

Risk Factors Comparison 2024-02-29 to 2023-03-06 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 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** We 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 may never achieve or maintain profitability.** We are a clinical-stage dermatology therapeutics company **with limited operating history developing and selling medications for skin diseases requiring medical intervention.** Since inception, we have incurred significant net losses. We incurred net losses of \$ **67.0 million and \$ 24.5 million and \$ 35.1 million** for the years ended December 31, **2023 and 2022 and 2021**, respectively. As of December 31, **2022 2023**, we had an accumulated deficit of \$ **163.230.54 million**. Since inception, we have financed our operations with \$ 123.2 million in gross proceeds raised in our initial public offering and private placements of convertible debt and convertible preferred stock and **\$ 55.85.03 million** in net proceeds from subsequent follow-on offerings, **and \$ 20.0 million from the Torii Agreement.** We have no products approved for commercialization and have never generated any revenue **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 ~~lead product candidate~~, **YCANTH (VP- 102)**, for the treatment of molluscum **contagiosum**, including preclinical studies and clinical trials. **YCANTH (VP- 102) was approved by the FDA for the treatment of molluscum contagiosum in July 2023.** We have completed two pivotal Phase 3 clinical trials and submitted an NDA for VP-102 for the treatment of molluscum. In addition to developing VP-102 for the treatment of molluscum, we are
- **Risks Related to Our Product Candidates** Our lead product candidate, VP-102, is being developed for the treatment of ~~oIf~~ **molluscum, external genital warts and common warts**, for which we are currently conducting clinical trials. If we are unable to successfully develop, receive regulatory approval for and commercialize ~~VP-102 for the treatment of molluscum, external genital warts and common warts or any other indications, or successfully develop any other 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** In light of our receipt of a CRL from the FDA regarding our NDA for VP-102, the timing for VP-102 approval is uncertain, and we may never obtain regulatory approval in the United States. We face substantial competition, including from compounded cantharidin products that may compete with VP-102 and any other product candidates, 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 success of **YCANTH (VP- 102)** for the treatment of molluscum **contagiosum**, external genital warts and common warts **our product candidates** will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these procedures. The market for **YCANTH (VP- 102 and any) for other-- 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** We currently rely on a third party to supply ~~our the~~ **raw material materials and applicator components used in 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 other product candidates we may develop, our business operations would be impaired. We 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** If 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 Legal and Regulatory Compliance Matters and Managing Our Growth** We expect to expand our development and regulatory capabilities and **our potentially implement** 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 Employee Matters and Managing Our Growth**
- **Risks Related to Ownership of Our Common Stock and Our Status as a Public Company** The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses. 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.**

also developing **YCANTH (VP- 102)** as a treatment for external genital warts and common warts. We are developing VP- 315 for the treatment of dermatological oncology indications and our second cantharidin-based product candidate, VP- 103, for the treatment of plantar warts. Therefore, we expect to continue to incur significant expenses and operating losses over until **revenue from YCANTH (VP- 102) for the next several years treatment of molluscum contagiosum is sufficient to fund our operations**. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we: • continue **clinical trials evaluating VP- 315 for the treatment of dermatological oncology indications, including basal cell carcinoma and squamous cell carcinoma**; • 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 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 molluscum, and eventually for the treatment of external genital warts and common warts or any other indications we may pursue for VP- 102**, as well as **our other current product candidates for VP- 315 and VP- 103**; • seek to discover and develop additional product candidates; • **continue to establish a our** commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize **any YCANTH (VP- 102) for the treatment of molluscum contagiosum and** product candidates for which we may obtain regulatory approval, **including VP- 102, VP- 315 and VP- 103**; • 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 clinical, manufacturing 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** In cases where we are successful in obtaining regulatory approval to market one or more of our product candidates, 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; **even if approved**. 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 **launching 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 and our product candidates**. 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 **and operating losses** over the next several years as we **commercialize YCANTH (seek marketing approval for 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, **common warts**, and other indications, pursue clinical trials and marketing approval for VP- 315 for the treatment of 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. **In addition YCANTH (VP- 102), for the treatment of molluscum contagiosum and** our product candidates, if approved, may not achieve commercial success. **Our Although YCANTH (VP- 102) has been approved by the FDA for the treatment of molluscum contagiosum, we do not expect to generate substantial** revenue, if any, will be derived from **YCANTH (sales of products that are not currently commercially available. If we obtain marketing approval for VP- 102) in** for the treatment of molluscum, external genital warts or common warts or any other -- **the product candidates that we develop near term. We have incurred, we 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 of December 31, **2022-2023**, we had cash and cash equivalents of \$ **34-69**. **3-5** million. We believe that our existing cash and cash equivalents as of December 31, 2022, **plus the net proceeds from the February-2023 offering of common stock and pre-funded warrants of \$ 30.1 million**, will be sufficient to support our planned operations into the **first-second** quarter of **2024-2025**. This estimate is based on assumptions that may

prove to be wrong, and we could use our available capital resources sooner than we expect. ~~As a result, our financials have been prepared on a going concern basis.~~ 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 future commercialization activities,** including product manufacturing, marketing, sales and distribution, for **YCANTH (VP- 102)** for the treatment of molluscum **contagiosum**, if approved, 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; • the extent to which we develop, in- license or acquire ~~other~~ product candidates or technologies; • the number and development requirements of ~~other~~ product candidates that we may pursue; • the costs, timing and outcome of regulatory review of our product candidates; • the revenue, if any, 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 ~~other~~ 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 ~~may 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 ~~for~~ common warts, **and** VP- 315 for the treatment of dermatological oncology indications and ~~for~~ VP- 103 for the treatment of plantar warts. If we receive regulatory approval for **YCANTH (VP- 102), VP-315 or for VP-103 the treatment of common warts and / for- or these indications 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. **We have entered into a Credit Agreement with OrbiMed, pursuant to which we may borrow up to \$ 125. 0 million. Our obligations under the Credit Agreement are secured by all or substantially all of our assets. 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 maintain at least \$ 10 million of unrestricted cash and cash equivalents at all times. 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 we are unable to achieve certain milestones, generate sufficient revenue and raise additional capital through a combination of equity offerings, debt financings and license and collaboration agreement we will no longer be in compliance with these 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 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 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. ~~We do not currently have any committed external source of funds.~~ 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. We commenced operations in 2013, and our operations to date have been largely focused on raising capital and developing ~~our novel topical solution~~ **YCANTH (VP- 102) for the treatment of** ~~eantharidin~~ **molluscum contagiosum** and our ~~lead product candidate~~ **candidates**, ~~VP-102, for the treatment of molluscum, external genital warts and common warts~~, 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** ~~candidate for which we have completed clinical trials~~. We have not yet demonstrated our ability to successfully ~~obtain regulatory approvals~~, 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 ~~developing and~~ commercializing products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. ~~We will need to~~ **With the approval of YCANTH (VP- 102) for molluscum contagiosum in July 2023, we are** ~~transitioning at some point~~ from a company with a development focus to a company **with capable of supporting** ~~commercial~~ **and development** activities. We may not be successful in such a transition. Our lead product candidate, VP-102, is being developed for the treatment of molluscum, external genital warts and common warts for which we are currently conducting clinical trials. If we are unable to successfully develop, receive regulatory approval for and commercialize VP-102 for the treatment of molluscum, external genital warts, common warts, or any other indications, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed. We currently have ~~no only one products~~ **product** that ~~are~~ **is** approved for commercial sale. ~~We have completed two pivotal Phase 3 clinical trials and submitted a New Drug Application, or NDA, for VP-102 for the treatment of molluscum in the U. S. We received a CRL from the FDA in May 2022 related to deficiencies identified at a general reinspection at a facility of our CMO, Sterling, that manufactures VP-102. Following the FDA's commentary, we selected a new CMO partner to produce the bulk solution. We completed the technology transfer in January 2023. We re-submitted the NDA in the first quarter of 2023, however, there can be no assurance that we will receive approval from the FDA. Although we announced, in January 2023, the successful transfer of technology to our new CMO partner for production of VP-102 bulk solution, Piramal Pharma Solutions, the FDA may inspect Piramal in conjunction with its review of our NDA and may object to conditions, including through issuance of 483 observations that may trigger another CRL for our NDA. In addition to developing VP-102 for the treatment of molluscum, we are also developing VP-102 as a treatment for external genital warts and common warts. We also plan to develop VP-315 for the treatment of dermatological oncology indications, including basal cell carcinoma and squamous cell carcinoma. In addition, we plan to develop our second eantharidin-based product candidate, VP-103, for the treatment of plantar warts. We have not completed the development and regulatory approval process of any product candidates and we may never be able to develop marketable products.~~ We have invested substantially all of our efforts and financial resources in the development of **YCANTH (our eantharidin formula and 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 , **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**. Our ability to generate **substantial** revenue from **YCANTH for the treatment of molluscum contagiosum or** our product candidates ~~;~~ will depend heavily on their successful development, regulatory approval and ~~eventual commercialization of these product candidates~~. The success of **YCANTH (VP- 102)**, **VP- 315 and VP-103 or for the treatment of molluscum contagiosum and** any other product candidates that we develop or otherwise may acquire 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; • ~~launching~~ commercial sales of **products YCANTH (VP- 102) for the treatment of molluscum contagiosum and**, if approved ~~;~~, **our product candidates** • acceptance of **our products 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) or for any other** ~~the treatment of molluscum contagiosum and, if approved, our~~ product candidates ~~;~~ **if approved;** • the prevalence and severity of adverse events experienced with **YCANTH (VP- 102) or for our other** ~~the treatment of molluscum contagiosum and our~~ product candidates; • the availability, perceived advantages, cost, safety and efficacy of alternative treatments for ~~molluscum, external~~

genital warts and/or common warts or any other-- ~~the indications addressed by which we may pursue for VP-102 or our any other product and~~ product candidates; • our ability to produce **YCANTH (VP- 102)** ~~or for any other-- 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 ~~VP-102, VP-315, VP-103 or our any of our other~~ product candidates ~~we may develop or otherwise acquire~~ 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. ~~For example, following the initiation of our Phase 2 trial of VP-102 for the treatment of common warts, we discovered the need to amend the treatment regimen of the protocol in order to introduce greater flexibility of the treatment interval. We amended the trial protocol in order to add a second cohort to the trial with the desired treatment frequency.~~ 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. ~~For example, if a competitor obtained FDA approval for a product containing cantharidin before we are able to obtain approval for our product, this could result in the approval of our product being delayed until the expiration of any NCE exclusivity or other regulatory exclusivity received by such competitor.~~ 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 compounded cantharidin** 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. ~~Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining patients in our clinical trials.~~ 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 As an organization, we succeeded in have limited experience designing and executing a clinical trials and may be unable to design and execute a clinical trial~~ to support regulatory approval **of YCANTH for the treatment of molluscum contagiosum, we may not be similarly successful with respect to the clinical trials for our product candidates, including YCANTH for the treatment of external genital warts 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 ~~one or more of our product candidates receives marketing approval, and~~ we or others identify undesirable side effects caused by ~~such 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 - ~~VP- 102 is a drug-device combination involving a proprietary applicator, which may result in additional regulatory and other risks. VP- 102 is a drug-device combination product for administration of our cantharidin formulation through our proprietary applicator. We may experience delays in obtaining regulatory approval of VP- 102 given the increased complexity of the review process when approval of a drug and a delivery device is sought under a single marketing application. VP- 102 will be regulated as a drug-device combination product, which requires coordination within the FDA and similar foreign regulatory agencies for review of the product candidate's device and drug components. We have filed a single marketing application for the approval of a drug-device combination product, with guidance by the FDA. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development, approval, and commercialization of our product candidate due to regulatory timing constraints and uncertainties in the product development and approval process, the inherent complexities of combination products, as well as coordination between two different centers within FDA responsible for review of the different components of the combination product. Failure to successfully develop or supply the device, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our company, our collaborators, or third-party providers to obtain or maintain regulatory approval or clearance of the device component of VP- 102 could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in VP- 102 reaching the market. Further, failure to successfully develop or supply the device, or to gain or maintain its approval, could adversely affect sales of VP- 102.~~ 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 ~~our current product candidate~~ **YCANTH (VP- 102) and VP- 315** or in-licensing or acquiring additional product candidates for other dermatological conditions. 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 and common** warts and potentially 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 **development, and potential future 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, or we may delay the development of **YCANTH for the treatment of** other indications ~~for VP- 102~~ 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. **We** ~~With the exception of YCANTH (VP- 102) for the treatment of molluscum contagiosum, we~~ have not obtained regulatory approval for ~~VP-102 or any product candidate~~ and it is possible that ~~neither VP- 102 nor 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 ~~VP-102 or any future drug product candidates~~ in the United States until we receive regulatory approval of an NDA 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 and) 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. ~~We have invested a significant portion of our time and financial resources in the development of VP- 102. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize VP- 102 and any future product candidates in a timely manner.~~ Even if we eventually complete clinical testing and receive approval of an NDA, **sNDA** or foreign marketing application for ~~VP-102 or any future product candidates, or additional YCANTH 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 ~~VP-102~~ **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 ~~will still need to develop a commercial organization, 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 VP- 102 and any future product candidates, we may not be able to generate sufficient revenue to continue our business.~~ **In November 2021, we resubmitted Risks Related to the Commercialization of Our Product an and Product Candidates YCANTH** NDA to the FDA for VP- 102 for the treatment of molluscum **contagiosum**. ~~On May 24, 2022, we announced that we received a CRL from the FDA as a direct result of deficiencies identified by the FDA during a general reinspection of our CMO, Sterling. As a result, the approval of our NDA for VP- 102 has been delayed and may never occur. On June 27, 2022, we held a Type A meeting with the FDA to discuss the resubmission and potential approval of the~~

NDA. During the Type A meeting the FDA indicated that it could not accept our NDA resubmission with Sterling listed as the primary manufacturer of the bulk solution for VP-102 if Sterling was on OAI status at the time of resubmission. Following the FDA's commentary, we selected a new CMO partner to produce the bulk solution, Piramal Pharma Solutions, and the technology transfer process was completed in January 2023. On January 23, 2023 we resubmitted the NDA for VP-102 to the FDA. The FDA accepted our NDA resubmission on February 27, 2023 and assigned a PDUFA goal date of July 23, 2023. We cannot predict the outcome of any interactions with the FDA. Nor can we guarantee when, or if, we will be successful in receiving regulatory approval for VP-102. If we do not obtain approval for VP-102 or are delayed in obtaining such approval, it would have a material adverse effect on our operations and financial condition. Even if any of our product candidates ~~that receives~~ **receive** marketing approval, ~~it~~ 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. ~~If YCANTH for the treatment of molluscum contagiosum and~~ any of our product candidates ~~that receives~~ **receive** marketing approval, ~~it~~ may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If **YCANTH for the treatment of molluscum contagiosum or** our product candidates, **if approved**, do not achieve an adequate level of acceptance, we may not generate ~~significant~~ **sufficient** revenue and we may not become profitable. The degree of market acceptance of **YCANTH for the treatment of molluscum contagiosum and** our product candidates, if approved for commercial sale, will depend on a number of factors, including: ~~• the othe~~ efficacy, safety and potential advantages compared to alternative treatments, including **YCANTH for VP-102**, compared to compounded cantharidin; ~~• our our~~ ability to offer our products for sale at competitive prices; ~~• the othe~~ convenience and ease of administration compared to alternative treatments, including compounded cantharidin; ~~• the othe~~ willingness of the target patient population to try new treatments and of physicians to prescribe these treatments; ~~• our our~~ ability to hire and retain a sales force in the United States; ~~• the othe~~ strength of marketing and distribution support; ~~• the othe~~ availability of third-party coverage and adequate reimbursement for **VP-102 YCANTH for the treatment of molluscum contagiosum** and any other potential product candidates ~~that receive marketing approval~~; ~~• the othe~~ prevalence and severity of any side effects; and ~~• any oany~~ restrictions on the use of our products together with other medications. ~~The~~ **In the case of VP-102**, the failure of healthcare professionals or patients to perceive the benefits of using **VP-102 YCANTH 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 **VP-102, if approved YCANTH for the treatment of molluscum contagiosum**. If we are unable to ~~establish~~ **maintain** sales, marketing and distribution capabilities for **YCANTH (VP-102)** ~~or 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 that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved. We do not have sales or marketing infrastructure. To achieve commercial success for **VP-102 and any other product candidate** for which we may obtain marketing approval, we will need to ~~establish a~~ **maintain an effective** sales and marketing organization. ~~We have~~ **In the future, we expect to build** ~~built~~ a focused sales and marketing ~~infrastructure organization to market launch YCANTH (VP-102) or for the treatment~~ **organization** to ~~market launch YCANTH (VP-102) or for the treatment~~ **co-promote some of our molluscum contagiosum in the United States but expect that we will need to expand upon it if we receive approval of other** product candidates ~~in the United States, if and when they are approved~~. There are **inherent risks to maintaining** involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force **standalone commercial organization, which is also** expensive and time-consuming and **requires significant financial resources** could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that **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 ~~establish~~ **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 ~~establish~~ **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** We are aware of several other product candidates in earlier stages of development as potential treatments for the indications we intend to target. Novan has submitted a NDA to the FDA seeking marketing approval for the **Zelsuvmi, a topical treatment of 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**, 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. **If Since we receive received approval for YCANTH (VP- 102) for the treatment of molluscum contagiosum**, any compounding by licensed pharmacists or licensed physicians under Section 503A ~~would is not be~~ 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)**, ~~if approved~~, 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 **if though we receive 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 ~~March 2019~~ **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, ~~and if VP-102 is approved~~, 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. ~~Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product, which could result in our competitors establishing a strong market position before we are able to enter the market or, if a competitor obtained FDA approval for a product containing cantharidin before we are able to obtain approval for our product, could result in the approval of our product being delayed until the expiration of any NCE exclusivity or other regulatory exclusivity received by such competitor.~~ 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. We **are seeking** ~~intend to seek~~ NCE exclusivity ~~and /or~~ **for YCANTH (pediatric exclusivity for VP- 102)** ~~and future product candidates~~, and we may be unsuccessful. As part of our business strategy, we **are seeking** ~~intend to seek~~ NCE exclusivity for **YCANTH (VP- 102)** ~~and will likely do so or 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 , if approved,~~ 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 ~~, and if any of our competitors obtains FDA approval of an NDA for a cantharidin drug product before we do, they, and not us, may be eligible for NCE exclusivity.~~ If we do not obtain NCE exclusivity for **YCANTH (VP- 102)**, ~~or if a competitor obtains NCE exclusivity for a cantharidin product before we receive approval of an NDA for VP- 102,~~ our ability to commence sales and generate **sustainable** revenue ~~would may~~ be adversely affected. Moreover, even if we obtain NCE exclusivity ~~and /or~~ **for YCANTH (pediatric exclusivity for VP- 102)**, such exclusivity would 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 ~~, external genital warts~~ **contagiosum as well as coverage and /adequate reimbursement or for common warts** ~~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 ~~. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. Even if the procedure using our product is covered, third- party payors may package the cost of the drug into the procedure payment and not separately reimburse the physician for the costs associated with our product.~~ A decision by a third- party payor not to cover or separately reimburse for our products could reduce physician utilization of our products once 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. 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 ~~and /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. **In November 2019 Under both APMs and MIPS, performance data collected each performance year CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will affect impact overall physician reimbursement under the Medicare program 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. 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 external genital warts and /or our common warts product candidates**, if approved for sale in the United States or in other countries, will 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. **Our lead indications for VP- 102 are for molluscum Molluscum contagiosum**, external genital warts and common warts, each of which are skin diseases that are currently undertreated with no standard of care. **Even with approval of YCANTH for the treatment of molluscum contagiosum and potential approval of any of these indications other product candidates**, individuals may continue to decline treatment for molluscum **contagiosum**, external genital warts and /or 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 for VP- 102 and any other 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 **VP- 102 YCANTH for the treatment of molluscum contagiosum and our product candidates**, if approved 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 **VP- 102 YCANTH for the treatment of molluscum contagiosum or our product candidates**, if approved as applicable, are accurate, the degree of market acceptance by the medical community and those infected by such skin diseases following regulatory approval, if any, could impact our assumptions and reduce the market size for **VP- 102 in YCANTH for the treatment of molluscum contagiosum and external genital warts, common warts or our product candidates** any other indication. For example, if **VP- 102 is approved for molluscum, external genital warts or common warts**, there can be no assurance that the medical community will prescribe **VP- 102 for patients over current forms of available alternative therapies**. 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 market **markets for VP- 102 in YCANTH for the treatment of molluscum contagiosum, external genital warts, common warts or any other indication we may pursue for or VP- 102, if approved, or our for any other product candidate candidates are** we may develop is 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 and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that **YCANTH (VP- 102) or our product candidates or drugs** 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; • **loss of revenue**; • 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 for the treatment of molluscum contagiosum and** may need to **further** increase our insurance coverage as we expand our clinical trials or **expand if we commence commercialization of 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** ~~our~~ **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 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 other 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 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 and, clinical testing and ~~expect to continue to do so for commercialization~~ **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** ~~delay, prevent or impair~~ 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 ~~manufacture~~ **manufacturing of commercial product for YCANTH (VP- 102), or 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, ~~for preclinical and clinical testing as well as for commercial manufacture if VP-102 or any other product candidate which we may pursue receives marketing approval.~~ 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 ~~or our other development or commercialization efforts.~~ We also ~~expect to~~ rely on third-party manufacturers or third-party collaborators for the ~~manufacture~~ **manufacturing of our** commercial supply of **YCANTH (VP- 102), and will do so or 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 ~~will be~~ **are routinely** conducted prior to ~~the~~ approval of ~~our an~~ **an NDA**. **In addition, if at all manufacturers remain subject**, and in the future of additional NDAs or comparable marketing application to the **periodic FDA or other regulatory authority 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. ~~For example, on May 24, 2022, we announced that we received a CRL regarding our NDA for VP-102 from the FDA. The only deficiency listed in the CRL was related to the deficiencies identified at a general reinspection at a facility of Sterling that manufactures VP-102.~~ 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 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 ~~will~~ **may** need to ~~successfully validate transition to an automated~~ **our- or proposed semi-** automated assembly process ~~as designed~~. If our current contract manufacturers cannot ~~perform as agreed~~ **successfully transition to automated and / or semi-automated assembly processes**, we may be required to replace such manufacturers. We may incur added costs ~~and/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 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. 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 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 **many YCANTH (VP- 102) and some** of our product candidates ~~has 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 applicator devices could affect our ability to obtain patent protection for our ~~planned~~ product applicator device or that disputes may arise related to whether third- party applicator devices infringe patents we have applied for. 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)** ~~our~~ **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 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)** ~~our~~ **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)** ~~our~~ **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~~ **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 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 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 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 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, ~~protect our product candidates,~~ 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 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 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 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 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 current and 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 and 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 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 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 candidates or activities. If a patent holder believes our drug 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 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 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 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 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 finding of infringement could prevent us from commercializing our 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, 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 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** future product candidates, or if we collaborate with additional third parties **for 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 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 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 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; • 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.

• ~~U. S. data privacy regulations, such as the CCPA, which creates new individual privacy rights for consumers and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches;~~

• ~~new U. S. data privacy regulations, such as the California Privacy Rights Act of 2020 (“CPRA”), effective January 1, 2023, which will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA. In addition, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors);~~

• ~~foreign data privacy regulations, such as the General Data Protection Regulation (2016/679), or GDPR, which went into effect on May 25, 2018 and applies to identified or identifiable personal data in electronic or paper form. Under the GDPR, fines of up to € 20~~

0 million or up to 4 % of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. The GDPR includes more stringent operational requirements for processors and controllers of personal data and creates additional rights for data subjects, including a private right of action. Other such foreign data privacy obligations include the EU GDPR as it forms part of United Kingdom (“UK”) law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (“UK GDPR”); and • data localization and cross-border laws and regulations, such as the GDPR, which generally restricts the transfer of personal data to countries outside of the EEA, such as the United States, which the European Commission does not consider to provide an adequate level of data privacy and security. The European Commission released a set of “Standard Contractual Clauses” that are designed to be a valid mechanism by which entities can transfer personal data out of the EEA to such jurisdictions. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal data out of the EEA. 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 ~~VP-102 or other product candidates that we may identify are approved and~~ **YCANTH for these – the treatment of molluscum contagiosum or any of our products– 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. ~~In particular, generally~~ **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** ~~Even if we obtain~~ **obtained** regulatory approval for **YCANTH VP-102 or for the treatment of molluscum contagiosum; however, YCANTH for the treatment of molluscum contagiosum and** any future product candidates ~~– they that are approved~~ will remain subject to ongoing regulatory oversight. **YCANTH** ~~Even if we obtain any regulatory approval for VP-102 or for the treatment of molluscum contagiosum and~~ any future ~~product candidates, such~~ 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**, ~~Any regulatory approvals that we receive for VP-102 or any future product candidates,~~ Any regulatory approvals that we receive for **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~~ **are** will further be 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 following approval of **YCANTH (VP- 102)** or for any future **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 commercialize **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 to certain aspects of the ACA. ~~While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or For example Tax Act includes a provision repealing, effective January 1, 2019, the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate ". In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA- mandated " Cadillac " tax on high- cost employer- sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole. " In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. 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, 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 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 **2031- 2032** unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester. Additionally,~~

on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 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 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. 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 HHS to negotiate the price of certain single-source drugs and biologics 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 effect progressively starting in fiscal year 2023. **On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations**, although ~~they~~ **the may be Medicare drug price negotiation program is currently** subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. **Further, in response to** the Biden administration **released an additional's October 2022** executive order, **on October February 14, 2022-2023**, directing HHS **released** to submit a report **outlining** within 90 days on how the **three** Center for Medicare and Medicaid Innovation can be further leveraged to test new models for **testing by the CMS Innovation Center which will be evaluated on their ability to lowering--- lower drug the costs- cost for Medicare of drugs, promote accessibility,** and Medicaid beneficiaries **improve quality of care**. It is unclear **how whether** these **the** developments could affect covered hospitals who might purchase our **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. 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 products- product as one factor and-- an agency can use when deciding to exercise march- affect the rates we may charge such facilities for our approved products-in the future rights. While march- in rights have not previously been exercised, it is uncertain if any 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 **VP-102 or our any future** 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) or for other--- 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 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. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. 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 with us at any time. We do not maintain "key person" insurance for any of our executives or employees. 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, 2022-2023, we had 22-100 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 **and, if any of our product candidates receives marketing approval, sales, marketing and distribution.** 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 common~~ 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 **molluscum, common warts and** external genital ~~warts and common~~ 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 ~~other of our~~ product ~~candidate~~ **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. 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 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 2/3 % 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 an **an "emerging growth smaller reporting company"** and, as a result of the reduced disclosure and governance requirements applicable to **emerging growth smaller reporting companies**, our common stock may be less attractive to investors. We are an **an "emerging growth smaller reporting company,"** meaning that as defined in the **market value Jumpstart Our Business Startups Act of 2012, or our the JOBS Act, shares held by non-affiliates is less than \$ 700 million** and **we intend to take advantage of some of our annual revenue was less than \$ 100 million during the exemptions from most recently completed fiscal year. We will continue to be a smaller reporting requirements that are applicable to other public companies 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 companies company, we may choose** including:

- being permitted to provide **present only the two most recent fiscal** years of audited financial statements, in addition to any required **unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations"** disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or **our Annual** a supplement to the auditor's report **Report on Form 10-K** providing additional information about the audit and **we have** the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic **reports**;
- **non-accelerated filer, we are** not being required to **comply with the auditor attestation requirements** hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved **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. **We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until December 31, 2023. Under Section 107 (b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.** If we fail to maintain proper and effective internal controls, 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. **We 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 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, ~~2022~~ **2023**, we had federal and state net operating loss carryforwards of approximately \$ ~~118.1 million and \$ 120.7 million~~ **149.6 million and \$ 152.1 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 ~~no more than 80 % of the excess, if any,~~ **no more than 80 % of the excess, if any,** 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 ~~have begun to~~ **have begun to** 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 ~~have begun to~~ **have begun to** 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 ~~intend~~ **intend** ~~continue~~ **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.

General Risk Factors **We 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 business and operations would suffer in the event of computer system failures—failure to comply with such obligations could lead**, ~~cyber-attacks or a deficiency in our cyber-security, including but not limited~~ 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. Despite** **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 the other implementation of 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. 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, our 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 litigation or suffer reputational harm 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 may has result 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 ~~, and may again raise,~~ 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 ~~. COVID-19 has impacted and could continue to adversely impact our business. COVID-19 has spread worldwide, resulting in governments implementing numerous containment measures such as travel bans and restrictions, quarantines and shutdowns. These measures have impacted, and may further impact, our workforce and operations. As COVID-19 continues to evolve, we may experience continued and additional disruptions or impairments that could impact our business, supply chain, clinical trials, or ability to obtain regulatory approval for, or commercialize, VP-102, including: • delays or inability to obtain raw material, ingredients, or components; • possible capacity constraints at key suppliers and service providers which could impact the ability to build launch stock; • further delays or difficulties in enrolling patients in our clinical trials; • further delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • limitations on travel or access to third-party facilities imposed or recommended by federal or state governments, employers, suppliers, and others; and • limitations of internal and third-party employee resources that would otherwise be focused on the above activities, including sickness of employees or their families, travel restrictions or social distancing, or the desire of employees to avoid contact with large groups of people.~~ 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 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.