the Torii Agreement or any other future collaboration agreement. If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans. Our product development programs and the potential

commercialization of our product candidates will require substantial additional capital. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For instance, we have entered into the Torii Agreement, pursuant to which we granted Torii an exclusive license to develop and commercialize our product candidates that contain a topical formulation of cantharidin for the treatment of molluscum contagiosum and common warts in Japan, including YCANTH (VP- 102). We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue. We plan to rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to YCANTH (VP- 102) and our other product candidates **(including VP- 315)** . The issuance, scope, validity, enforceability, strength, and commercial value of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. Although we currently have several issued United States and foreign patents, other patent applications that we own may fail to result in other issued patents with claims that cover YCANTH (VP- 102) and ~~the~~ **our** other product candidates in the United States or in foreign jurisdictions. If this were to occur, early generic competition could be expected against YCANTH (VP- 102) and our other product candidates ~~in development in certain jurisdictions~~ . There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the API in YCANTH (VP- 102) and some of our product candidates have been available and used for many years, it is possible that these products have previously been used in such a manner that such prior usage would affect our ability to obtain patents based on our patent applications. Moreover, because numerous parties have developed and / or commercialized, or are developing, a wide variety of applicator devices for use with topical dermatological medications, it is possible that prior art related to **such** applicator devices could affect our ability to obtain patent protection for our product applicator device **,** or that disputes may arise related to whether third- party applicator devices infringe patents we have applied for **or obtained** . The patent prosecution process is expensive and time- consuming. We may not be able to prepare, file, and prosecute all necessary or desirable patent applications for a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may 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, depending on the terms of any future in- licenses to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology in- licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. In addition to the protection we hope to receive from patents we have applied for, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development and reformulation processes that involve proprietary know- how, information, or technology that is not covered by patents. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know- how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. Moreover, our competitors may independently develop knowledge, methods, and know- how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. The FDA has recently made changes to its rules that may make it harder

for the FDA to withhold information from the public and may require the FDA to make certain information publicly accessible, and it is not clear how these new rules will be interpreted. If we are unable to prevent material disclosure of the non- patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations, and financial condition. We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world. Filing and prosecuting patent applications and defending patents covering YCANTH (VP- 102) and our other product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with YCANTH (VP- 102) or our other product candidates, and our current and future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we may decide to abandon national and regional patent applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product **, product** candidate **,** or technology. While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market YCANTH (VP- 102) or our other product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize YCANTH (VP- 102) or our other product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents. Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first- to- file provisions, only became effective in March 2013. The Leahy- Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy- Smith Act contains new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy- Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents. Further, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed **,** or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely

affect our business prospects and financial condition. Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims, or the written description **, support** or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and / or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and / or **patent** applications and any patent rights we may obtain in the future. We rely on our outside counsel to pay these fees. The USPTO and various non- U. S. government patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, and this circumstance could harm our business. The patent applications that we have covering YCANTH (VP- 102) and our cantharidin- based product candidates are limited to specific formulations, preparations, and devices, and methods of use and manufacturing processes, and our market opportunity for YCANTH (VP- 102) and our cantharidin- based product candidates may be limited by the lack of patent protection for the active ingredient itself and by competition from other formulations and manufacturing processes, as well as administration methods that may be developed by competitors. Cantharidin is a naturally occurring compound found in many species of blister beetles and has been used since ancient times for medicinal purposes. Therefore, the composition of matter for the chemical structure of cantharidin itself, which is the API used in YCANTH (VP- 102) and our cantharidin- based product candidates, is not eligible for patent protection. We seek to obtain patent protection for our manufacturing technology, drug administering technology, and YCANTH (VP- 102) and our cantharidin- based product candidates, including specific formulations, preparations, and devices, and methods of use and manufacturing processes. Although the protection afforded by our patents and patent applications may be significant with respect to YCANTH (VP- 102), when looking at the ability of the patents and patent applications to block competition, the protection offered by the patents and ~~patents~~ **patent** applications may be, to some extent, more limited than the protection provided by a patent claiming the composition of matter of an entirely new chemical entity previously unknown. As a result, generic products that do not infringe the claims of our patents covering formulations, preparations, devices, methods of use, and manufacturing processes may be available while we are marketing our products. In general, method of use patents are more difficult to enforce than composition of matter patents because, for example, of the risks that the FDA may approve alternative uses of the subject compound not covered by method of use patents, and others may engage in off- label sale or use of the subject compound. Physicians are permitted to prescribe an approved product for uses that are not described in the product' s labeling. Although off- label prescriptions may infringe the method of use patents we have applied for, the practice is common across medical specialties, and such infringement is difficult to prevent **, detect,** or prosecute. In addition, competitors who obtain the requisite regulatory approval will be able to commercialize products with the same active ingredient as YCANTH (VP- 102) and our cantharidin- based product candidates so long as the competitors do not infringe any process, use, formulation, preparation, or device patents issued to us, subject to any regulatory exclusivity we may be able to obtain for YCANTH (VP- 102) and our cantharidin- based product candidates. Patent applications covering products containing the same active ingredient as YCANTH (VP- 102) and our cantharidin- based product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for YCANTH (VP- 102) and our cantharidin- based product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of YCANTH (VP- 102) and our cantharidin- based product candidates that are different from ours and do not infringe our issued patents covering YCANTH (VP- 102) and our cantharidin- based product candidates, our device, our manufacturing processes, or uses of YCANTH (VP- 102) and our cantharidin- based product candidates. We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Competitors may infringe the patents we have been granted. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. If we initiate legal proceedings against a third party to enforce a patent covering **YCANTH (VP- 102) or** one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation.

Such mechanisms include re- examination, post grant review, inter partes review (IPR), and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our **product or** product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product **or product** candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing **,** and could have a material adverse impact on our business. Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. An unfavorable outcome could require us to cease using the related technology 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 a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. 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 common stock. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain. As **commercial efforts related to YCANTH (VP- 102) continue, and as** our current and future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There can be no assurance that our **product and** current ~~and~~ **or** future product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current **product** and **current or** future product candidates, including interference or derivation proceedings before the USPTO. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable, and infringed, which could have a negative impact on our ability to commercialize YCANTH (VP- 102) and any current **product** or future product candidates. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents, or that we will not infringe patents that may be granted in the future. Because numerous parties have developed and / or commercialized, or are developing, a wide variety of applicator devices for use with topical dermatological medications, it is possible that third parties may assert that our applicator device infringes patents they own or have applied for. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, or sale of our product **or product** candidates. Regardless of when filed, we may fail to identify relevant third- party patents or patent applications, or we may incorrectly conclude that a third- party patent is invalid or not infringed by our product **, product** candidates **,** or activities. If a patent holder believes our drug **, product,** or product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non- practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing, or sales of the drug **, product,** or product candidate that is the subject of the actual or threatened suit. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our **product or** product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non- exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market **products or** product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease commercializing our product **or product** candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed **a third party' s patent rights** . A finding of infringement could prevent us from commercializing our **product or** product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management' s attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively

than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents and patent applications, our future patents **and patent applications** , or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our **product or** product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them, or that our trade secrets will be misappropriated or disclosed. If we rely on third parties to manufacture or commercialize YCANTH (VP- 102) or any current **or** future product candidates, or if we collaborate with additional third parties on the development of YCANTH (VP- 102) or any current or future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets **or other confidential information** under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements, or other similar agreements with our advisors, employees, third- party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors, and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know- how **,** ~~or other~~ trade secrets **, or other confidential information** by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors, and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third- party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative: • others may be able to make products that are similar to our product **or product** candidates but that are not covered by the claims of our patents or future patents; • we or future collaborators might not have been the first to make the inventions covered by our patents, future issued patents, ~~or~~ our pending **patent applications, or future** patent applications; • we or future collaborators might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own may be held invalid or unenforceable as a result of legal challenges by our competitors; • issued patents that we own may not provide coverage for all aspects of our product candidates in all countries; • our competitors might conduct research and development activities in

countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, results of operations, and prospects. Risks Related to Legal and Regulatory Compliance Matters Our relationships with customers, physicians, and third- party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers, including physicians and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The term " remuneration " has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act and the civil monetary penalties statute; • the federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes " any request or demand " for money or property presented to the U. S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved or off- label, and thus non- reimbursable, uses; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, independent contractors that perform certain services involving the use or disclosure of individually identifiable health information and their subcontractors that use, disclose, access, or otherwise process individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions; • the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to ~~the Centers for Medicare & Medicaid Services, or~~ CMS, information related to: (i) payments or other " transfers of value'' made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members; and • state and foreign law equivalents of each of the above federal laws; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; state laws that require the reporting of information related to drug prices; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways

and often are not preempted by HIPAA, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving 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 governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found to have improperly promoted off-label uses of YCANTH **(VP- 102)** for the treatment of molluscum contagiosum or any of our product candidates that are approved, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. Generally, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. However, physicians may, in their independent medical judgment, prescribe legally available products for off- label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer' s communications on the subject of off- label use of their products. If we are found to have promoted such off- label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. We have obtained regulatory approval for YCANTH **(VP- 102)** for the treatment of molluscum contagiosum; however, YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and any future product candidates that are approved will remain subject to ongoing regulatory oversight. YCANTH **(VP- 102)** for the treatment of molluscum contagiosum and any future product candidates, once approved, will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record- keeping and submitting of safety and other post- market information among other things. YCANTH **(VP- 102)** , or any future product candidates, may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post- marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We are required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval. The holder of an approved NDA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements of YCANTH (VP- 102) for the treatment of molluscum contagiosum or our product candidates, a regulatory authority may: • issue an untitled letter or warning letter asserting that we are in violation of the law; • seek an injunction or impose administrative, civil or criminal penalties or monetary fines; • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve a pending NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners; • restrict the marketing or manufacturing of the drug; • seize or detain the drug or otherwise require the withdrawal of the drug from the market; • refuse to permit the import or export of product candidates; or • refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to sell YCANTH

(VP- 102) for the treatment of molluscum contagiosum or any future product candidates and harm our business, financial condition, results of operations and prospects. Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post- approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U. S. pharmaceutical industry. The ACA, among other things: (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (ii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (iii) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (iv) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23. 1 % and 13 % of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100 % of the Average Manufacturer Price, or AMP; (v) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133 % of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vi) created a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (vii) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. There have been judicial, Congressional and executive branch challenges **and amendments** to certain aspects of ~~the ACA. For example, on June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further, there have been a number of health reform measures by the Biden administration that have impacted~~ the ACA. For example, on August 16, 2022, ~~President Biden signed~~ the Inflation Reduction Act of 2022, or IRA, **was signed** into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the ~~Biden~~ **second Trump** administration will impact the ACA and our business. Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, ~~President Biden signed~~ the American Rescue Plan Act of 2021 **was signed** into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, ~~beginning~~ **effective** January 1, 2024 ~~. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years~~ . These new laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations. Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. **The** ~~At the federal level, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the Department of Health and Human Services, or HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the~~ IRA, among other things, (1) directs **the Department of Health and Human Services, or** HHS **,** to negotiate the price of certain single- source drugs and biologics **that have been on the market for at least 7 years** covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~will take~~ **went into** effect ~~progressively starting~~ in fiscal year 2023. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list~~ **agreed- upon price** of the first ten drugs that **were** ~~will be~~ subject to price negotiations, although the Medicare ~~drug~~ **Drug** ~~price~~ **Price** ~~negotiation~~ **Negotiation** ~~program~~ **Program** is currently subject to legal challenges. ~~It is currently unclear how the IRA~~ **On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products** will **become subject** ~~be implemented but is likely~~ to ~~have a significant impact on the pharmaceutical industry. In response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three~~ -- **the Medicare Drug Price Negotiation Program** ~~new models for~~

~~testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future~~ . Further, on December 7, 2023, ~~the Biden administration announced~~ an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act **was announced** . On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures are increasingly 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. For example, on January 5, 2024, the FDA approved Florida' s Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. ~~In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration undertook several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA' s ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented and the extent to which they will impact the FDA' s ability to exercise its regulatory authority, particularly in light of the new Biden administration. If these executive actions impose restrictions on the FDA' s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.~~ Any new regulations or guidance, including implementation of or new guidance regarding the frameworks for compounding under Sections 503A and 503B of the FDCA, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require: • additional clinical trials to be conducted prior to obtaining approval; • changes to manufacturing methods; • recalls, replacements, or discontinuance of one or more of our products; and • additional recordkeeping. Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of YCANTH (VP- 102) for the treatment of molluscum contagiosum or our product candidates by authorizing competition in the form of compounded cantharidin products, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations. Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti- bribery and anti- corruption laws. Our business activities may be subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. We may engage third parties to sell our products sell our ~~products~~ **product** outside the United States, to conduct clinical trials, and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition. We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we

violate them. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations and various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls. Exports of our product candidates outside of the U. S. must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers. In addition, changes in our product candidates or changes in applicable export or import laws and regulations may create delays in the introduction, provision or sale of our product candidates in international markets, prevent customers from using our product candidates or, in some cases, prevent the export or import of our product candidates to certain countries, governments or persons altogether. Any limitation on our ability to export, provide or sell our product candidates could adversely affect our business, financial condition and results of operations. **Risks Related to Employee Matters and Managing Our Growth** Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. **Each** ~~We are highly dependent on the management, development, clinical, financial and business development expertise~~ of ~~Ted White, our President and Chief Executive Officer, Joe Bonaccorso, our Chief Commercial Officer, Gary Goldenberg, our Chief Medical Officer, P. Terence Kohler Jr., our Chief Financial Officer, Chris Hayes, our Chief Legal Officer and the other members of our scientific and clinical teams. While we have entered into employment agreements with~~ our executive officers ~~, each of them~~ may currently terminate their employment **or service** with us at any time. We do not maintain " key person " insurance for any of our executives or employees. **In 2024, we reduced our headcount by approximately 29 %, including the transition of our former Chief Executive Officer, Chief Commercial Officer and Chief Financial Officer. As a result of our headcount reductions, we have engaged various outside consultants, principally in the capacity of Interim Chief Financial Officer and Head of Commercial. Although we believe these employee transitions are in the best interest of our company and our stockholders, these transitions may result in the loss of personnel with deep institutional or technical knowledge. Further, the transition could potentially disrupt our operations and relationships with employees, suppliers and partners and due to added costs, operational inefficiencies, decreased employee morale and productivity and increased turnover. In addition, our competitors may seek to use these transitions and the related potential disruptions to gain a competitive advantage over us. Furthermore, these changes increase our dependency on the other members of our leadership team and sales teams that remain with us, who are not contractually obligated to remain employed with us and may leave at any time. Any such departure could be particularly disruptive and, to the extent we experience additional turnover, competition for top talent is high such that it may take some time to find a candidate that meets our requirements. Our future operating results depend substantially upon the continued service of our key personnel and in significant part upon our ability to attract and retain qualified management personnel. If we are unable to mitigate these or other similar risks, our business, results of operation and financial condition may be adversely affected.** Recruiting and retaining qualified scientific ~~and~~ **,** clinical ~~personnel and~~ , ~~if we progress the development of our product pipeline toward scaling up for~~ commercialization ~~, manufacturing~~ and sales and marketing personnel ~~,~~ will ~~also~~ be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited ~~. We expect to expand our development and regulatory capabilities and continue to grow our sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of December 31, 2023, we had 100 full- time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales, marketing and distribution, as well as product development and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations~~ . Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that

require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations. Our stock price may be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including: • our ability to meet external revenue and profitability expectations for YCANTH (VP- 102) for the treatment of molluscum contagiosum; • the commencement, enrollment or results of our clinical trials of YCANTH (VP- 102) for the treatment of common warts and ~~external genital warts and~~ any future clinical trials we may conduct, or changes in the development status of our product candidates; • any delay in our regulatory filings for YCANTH (VP- 102) for the potential treatment of common warts ~~and external genital warts~~ or any other product candidate we may develop, including VP- 315 ~~and VP- 103~~, and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; • adverse results from, delays in or termination of clinical trials; • adverse regulatory decisions, including failure to receive regulatory approval of our product candidates; • unanticipated serious safety concerns related to the use of YCANTH (VP- 102) for the treatment of molluscum contagiosum or any of our product candidates; • changes in financial estimates by us or by any securities analysts who might cover our stock; • conditions or trends in our industry; • changes in the market valuations of similar companies; • stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry; • publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; • announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures; • announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; • investors' general perception of our company and our business; • recruitment or departure of key personnel; • overall performance of the equity markets; • trading volume of our common stock; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including patent or stockholder litigation; • changes in the structure of healthcare payment systems; • general political and economic conditions; and • other events or factors, many of which are beyond our control. In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources from our business. **We have a substantial number of warrants outstanding. The exercise of our outstanding warrants will dilute existing stockholders and could adversely affect the trading price of our common stock. As of December 31, 2024, we had (i) outstanding pre- funded warrants to purchase, without regard to any beneficial ownership limitations, up to 3, 056, 481 shares of our common stock at an exercise price of $ 0. 0001 per share and (ii) outstanding warrants to purchase, without regard to any beneficial ownership limitations, up to 48, 772, 769 shares of common stock at a weighted average exercise price of $ 1. 31 share. The exercise of our outstanding warrants could result in significant dilution to existing stockholders, cause the trading price of our common stock to decline and impair our ability to raise capital through the sale of additional equity securities. Moreover, the expectation of such exercises could encourage the short selling of our common stock, which could place further downward pressure on the trading price of our common stock.** Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to ~~drop~~ **decline** significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to the restrictions and limitations described below. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates. In addition, we have filed registration statements on Form S- 8 under the Securities Act registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S- 8 are available for sale in the public market subject to vesting arrangements and exercise of options, the lock- up agreements described above and the restrictions of Rule 144 in the case of our affiliates. Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result. There are provisions in our certificate of incorporation and bylaws that may

make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10, 000, 000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders. Our charter documents contain other provisions that could have an anti- takeover effect, including: • only one of our three classes of directors are elected each year; • stockholders are not entitled to remove directors other than by a 66 ~~⅔~~ **. 67** % vote and only for cause; • stockholders are not permitted to take actions by written consent; • stockholders cannot call a special meeting of stockholders; and • stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings. In addition, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent our other stockholders from influencing significant corporate decisions. Our executive officers, directors and current beneficial owners of 5 % or more of our common stock and their respective affiliates, including entities affiliated with Paul B. Manning, in the aggregate, beneficially own a majority of our outstanding common stock. As a result, these persons, acting together, can significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions. Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. We are a " smaller reporting company " and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors. We are a " smaller reporting company, " meaning that the market value of our shares held by non- affiliates is less than $ 700 million and our annual revenue was less than $ 100 million during the most recently completed fiscal year. We will continue to be a smaller reporting company if either (i) the market value of our shares held by non- affiliates is less than $ 250 million or (ii) our annual revenue was less than $ 100 million during the most recently completed fiscal year and the market value of our shares held by non- affiliates is less than $ 700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K and we have reduced disclosure obligations regarding executive compensation. In addition, as a smaller reporting company and non- accelerated filer, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. If we fail to maintain proper and effective internal ~~controls~~ **control over our financial reporting** , our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes- Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Because we are a smaller reporting company and a non- accelerated filer, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act. However, we perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10- K filing for that year, as required by Section 404 of the Sarbanes- Oxley Act. This requires that we incur substantial additional professional fees and internal costs to ~~expand~~ **maintain** our accounting and finance functions and that we expend significant management efforts. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission, or SEC, or other regulatory authorities. We might not be able to utilize a significant portion of our net operating loss carryforwards. As of December 31, ~~2023~~ **2024** , we had federal and state net operating loss carryforwards of approximately $ ~~149~~ **218** . ~~6~~ **4** million and $ ~~152~~ **204** . ~~1~~ **0** million, respectively. The federal net operating loss carryforwards included in the foregoing totals that were generated in tax years prior to 2018 (federal of approximately $ 6. 9 million) will begin to expire, if not utilized, by 2033. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the 2017 federal income tax law changes, as modified by subsequent legislation the federal net operating losses incurred in tax years beginning in 2018 and future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80 % of current year taxable income. In addition, under Section 382 of the Internal Revenue Code of 1986, as

amended, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of the Loan Agreements restrict us from paying dividends, subject to limited exceptions, and any future debt agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock. We incur increased costs and demands upon management as a result of being a public company. As a public company listed in the United States, we incur significant additional legal, accounting and other costs. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time- consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We continue to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums 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 the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. These exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery and federal district courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either 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 adversely affect our business and financial condition. For example, the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision has been appealed and may be reviewed and ultimately overturned by the Delaware Supreme Court. If this ultimate adjudication were to occur, we would enforce the federal district court exclusive forum provision in our amended and restated certificate of incorporation. **On January 24, 2025, we received a letter from Nasdaq, notifying us that the listing of our common stock was not in compliance with Nasdaq Listing Rule 5450 (a) (1) for continued listing on the Nasdaq Global Market, as the minimum bid price of our common stock was less than $ 1. 00 per share for the previous 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A) we were provided an initial period of 180 calendar days, or until July 23, 2025, to regain compliance with Nasdaq' s bid price requirement. If, at any time before July 23, 2025, the bid price for our common stock closes at $ 1. 00 or more for a minimum of 10 consecutive business days, we will regain compliance with the bid price requirement, unless Nasdaq staff exercises its discretion to extend this 10- day period pursuant to Nasdaq rules. There can be no assurance that we will regain compliance with the requirements for listing our common stock on Nasdaq. If we are unable to satisfy the Nasdaq criteria for continued listing, our common stock would be subject to delisting. A delisting of our common stock could negatively impact us by,**

among other things, reducing the liquidity and market price of our common stock; reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; decreasing the amount of news and analyst coverage of us; and limiting our ability to issue additional securities or obtain additional financing. General Risk Factors We are subject to **legal proceedings and claims from time to time that may seek material damages or otherwise may have a material adverse effect on our business. The costs we incur in defending ourselves or associated with settling any of these proceedings, as well as a material final judgment or decree against us, could materially adversely affect our financial condition. We are subject to legal proceedings and claims from time to time that may seek material damages or otherwise may have a material adverse effect on our business. For example, in June 2022, we were named a defendant in a putative class action complaint against us and certain of our current and former officers and directors in the U. S. District Court for the Eastern District of Pennsylvania. The lawsuit seeks unspecified compensatory damages and other relief on behalf of Plaintiff and all other persons and entities which purchased or otherwise acquired our securities between May 19, 2021 and May 24, 2022. In addition, on October 21, 2024, a plaintiff filed a putative stockholder derivative lawsuit in the U. S. District Court for the Eastern District of Pennsylvania. The complaint names us as a nominal defendant and purports to bring claims on our behalf against certain of our current and former directors and officers for alleged violations of the federal securities laws and breaches of their fiduciary duties in relation to substantially the same factual allegations as the above- described putative class action lawsuit. See " Item 3 — Legal Proceedings " and " Part II, Item 8, Note 6- Commitments and Contingencies " in this Annual Report on Form 10- K for more information. Due to the inherent uncertainties in legal proceedings, we cannot accurately predict the ultimate outcome of any such proceedings. This or any future litigation, regardless of the merits of any such proceeding, could harm our reputation and result in substantial costs and diversion of management' s attention and resources, which could adversely impact our business. Although we have directors' and officers' liability insurance, it provides for a substantial retention of liability and is subject to limitations and may not cover a significant portion, or any, of the expenses or liabilities we may incur or be subject to in connection with these lawsuits or other litigation to which we are party. The costs we incur in defending ourselves or associated with settling such proceedings, as well as a material final judgment or decree against us, that are not covered by our directors' and officers' liability insurance could materially adversely affect our financial condition. In addition, additional lawsuits may be filed, the conclusion of which in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance could have a material adverse effect on our financial condition and business. We and the third parties with whom we work are subject to** stringent and evolving U. S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply **(or the actual or perceived failure by the third parties with whom we work)** with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third- party data, and other sensitive data the Company may process. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. **Numerous** ~~At the state level, at least ten~~ U. S. states ~~— including California, Virginia, Colorado, Connecticut, and Utah —~~have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines ~~of up to $ 7, 500 per intentional violation~~ and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union' s General Data Protection Regulation, or EU GDPR, and the United Kingdom' s GDPR, or UK GDPR, impose strict requirements for processing personal data. Under the GDPR, companies may face temporary or definitive bans on data

processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each case, 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Our employees and personnel may use generative artificial intelligence, or AI, technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Our business model materially depends on our ability to process personal data, so we are particularly exposed to the risks associated with the rapidly changing legal landscape. For example, we may be at heightened risk of regulatory scrutiny, and any changes in the regulatory framework could require us to fundamentally change our business model. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- action claims) and mass arbitration demands; additional reporting requirements and / or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); interruptions or stoppages of data collection needed to train our algorithms; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. If our information technology systems or those third parties upon which we rely or our data, are or were compromised or were to encounter computer system failures, we could experience adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely may process, receive, store, generate, use, secure, or share proprietary, confidential, and sensitive data, including personal data (such as health- related data), intellectual property, trade secrets and other sensitive data. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber- attacks or cyber- intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. Cyberattacks, malicious internet- based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources. In addition to traditional computer " hackers, " threat actors, personnel (such as through theft or misuse), sophisticated nation- states, and nation- state- supported actors now engage in attacks. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through deep fakes (which may be increasingly more difficult to identify as fake) and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. We rely on third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. We may also rely on third- party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. Any of the foregoing could result in a material disruption of our clinical and product development activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. For example, the loss or compromise of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce

the data. To the extent that any disruption or security incident was to result in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur significant unexpected losses, expenses and liabilities, ~~we could face~~ **such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data);** litigation ~~or suffer~~ **(including class claims); indemnification obligations; negative publicity;** reputational harm **; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms** and the further development of our product candidates could be delayed. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Unfavorable conditions, including inflationary pressure, in the global economy could ~~limit our ability to grow our business and~~ negatively affect our operating results. General worldwide economic conditions have experienced significant instability in recent years including the recent global economic uncertainty and financial market conditions. For example, inflation rates, particularly in the United States and United Kingdom, have increased recently to levels not seen in years, and increased inflation has resulted in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. In addition, the Federal Reserve has raised interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. These conditions make it extremely difficult for us to accurately forecast and plan future business activities. An active trading market for our common stock may not continue to develop or be sustained. Prior to our initial public offering, there was no public market for our common stock, and we cannot assure you that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for you to sell shares at an attractive price or at all. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we continue to have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline. Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts. We are subject to taxation in more than one tax jurisdiction. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including **changes in** ~~passage of the 2017~~ federal income tax law, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations.