UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-38529

Verrica Pharmaceuticals Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**46-3137900**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10 North High Street, Suite 200 West Chester, PA	**19380**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (484) 453-3300

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on which Registered**
Common Stock, $0.0001 par value	VRCA	The Nasdaq Stock Market, LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Small reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of Verrica Pharmaceuticals Inc.'s voting and non-voting common equity held by non-affiliates as of June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter) based on the closing sale price of $11.01 as reported on the Nasdaq Global Market on that date was approximately $173.2 million.

As of March 15, 2021, the registrant had 25,441,113 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement, to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2021 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- our plans to develop and commercialize our product candidates;
- the timing of our planned clinical trials for VP-102 and our other product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for VP-102 for the treatment of molluscum and our other product candidates;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations about the willingness of healthcare professionals to use VP-102;
- our expectations about third-party payors to reimburse or patients to pay for VP-102;
- our intellectual property position;
- our plans to in-license, acquire, develop and commercialize additional product candidates for other dermatological conditions to build a fully integrated dermatology company;
- our competitive position and the development of and projections relating to our competitors or our industry;
- our ability to identify, recruit and retain key personnel;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- the impacts of the COVID-19 pandemic on our business;
- our plans to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives; and
- our estimates regarding future revenue, expenses and needs for additional financing.

You should refer to Item 1A. "Risk Factors" in this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments may cause our views to

change. However, while we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

Unless otherwise indicated or the context otherwise requires, all references in this Annual Report to "the Company," "we," "our," "ours," "us" or similar terms refer to Verrica Pharmaceuticals Inc. "Verrica," the Verrica logo, YCANTH and other trademarks or service marks of Verrica Pharmaceuticals Inc. appearing in this Annual Report are the property of Verrica Pharmaceuticals Inc. This Annual Report contains additional trade names, trademarks and service marks of others, which are the property of their respective owners.

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PART I

ITEM 1. BUSINESS

Overview

We are a dermatology therapeutics company committed to the development and commercialization of novel treatments that provide meaningful benefit for people living with skin diseases. Our lead product candidate, VP-102, is a proprietary drug-device combination of our novel topical solution of cantharidin, a widely recognized, naturally sourced agent to treat topical dermatological conditions, administered through our single-use precision applicator. We are initially developing VP-102 for the treatment of molluscum contagiosum, or molluscum, a highly contagious and primarily pediatric viral skin disease, and common warts. There are currently no products approved by the U.S. Food and Drug Administration, or FDA, nor is there an established standard of care for either of these diseases, resulting in significant undertreated populations in two of the largest unmet needs in dermatology. In addition to patent protection we are seeking, VP-102 has the potential to be the first FDA-approved product for molluscum and for its active pharmaceutical ingredient, or API, to be characterized as a new chemical entity, or NCE, with the five years of non-patent regulatory exclusivity associated with that designation. We also believe VP-102 has the potential to qualify for pediatric exclusivity in common warts, which would provide for an additional six months of non-patent exclusivity.

In January 2019, we reported positive top-line results from our Phase 3 CAMP-1 and CAMP-2 pivotal trials with VP-102 for the treatment of molluscum. Both clinical trials evaluated the safety and efficacy of VP-102 compared to placebo. In each trial, we observed that a clinically and statistically significant proportion of subjects treated with VP-102 achieved complete clearance of all treatable molluscum lesions compared to subjects treated with placebo. VP-102 was well-tolerated in both trials, with no serious adverse events reported in VP-102 treated subjects CAMP-1 was conducted under a special protocol assessment, or SPA, agreement with the FDA. Based on the results from these trials, we submitted a new drug application, or NDA, to the FDA for VP-102 for the treatment of molluscum in September 2019. In November 2019, we received notice that the FDA accepted the NDA for filing, with a Prescription Drug User Fee Act, or PDUFA, goal date of July 13, 2020. In July 2020, we received a Complete Response Letter, or CRL, from the FDA for our NDA. The CRL indicated the need for additional information regarding certain aspects of the chemistry, manufacturing and controls, or CMC, processes for the drug/device combination as well as human factors validation. The FDA did not identify any clinical deficiencies. A Type A meeting was held with the FDA to discuss the issues that were identified in the CRL and the resubmission of the NDA for VP-102 in October 2020. We resubmitted our NDA for VP-102 for the treatment of molluscum in December 2020. In February 2021, we received notice that the FDA accepted the resubmitted NDA for filing, with a PDUFA goal date of June 23, 2021.

In June 2019, we announced positive topline results from our COVE-1 Phase 2 open label clinical trial of VP-102 for the treatment of verruca vulgaris, or common warts. Based on feedback from the FDA regarding a potential Phase 3 trial protocol, we are currently evaluating conducting an additional Phase 2 clinical trial of VP-102 for the treatment of common warts.

In addition, we are also developing VP-102 for the treatment of external genital warts. We initiated a Phase 2 clinical trial evaluating the optimal dose regimen, efficacy, safety and tolerability of VP-102 in patients with external genital warts in June 2019. In November 2020, we announced positive topline results from our Phase 2 clinical trial of VP-102 for the treatment of external genital warts. Based on the results of the Phase 2 trial, we requested an end of Phase 2 meeting with the FDA in the first quarter of 2021. In addition, we are conducting necessary drug development activities for VP-103, our second cantharidin-based product candidate, and are evaluating when to initiate a Phase 2 clinical trial for the treatment of plantar warts. Except as provided for in the Torii Agreement, we retain exclusive, royalty-free rights to VP-102 and VP-103 across all indications.

On March 17, 2021, we entered into a collaboration and license agreement, or the Torii Agreement, with Torii Pharmaceutical Co., Ltd., or Torii, 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 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. Pursuant to the Torii Agreement, we are entitled to receive an up-front payment from Torii of $11.5 million. Additionally, we are entitled to receive from Torii an additional $58.0 million in aggregate payments contingent on achievement of specified development, regulatory, and sales milestones, in addition to tiered transfer price payments for supply of product in the percentage range of the mid-30s to the mid-40s of net sales.

In August 2020, we entered into an exclusive license agreement with Lytix Biopharma AS, or Lytix, pursuant to which we obtained an exclusive worldwide license for certain technology of Lytix to develop LTX-315 for use in all malignant and pre-malignant dermatological indications, other than metastatic melanoma and metastatic merkel cell carcinoma. We intend to initially focus our development of LTX-315 on basal cell and squamous cell carcinomas. We intend to submit an Investigational New Drug Application, or IND, for LTX-315 in the first half of 2021.

Molluscum is a highly contagious common skin disease caused by a pox virus that produces multiple raised flesh-colored papules, or skin lesions. Molluscum typically presents with 10 to 30 lesions and can present with over 100 lesions. If left untreated, molluscum lesions persist for an average of 13 months, with some cases remaining unresolved for more than two years. The symptoms of molluscum tend to cause considerable anxiety, and parents frequently seek treatment due to its highly contagious nature and physical appearance.

We estimate approximately 6 million people in the United States have molluscum. Of the 6 million people with molluscum, we estimate that approximately 1 million are diagnosed annually. Molluscum has a 5% to 11% prevalence rate in children with the greatest incidence in individuals aged one to 14 years old. Accordingly, we estimate this represents a total addressable U.S. market of over $1 billion. We believe that the molluscum prevalence rate in the European Union is at least as high as in the United States.

Compounded cantharidin has been used for many years by dermatologists to treat molluscum, but it has many limitations. Those limitations include that it is not FDA-approved, could have highly variable purity, is not readily available and is often not produced in accordance with good manufacturing practices, or GMP. In addition, the formulation and administration of compounded cantharidin is not standardized and is poorly controlled. Other existing therapies, such as cryotherapy, curettage and laser surgery are also used, but are often painful and may lead to scarring. The potential for scarring and pain makes many of these treatments particularly unsuitable for children. As a result, a significant need exists for a clinically proven and FDA-approved treatment for molluscum.

We have designed VP-102 to address the significant limitations of current compounded cantharidin formulations for the treatment of molluscum, including with respect to safety, purity, efficacy, stability and ease of administration. VP-102 contains the first GMP-controlled formulation of cantharidin with a defined pharmaceutical batch process and an API that is greater than 99% pure. We believe VP-102 addresses the shortcomings associated with current therapies, including pain and discomfort, potential scarring and inconsistent outcomes, and has the potential to be the first FDA-approved product for the treatment of molluscum.

We are also developing VP-102 for the treatment of common warts. Common warts typically result in two to five lesions. We estimate approximately 22 million people in the United States have common warts and the total addressable U.S. market to be over $1 billion with an estimated 2 million patient visits for common warts each year. In the United States, approximately 50% of the patients who seek treatment for common warts are children, and approximately 25% of common warts patients are treated by pediatricians. We believe that the common wart patient opportunity in the European Union is at least as large as that in the United States. There are currently no FDA-approved products indicated for the treatment of common warts. While common warts can be treated with slow acting, over-the-counter products, the warts tend to be highly refractory and a cause for multiple consultations. We believe that cantharidin's role as a widely recognized and effective blistering agent for the treatment of skin lesions, coupled with VP-102's safety and efficacy data in clinical trials for the treatment of molluscum and convenient ease of administration, will allow VP-102 to address many of the shortcomings associated with current therapies. In June 2019, we announced positive topline results from our COVE-1 Phase 2 open label clinical trial of VP-102 for the treatment of common warts. COVE-1 included two cohorts that evaluated the safety and efficacy of VP-102 in

subjects with up to six warts. In both cohorts, VP-102 achieved positive results in both the primary endpoint of complete clearance of all treatable warts at Day 84 and the secondary endpoint of the percentage reduction of warts, VP-102 was well-tolerated with no serious adverse events reported. Based on feedback from the FDA regarding a potential Phase 3 trial protocol, we are currently evaluating conducting an additional Phase 2 clinical trial of VP-102 for the treatment of common warts.

In addition, we are also developing VP-102 for the treatment of external genital warts. External genital warts are a viral skin disease caused by the human papilloma virus, or HPV, which forms lesions on the surface of the skin. An estimated 17% of the approximately 4.1 million patient visits for all types of warts are for the treatment of external genital warts. We initiated a Phase 2 clinical trial evaluating the optimal dose regimen, efficacy, safety and tolerability of VP-102 in patients with external genital warts in June 2019. In November 2020, we announced positive topline results from our Phase 2 clinical trial of VP-102 for the treatment of external genital warts. Based on the results of the Phase 2 trial, we requested an end of Phase 2 meeting with the FDA in the first quarter of 2021.

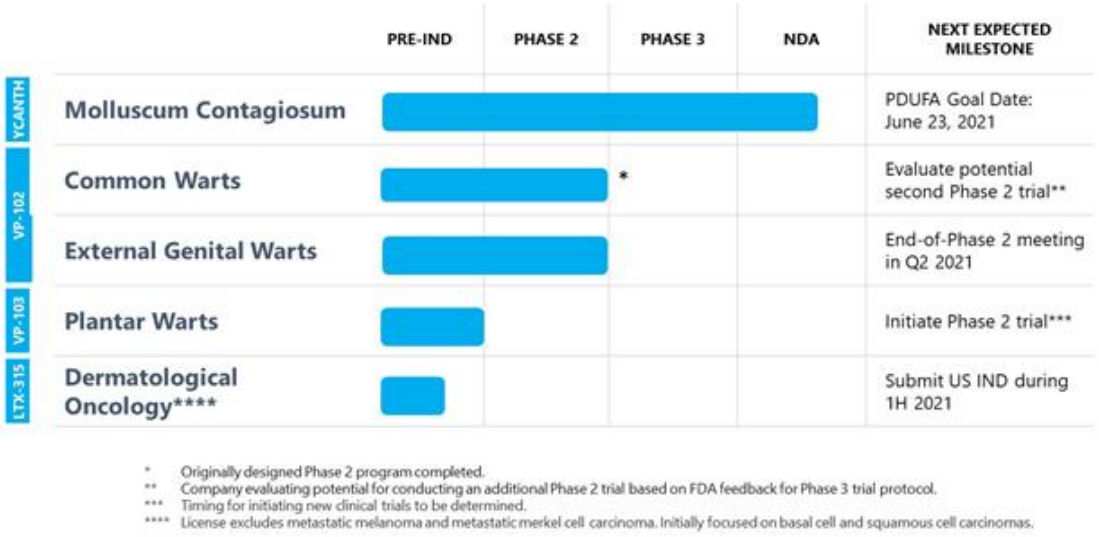
We also intend to develop our second cantharidin-based product candidate, VP-103, for the treatment of plantar warts. An estimated one-third of the approximately 4.1 million annual patient visits for all types of warts are for the treatment of plantar warts, which are warts located on the bottom of the foot. We are conducting necessary drug development activities for VP-103 and are evaluating when to initiate a Phase 2 clinical trial for the treatment of plantar warts. We believe we have the opportunity to expand our proprietary cantharidin formulations for the treatment of additional dermatological conditions with high unmet needs.

We also intend to develop our third product candidate, LTX-315, for the treatment of dermatological oncology indications. We intend to submit an IND for LTX-315 in the first half of 2021.

We believe the current medical dermatology landscape provides an opportunity to establish ourselves as a leader in the space. With a more concentrated prescribing base of dermatologists versus other medical specialties, our management's proven track record and experience in new product launches, and the significant clinical benefits described above, we believe a targeted sales and marketing organization of approximately 50 to 60 sales representatives should enable us to capture market share swiftly in the United States, particularly in our current indications of focus.

Our Pipeline

The following table summarizes our product candidates. Except as provided by the Torii Agreement, we retain exclusive, royalty-free rights for VP-102 (YCANTH) and VP-103.



* Originally designed Phase 2 program completed.
** Company evaluating potential for conducting an additional Phase 2 trial based on FDA feedback for Phase 3 trial protocol.
*** Timing for initiating new clinical trials to be determined.
**** License excludes metastatic melanoma and metastatic merkel cell carcinoma. Initially focused on basal cell and squamous cell carcinomas.

VP-102 for the Treatment of Molluscum

We are developing VP-102 as a proprietary drug-device combination of a novel 0.7% w/v topical solution of cantharidin administered through our single-use precision applicator. VP-102 has the potential to be the first FDA-approved treatment for molluscum and we believe it will address many of the shortcomings associated with current therapies, including pain and discomfort, scarring and lack of effectiveness.

We have designed VP-102 to address the significant limitations of current compounded cantharidin formulations for the treatment of molluscum, with respect to safety, purity, efficacy, stability and ease of administration. VP-102 contains the first GMP-controlled formulation of cantharidin with a defined pharmaceutical batch process and an API that is greater than 99% pure.

Our proprietary single-use applicator allows for precise application to each lesion. Our applicator contains a sealed glass ampule providing long-term room temperature stability without the changes in concentration due to evaporation seen in compounded formulations.

Clinical Development for Molluscum

In January 2019, we announced positive topline results from our Phase 3 CAMP-1 and CAMP-2 pivotal trials with VP-102 for the treatment of molluscum. Based on the results from these trials, we submitted an NDA to the FDA for VP-102 for the treatment of molluscum in September 2019. In November 2019, we received notice that the FDA accepted the NDA for filing, with a PDUFA goal date of July 13, 2020.

In July 2020, we received a CRL, from the FDA for our NDA. The CRL indicated the need for additional information regarding certain aspects of the CMC processes for the drug/device combination as well as human factors validation. The FDA did not identify any clinical deficiencies. A Type A meeting was held with the FDA in October 2020 to discuss the issues that were identified in the CRL and the resubmission of the NDA for VP-102. We resubmitted our NDA for VP-102 for the treatment of molluscum in December 2020. In February 2021, we received notice that the FDA accepted the resubmitted NDA for filing, with a PDUFA goal date of June 23, 2021.

Below is a summary of our clinical development for the indication of molluscum.

Trial and Status	Formulation and Application Method	Trial Design	Trial Objectives
Phase 3 Clinical Trials (CAMP-1 and CAMP-2) (n=266 and 262, respectively) Top-line results reported in January 2019	VP-102	• Randomized, double-blinded, multicenter, placebo-controlled • Safety and efficacy evaluated every 21 days for up to 4 applications	• To evaluate the efficacy of dermal application of VP-102 relative to placebo for complete clearance at Day 84 • To assess the safety and tolerability of VP-102
Phase 2 Innovate Trial (n=32) Results reported in September 2018	VP-102	• Open-label, single- center • 24-hour treatment • Blood draws in subjects with more than 21 lesions for evaluating PK • Safety and efficacy evaluated every 21 days for up to four applications • Impact of quality of life assessed via the CDLQI • Duration: 12 weeks	• To determine any possible systemic exposure from a single 24-hour application of VP-102 • To confirm safety and efficacy with applicator • To assess impact on quality of life
Phase 2 Pilot Trial (n=30) Completed in September 2017	Our proprietary formulation of cantharidin used in VP-102, applied with the wooden stick part of a cotton-tipped swab	• Open-label, single- center • Six hour and 24- hour treatment cohorts • Safety and efficacy evaluated every 21 days for up to four applications • Impact of quality of life assessed via the CDLQI • Duration: 12 weeks	• To evaluate safety and efficacy and determine optimal treatment duration • To assess impact on quality of life

Phase 3 Clinical Trials—CAMP-1 and CAMP-2

In January 2019, we announced positive topline results from our Phase 3 CAMP-1 and CAMP-2 pivotal trials with VP-102 for the treatment of molluscum. The two trials, identical in design, were randomized, double-blind, multicenter, placebo-controlled trials of VP-102 for the treatment of molluscum. CAMP-1 was conducted under a SPA with the FDA. The primary objective of the trials was to evaluate the efficacy of dermal application of VP-102 relative to placebo in subjects 2 years of age and older with molluscum, when treated once every 21 days for up to four applications, by assessing the proportion of subjects achieving complete clearance of all treatable molluscum lesions at Day 84 (Week 12/End of Study visit). Secondary endpoints included the proportion of subjects with complete clearance at study visits on Days 21 (Week 3), 42 (Week 6) and 63 (Week 9).

CAMP-1 and CAMP-2 enrolled 528 subjects in total and were conducted at 31 centers in the United States. Results from CAMP-1 and CAMP-2 showed 46% and 54% of subjects treated with VP-102, respectively, achieved complete clearance of all treatable molluscum lesions at Day 84 versus 18% and 13% of subjects in the placebo groups ($p<0.0001$). By Day 84, VP-102 treated subjects had a 69% and 83% mean reduction in the number of molluscum lesions, a pre-specified endpoint, in CAMP-1 and CAMP-2, respectively, compared to a 20% increase and a 19% reduction for subjects on placebo.

Consistent with the results from the Phase 2 clinical trials, VP-102 was also well-tolerated in the Phase 3 trials, with side effects that were primarily mild to moderate. The most frequently reported adverse events were application site reactions that are well-known, reversible side effects related to the mechanism of action of cantharidin, a blistering agent, which is the active ingredient in VP-102. There were no treatment-related serious adverse events reported in CAMP-1 or CAMP-2.

Based on the results of these trials, we submitted an NDA to the FDA for VP-102 for the treatment of molluscum. In November 2019, we received notice that the FDA accepted the NDA for filing, with a PDUFA goal date of July 13, 2020. In July 2020, we received a CRL, from the FDA for our NDA. The CRL indicated the need for additional information regarding certain aspects of the CMC processes for the drug/device combination as well as human factors validation. The FDA did not identify any clinical deficiencies. A Type A meeting was held with the FDA in October 2020 to discuss the issues that were identified in the CRL and the resubmission of the NDA for VP-102. We resubmitted our NDA for VP-102 for the treatment of molluscum in December 2020. In February 2021, we received notice that the FDA accepted the resubmitted NDA for filing, with a PDUFA goal date of June 23, 2021.

Phase 2 Clinical Trial—Innovate Trial

In September 2018, we announced results from an open-label Phase 2 clinical trial, which we refer to as the Innovate trial. The primary objective of the Innovate trial was to determine any potential systemic exposure from a single 24-hour dermal application of VP-102 when applied to molluscum lesions on pediatric subjects 2 years of age and older. The trial enrolled 33 subjects at a single center into either an exposure group (n=17) or a standard group (n=16) with 32 subjects completing the trial. Following an initial treatment of all subjects with VP-102 and a 21-day evaluation period, treatment continued once every 21 days for three additional applications allowing further evaluation of safety, efficacy and impact on quality of life.

Systemic exposure was negligible, as indicated by plasma drug levels that were below the limits of quantification in 65 of 66 samples which were taken either pre-dose or post-dose at timepoints of 2, 6 and 24 hours after treatment with VP-102. One sample was above the limit of quantification at 2 hours after VP-102 treatment, but systemic exposure was not detectable at the 6-hour and 24-hour timepoints in this subject. At the end of trial visit (Week 12), there was a mean reduction in molluscum lesions of 90% compared to baseline across all subjects enrolled in the Innovate trial and 50% of subjects who completed the trial experienced complete clearance of their treatable molluscum lesions. VP-102 was well-tolerated and no serious adverse events were reported.

Phase 2 Clinical Trial—Pilot Trial

In 2016, we conducted an open-label, Phase 2 clinical trial, which we refer to as the Pilot Trial, to evaluate the safety and efficacy of our proprietary cantharidin formulation and to determine the optimal treatment regimen and

estimate power for the pivotal trials. The trial enrolled 30 subjects at a single center and was completed in September 2017. The trial utilized a single-use screw-top vial of our proprietary 0.7% cantharidin formulation, with application via the wooden part of a cotton-tipped swab, which is the method of application historically used with compounded cantharidin. The subjects were divided into two cohorts, with the first cohort instructed to wash off the treatment after a six-hour exposure and the second cohort washing off the product after 24-hour exposure. Subjects were treated every three weeks for up to four treatments. Safety and efficacy measures were evaluated every three weeks. Primary efficacy measures were the percentage of subjects who achieved complete clearance by Day 42 (visit 3) and Day 84 (visit 5). Secondary efficacy measures included a quality of life assessment, as measured by the Children's Dermatology Life Quality Index, or CDLQI, score, and the percentage of subjects who achieved clearance of at least 90% of their lesions with comparison to the efficacy data obtained with compounded cantharidin. The CDLQI scale is a validated tool for measuring the impact of skin disease on quality of life for subjects five to sixteen years of age and ranges from a score of 0 to 30. Lower CDLQI scores indicate lower impairment of a patient's quality of life.

In the Pilot Trial, our proprietary cantharidin formulation was applied to over 1,700 molluscum lesions in 30 subjects, and was observed to be well tolerated, with no serious adverse events or unexpected treatment related adverse events recorded. The trial's first cohort investigated a six-hour treatment duration. Fourteen subjects were enrolled in this cohort and 13 subjects completed the trial. Of these 13 subjects, six showed complete clearance on or before Day 84 (visit 5) (46% complete clearance rate). The second cohort investigated a 24-hour treatment duration. Sixteen subjects were enrolled in this cohort and 12 completed the trial. Of these 12 subjects, five showed complete clearance on or before Day 84 (visit 5) (42% complete clearance rate).

VP-102 for the Treatment of Common Warts

We are also developing VP-102 for the treatment of common warts. Published studies and clinical use provide support for cantharidin as a safe and effective treatment for common warts. We believe that VP-102 has the potential to address many of the shortcomings associated with current therapies, including pain and discomfort, scarring, and lack of effectiveness. In addition, we believe VP-102's convenient ease of administration will differentiate it from existing alternative unapproved therapies.

We conducted an open-label COVE-1 Phase 2 clinical trial to evaluate the efficacy, safety and tolerability of VP-102 in subjects with up to six common warts. In this study, there were two cohorts. Cohort 1 was conducted at a single site with 21 subjects age 2 years and older receiving up to 4 treatments with VP-102 at least 14 days between treatments with longer treatment intervals allowed at the discretion of the investigator depending on a specific subject's clinical response. Cohort 2 was conducted at four sites with 35 subjects age 12 years and older receiving up to 4 treatments with VP-102 every 21 days. Paring of warts, a technique commonly used by dermatologists to prepare the wart for treatment, was allowed in Cohort 2 to remove any adherent thick scale from a wart prior to application of study drug. The primary objective of both cohorts was to evaluate the efficacy of up to 4 dermal applications of VP-102 when applied to common warts by assessing the proportion of subjects achieving complete clearance of all treatable warts at Day 84. Complete clearance of warts at Day 84 for Cohort 1 was observed in 19.0% of subjects, and for Cohort 2 complete clearance was observed in 51.4% of subjects. By Day 84, there was a mean decrease from baseline in the number of warts of 31.2% for Cohort 1 subjects and 53.8% for Cohort 2 subjects. In both cohorts, the most frequently reported adverse events were anticipated application site skin reactions that were primarily mild or moderate in intensity, including vesicles, pain, erythema, pruritus, scabbing, dryness, edema, and post-inflammatory pigmentation changes. There were no deaths or serious adverse events reported, and there were no adverse events leading to trial drug discontinuation.

Trial and Status	Formulation	Trial Design	Trial Objectives
Phase 2 COVE-1 Trial Results reported in June 2019	VP-102	• Open-label, multi- center • 2 cohorts • Dosing regimens of 14 (Cohort 1) and 21 (Cohort 2) days evaluated for up to 4 applications • 24-hour treatment • Wart paring allowed in the second cohort	• To evaluate safety and efficacy over four treatments

Based on feedback from the FDA regarding a potential Phase 3 trial protocol, we are currently evaluating conducting an additional Phase 2 clinical trial of VP-102 for the treatment of common warts.

VP-102 for the Treatment of External Genital Warts

We are also developing VP-102 for the treatment of external genital warts. External genital warts are a viral skin disease caused by HPV which forms lesions on the surface of the skin. An estimated 17% of the approximately 4.1 million patient visits for all types of warts are for the treatment of external genital warts. We believe VP-102 may have the potential to offer a safe and effective treatment for external genital warts because of the shared characteristics with molluscum. We initiated a Phase 2 clinical trial evaluating the optimal dose regimen, efficacy, safety and tolerability of VP-102 in patients with external genital warts in June 2019, as summarized in the table below. In November 2020, we announced positive topline results from our Phase 2 clinical trial of VP-102 for the treatment of external genital warts. Based on the results of the Phase 2 trial, we requested an end of Phase 2 meeting with the FDA in the first quarter of 2021.

Trial and Status	Formulation	Trial Design	Trial Objectives
Phase 2 CARE-1 Trial Completed	VP-102	• Randomized, placebo-controlled, multi-center • Two-part (n=108 total) • Dosing regimens of every 21 days evaluated for up to 4 applications • Duration of skin exposure was evaluated for 2, 6 and 24-hours treatment	• To evaluate safety and efficacy over four treatments

VP-103 for the Treatment of Plantar Warts

We also intend to develop our second cantharidin-based product candidate, VP-103, for the treatment of plantar warts, which are warts located on the bottom of the foot. An estimated one-third of the approximately 4.1

million patient visits for all types of warts are for the treatment of plantar warts. To date, plantar warts have been difficult to treat, as they are refractory and available treatments often lead to both pain and scarring. We are conducting necessary drug development activities for VP-103 and are evaluating when to initiate a Phase 2 clinical trial for the treatment of plantar warts.

LTX-315 for the Treatment of Dermatological Oncology Indications

We also intend to develop our third product candidate, LTX-315, for the treatment of dermatological oncology indications. We intend to submit an IND for LTX-315 in the first half of 2021.

Manufacturing

We do not have any manufacturing facilities. We have been relying on third parties for the manufacture of our product candidates for preclinical studies and clinical trials and will continue to rely on these third parties in the near term for the commercial manufacture of our drug products if they are approved during the initial commercial phase. Manufacturing of the API for our product candidates requires a raw material that is derived from a natural source.

To date, we have obtained naturally-sourced cantharidin directly or indirectly from suppliers based in the People's Republic of China. On July 16, 2018, we entered into a Supply Agreement, or the Supply Agreement, with Funing County Development Brucea Javanica Professional Cooperatives, or the Supplier, pursuant to which the Supplier has agreed to supply naturally-sourced cantharidin to us for a specified fixed price. Pursuant to the Supply Agreement, the Supplier has agreed that it will not supply cantharidin, any beetles or other raw material from which cantharidin is derived to any other customer in North America, subject to specified minimum annual purchase orders and forecasts.

Pursuant to the Supply Agreement, we have provided the Supplier with purchase orders in 2018, 2019 and 2020 and may submit additional purchase orders from time to time, so long as the purchase orders are at least six months prior to the proposed delivery date. As of January 31, 2021, we possessed total inventories in a combination of raw cantharidin and converted API adequate to produce over 14 million finished drug product applicators in the United States, with additional raw cantharidin already manufactured awaiting shipment.

The term of the Supply Agreement is five years and thereafter will be renewed automatically for 12-month periods, unless terminated by either party at least 12 months prior to the end of the applicable term. In addition, either party has the right to terminate the Supply Agreement under certain circumstances, including (i) upon a material breach of the Supply Agreement if the breaching party has failed to remedy the breach within 45 days or if the breach is not capable of remedy within 45 days or (ii) the other party becomes insolvent or goes into liquidation.

Our contract manufacturers and primary packaging vendor are FDA-registered establishments and have a history of supplying products to the pharmaceutical industry.

We have demonstrated capability to successfully manufacture the API the bulk drug intermediate, filled ampules and assembled applicators at our proposed commercial batch sizes. Validation activities for the commercial manufacturing and assembly processes were completed in 2020. Given the nature of both the API as well as several of the excipients, special handling will be required to minimize risks to personnel during processing. Analytical testing methods for both the API as well as the finished drug product have been developed and qualified. It is expected that these methods will prove appropriate for release of commercial product with minimal additional effort.

Our proprietary individual applicator and its parts are fabricated using common methods and materials and we currently plan to have our applicators built using semi-custom equipment performing well established automated assembly techniques. As part of the proposed resolution to FDA comments in the CRL regarding the human factors validation, we have designed and developed an accessory to facilitate the preparation of the applicator assembly by the healthcare professional. The proposed commercial applicator assembly and this accessory have successfully undergone both engineering testing as well as evaluation in a simulated clinical setting.

Commercialization

We intend to commercialize VP-102, or any other product candidates that we may successfully develop, in the United States by building a specialized sales organization focused on pediatric dermatologists, dermatologists and select pediatricians. We believe a scientifically oriented, customer-focused team of approximately 50 to 60 sales representatives would allow us to reach the approximately 400 pediatric dermatologists and 5,000 to 6,000 dermatologists in the United States with the highest potential for using VP-102. In the future, we may develop and commercialize VP-102 for additional geographic regions, independently or with a strategic partner. For instance, 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 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 intend to seek drug product reimbursement for VP-102. Based on a survey of 40 physicians that we commissioned, 87% of physicians reported they would use VP-102 if the cost of the drug were covered. Furthermore, in April 2018, we commissioned a market research study, which surveyed 15 payor organizations representing over 105 million lives. The surveyed payors recognized that there is a significant unmet need for molluscum and a current lack of an effective treatment. Given the unmet need and the results of clinical trials of VP-102 to date, the surveyed payors anticipate the majority of patients would have access to VP-102, if approved, with minimal to no restrictions. We believe dermatologists tend to be particularly focused on the safety of pharmaceutical products because, while skin diseases can have profound effects on patients' quality of life, few are life-threatening. As a result, we believe that dermatologists, as well as their patients, often prefer to use topical treatments when possible to limit the risk of systemic side effects. Dermatologists also tend to place a high level of emphasis on products that are easy to use because they often manage high volumes of patients. We believe this also contributes to a general preference for topical treatments. Finally, in our experience, dermatologists tend to engage with sales and medical affairs personnel from the pharmaceutical industry regarding the scientific evidence supporting dermatology products and the challenges experienced by physicians and patients in the use of these products. Dermatologists often rely on trusted relationships with scientifically oriented, customer-focused sales representatives who can provide them with the necessary information to support their use of appropriate treatments.

Competition

The pharmaceutical industry is subject to rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, compounding facilities, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that may become available in the future.

The key competitive factors affecting the success of VP-102, if approved, are likely to be its efficacy, safety, convenience, pricing and stability. With respect to VP-102 for the treatment of molluscum, we will be primarily competing with therapies such as other topical products, curettage, cryotherapy, laser surgery, natural oils, off-label drugs, natural remedies and compounded unstandardized cantharidin. Under Section 503A of the FDCA, if VP-102 is approved, compounded topical cantharidin products with the same, similar or an easily substitutable dosage strength would be considered essentially copies of VP-102 and may not be compounded regularly or in inordinate amounts, subject to certain limited individual exceptions. These exceptions include if there is a difference between the compounded product and VP-102 that is made for an individual patient, and a prescribing practitioner determines produces a significant difference for that patient. In addition, pursuant to Section 503B of the FDCA, once VP-102 is approved, compounding facilities registered as outsourcing facilities would not be able to compound cantharidin products, unless there is a difference from VP-102 that produces a clinical difference for an individual patient, as determined by a prescribing practitioner. With respect to VP-102 for common warts and VP-103 for plantar warts, we will primarily be competing with over-the-counter products, cryotherapy, curettage, laser surgery, or other off-label therapies. There are currently no FDA-approved prescription pharmaceutical therapies for the treatment of molluscum, common warts, or plantar warts. With respect to VP-102 for external genital warts, we will be competing with cryosurgery, laser surgery, and topical destructive therapies such as trichloroacetic acid. There are also several FDA-approved prescription pharmaceutical therapies for external genital warts including

imiquimod, podofilox, and sinecatechins. In addition, external genital warts are caused by HPV and may be prevented or treated by HPV vaccines that are FDA-approved.

We are aware of several other product candidates in earlier stages of development as potential treatments for the indications we intend to target. Veloce Biopharma, Leo Pharma and Novan have initiated clinical trials with different programs in molluscum. There are a number of other companies developing products for common wart, including Aclaris Therapeutics. Aclaris has conducted late-stage clinical trials and is pursuing FDA approval for their common wart product candidate. In addition, other drugs have been used off label as treatments for molluscum and common warts.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for VP-102 and our proprietary applicator and any of our future product candidates, medical devices, synthetic methodologies, novel discoveries, drug development technologies and know-how; to operate without infringing on or otherwise violating the proprietary rights of others; and to prevent others from infringing or otherwise violating our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our product candidate and other proprietary technologies, inventions, and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position.

While we seek broad coverage under our pending patent applications, our granted patent and pending patent applications do not include any claims drawn to the active pharmaceutical agent cantharidin *per se* or for the broad use of our API alone for the treatment of warts or molluscum. However, our granted patent and pending patent applications do claim our cantharidin preparations, cantharidin formulations, applicator devices, dosing regimens, methods of preparation including methods of synthesis, and methods of use. Despite these patent filings, there is always a risk that modification of the specific formulation, manufacturing process, method of application, and/or specific method of use may allow a competitor to avoid infringement claims. In addition, patents, if granted, will expire, and we cannot provide any assurance that any additional patents will issue from our pending or any future patent applications.

We currently have one granted Japanese patent covering cantharidin formulations, as well as one granted Australian patent covering cantharidin formulations, applicator devices and systems comprising the formulation and methods of using the same. Additionally, we have one allowed Israeli patent application covering our cantharidin formulation, applicator devices and systems comprising the formulation, and methods of using the same. We also have one issued United States patent, as well as patent applications allowed in Israel and Japan, each covering methods for preparing cantharidin. We also have one issued United States design patent covering the design of our VP-102 applicator. Additionally, as of February 4, 2021, we have nationalized five international patent applications for utility patents, four of which have been nationalized in the United States, Australia, Brazil, Canada, China, Europe, Israel, India, Japan, South Korea, and Mexico, and one of which has been nationalized in the United States, Europe, and Japan. Four of these European patent applications have been registered in Hong Kong. In addition, we have one pending United States provisional patent application and two pending United States design patent applications. These patents and patent applications relate to VP-102, our proprietary applicator, and other inventions related to VP-102. Our patents and patent applications related to VP-102 and our proprietary applicator include proposed claims relating to (i) methods for the synthesis of cantharidin, (ii) our specific formulations and preparations of VP-102, (iii) methods for purifying cantharidin, (iv) methods for detecting impurities in cantharidin, (v) the design of our proprietary applicator, including both the general design and specific design elements, (vi) claims related to safety features included in the VP-102 formulation, including colorants and bittering agents, and (vii) the method of administration of VP-102 for the treatment of skin lesions. Excluding any patent term adjustment and patent term extension, any utility patents to issue from these patent applications are projected to expire between 2034 and 2041. The issued United States design patent will expire on October 27, 2035, and any additional design patents to issue from our pending design patent applications will each expire fifteen years from the date of issuance. We cannot provide any assurance as to whether any additional patents will issue from these patent applications or, if any patents do issue, the scope of the claims that will be allowed.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries, in which they are obtained. Generally, utility patents issued from regularly filed applications in the United States are granted for a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent's term can be adjusted to recapture a portion of the United States Patent and Trademark Office, or the USPTO, delay in examining and issuing the patent, and extended to recapture a portion of the patent term effectively lost as a result of the FDA regulatory review period of the drug covered by the patent. However, as to the FDA component, the restoration period cannot be longer than five years, the total patent term including the restoration period must not exceed 14 years following FDA approval of the drug, and the extension may only apply to one patent that covers the approved drug (and to only those patent claims covering the approved drug or a method for using it). There can be no assurance that any such patent term adjustment or extension will be obtained. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

Furthermore, we rely upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees, and consultants and invention assignment agreements with our employees. We also have confidentiality agreements and/or invention assignment agreements with our commercial partners and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Lytix License Agreement

On August 7, 2020, we entered into the Lytix Agreement, pursuant to which we obtained a worldwide, exclusive, royalty-bearing license, with the right to sublicense, for certain technology of Lytix to research, develop, manufacture, have manufactured, use, sell, have sold, offer for sale, import and otherwise commercialize LTX-315 for use in all malignant and pre-malignant dermatological indications, other than metastatic melanoma and metastatic merkel cell carcinoma. Our right to manufacture the active pharmaceutical ingredient is limited to certain instances, and Lytix is obligated to manufacture and supply our clinical and commercial needs for such active pharmaceutical ingredient. We are obligated to use commercially reasonable efforts to develop and to commercialize the product, which development and commercialization will be overseen by a joint steering committee. Lytix has agreed not to pursue any products in the field of dermatology other than LTX-315 for use in metastatic melanoma and metastatic merkel cell carcinoma. Lytix has granted us an exclusive option to negotiate for an exclusive license for use of LTX-315 in additional dermatological indications.

In connection with entering the Lytix Agreement, we made initial payment of $250,000. We made an additional payment of $2.25 million upon the achievement by Lytix of a regulatory milestone. Additionally, we are obligated to pay up to $111.0 million contingent on achievement of specified development, regulatory, and sales milestones, and tiered royalties based on worldwide annual net sales ranging in the low double digits to the mid-teens, subject to certain customary reductions. Our obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of the expiration or abandonment of the last to expire licensed patent covering LTX-315 anywhere in the world and expiration of regulatory exclusivity for LTX-315 in such country. Additionally, all upfront fees and milestone-based payments received by us from a sublicensee will be treated as net sales and will be subject to the royalty payment obligations under the Lytix Agreement, and all royalties received by us from a sublicensee shall be shared with Lytix at a rate that is initially 50% but decreases based on the stage of development of LTX-315 at the time such sublicense is granted.

The Lytix Agreement expires on a product-by-product and a country-by-country basis upon expiration of the royalty term for such product in such country. At any time after the first anniversary of the execution of the Lytix

Agreement, we have the right to terminate the agreement, either on a region-by-region basis or in its entirety, upon specified written notice to Lytix. Lytix may terminate the agreement, either on a region-by-region basis or in its entirety, if we develop or commercialize a competing product in the licensed field, or in its entirety if we challenge the validity, enforceability or scope of any licensed patent, subject in each case to certain cure rights. Either party may terminate the Lytix Agreement in the event of an uncured material breach or insolvency of the other party.

Torii Collaboration and License Agreement

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 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.

Under the Torii Agreement, Torii is responsible for all development activities and 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. Torii is required to use commercially reasonable efforts to conduct all development necessary to obtain regulatory approval for licensed products in Japan, to obtain and maintain such approvals, and to commercialize licensed products upon receipt of such approvals.

Pursuant to the Torii Agreement, we are entitled to receive an up-front payment from Torii of $11.5 million. Additionally, we are entitled to receive from Torii an additional $58.0 million in aggregate payments contingent on achievement of specified development, regulatory, and sales milestones, in addition to tiered transfer price payments for supply of product in the percentage range of the mid-30s to the mid-40s of net sales. The transfer payments shall be payable, on a product-by-product basis, beginning on the first commercial sale of such product and ending on the latest of (a) expiration of the last-to-expire valid claim contained in certain licensed patents in Japan that cover such product, (b) expiration of regulatory exclusivity for the first indication for such product in Japan, and, (c) (i) with respect to the first product, ten years after first commercial sale of such product, and, (ii) with respect to any other product, the later of (x) ten years after first commercial sale of the first product and (y) five years after first commercial sale of such product.

The Torii Agreement expires on a product-by-product basis upon expiration of Torii's obligation under the agreement to make transfer price payments for such product. Torii has the right to terminate the agreement upon specified prior written notice to us. Additionally, either party may terminate the agreement in the event of an uncured material breach of the agreement by, or insolvency of, the other party. We may terminate the agreement in the event that Torii commences a legal action challenging the validity, enforceability or scope of any licensed patents.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local levels, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products, such as those we are developing. We, along with third-party contractors, will be required to navigate the various chemistry, manufacturing and controls, preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the drug development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending new drug applications, or NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of chemistry, manufacturing and controls testing, an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of an FDA inspection of selected clinical sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees; and
- FDA review and approval of the NDA.

VP-102 is designed to be administered to patients via a proprietary applicator by a healthcare professional. In the United States, products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA's Office of Combination Products assigns a combination product to a specific Agency center as the lead reviewer. The FDA determines which center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. We anticipate that VP-102 will be regulated as a drug, and that the FDA will permit a single regulatory submission seeking approval of VP-102 with the applicator in each indication for which we seek approval. Even when a single marketing application is required for a combination product, such as an NDA for a combination pharmaceutical and device product, both the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health may participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some nonclinical testing may continue even after the IND is submitted.

An IND automatically becomes effective and a clinical trial proposed in the IND may begin 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must continue to oversee the clinical trial while it is being conducted. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the safety and efficacy of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor’s agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post approval to gain more information about the drug. Such post approval trials are typically referred to as Phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted, at least annually, to the FDA, and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements, or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls data and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has sixty days from receipt to make a decision as to whether the application has been accepted for filing.

In addition, under the Pediatric Research Equity Act of 2003 as amended and reauthored, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP requirements.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of an NDA on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional chemistry, manufacturing and controls documentation, clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Special Protocol Assessment

A sponsor may request a Special Protocol Assessment, or (SPA), the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins for a SPA to be approved. If a written agreement is reached, it will be documented in a SPA letter or the minutes of a meeting between the sponsor and the FDA and made part of the administrative record.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- a sponsor fails to follow a protocol that was agreed upon with the FDA; or
- the relevant data, assumptions, or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

A documented SPA may be modified, and such modification will be deemed binding by the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. A SPA, however, does not guarantee that a trial will be successful.

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, known as the Orange Book. Any applicant who files an Abbreviated New Drug Application, or ANDA, seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify, for each patent listed in the Orange Book for the referenced drug, to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA, (2) such patent has expired, (3) the date on which such patent expires or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. The fourth certification described above is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. This section viii statement does not require notice to the patent holder or NDA owner. There might also be no relevant patent certification.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. Even if the 45 days expire, a patent infringement lawsuit can be brought and could delay market entry, but it would not extend the FDA-related 30-month stay of approval.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired. Specifically, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a New Chemical Entity, or (NCE), which is a drug that contains an active moiety that has not been approved by 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.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications, manufacturing changes or other labeling claims, are subject to further testing requirements and prior FDA review and approval. There also are continuing annual program fee requirements for any marketed products.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market or if requested by the Sponsor. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential FDA enforcement actions include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. Companies may also share truthful and not misleading information that is otherwise consistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. However, physicians may, in their independent medical judgement, 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.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Regulation of Compounding Pharmacies

Compounding is a practice in which a licensed pharmacist, a licensed physician, or in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although we are not engaged in compounding, the active pharmaceutical ingredient in our product candidate VP-102 has historically been used in the compounding of topical pharmaceutical products, and we could be subject to competition by compounders upon approval of VP-102, subject to the requirements set forth in Sections 503A and 503B of the FDCA.

Section 503A of the FDCA exempts licensed pharmacists or licensed physicians who compound products for identified, individual patients, based on the receipt of a valid prescription order, from the FDCA's new drug approval requirements, cGMP requirements, and the requirement to label products with adequate directions for use, provided certain conditions are met. These conditions include that the pharmacist or physician does not compound regularly or in inordinate amounts any drug product that is essentially a copy of a commercially available drug product, unless there is a difference between the compounded product and the commercially available product that is made for an individual patient, and which the prescribing practitioner determines produces a significant difference for that patient. The FDA has interpreted this prohibition to mean that the compounding of a product with the same active pharmaceutical ingredient as a commercially available drug, that has the same, similar, or an easily substitutable dosage strength as the commercially available drug, and that can be used by the same route of administration as the commercially available drug, cannot be conducted under Section 503A usually, very often, or at regular times or intervals, or more frequently or in larger quantities than needed to address unanticipated emergency circumstance, unless the limited exception described above applies.

In addition, compounding under Section 503A may only use bulk drug substances that appear on a list issued by FDA through regulations, and/or that comply with certain other conditions specified in the statute.

Unlike Section 503A, Section 503B of the FDCA allows certain entities to compound drugs that are not necessarily prepared in response to prescriptions for identified, individual patients. Such facilities must register with the FDA as outsourcing facilities, and once registered (including payment of a fee), the outsourcing facility must meet certain conditions in order to be exempt from the FDCA's approval requirements and the requirement to label products with adequate directions for use. Under Section 503B, a drug must be compounded in compliance with cGMP, by or under the direct supervision of a licensed pharmacist in order to be so exempt. The outsourcing facility must also report specific information about the products that it compounds, including a list of all of the products it compounded during the previous six months, and information about the compounded products, such as the source of the active ingredients used to compound pursuant to Section 503B(b)(2). If the outsourcing facility compounds using bulk drug substances, the bulk drug substances must either appear on a list established by the FDA of bulk drug substances for which there is a clinical need or be used to compound drugs that appear on a list established by the FDA of drugs for which there is a shortage. 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, 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 FDA implements these criteria as in the Guidance for Industry, and if VP-102 is approved, an outsourcing facility would need to satisfy these criteria before being permitted to compound a cantharidin product using bulk cantharidin.

In addition, an outsourcing facility must meet other conditions described in Section 503B, including reporting adverse events and labeling compounded products with certain information. Registered outsourcing facilities are prohibited from selling compounded drugs through a wholesale distributor, or from compounding drugs that are essentially copies of FDA-approved drugs. A drug is "essentially a copy of an approved drug" if it is identical or nearly identical to an approved drug, 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 has the same active ingredient as an approved drug and there is not a change from the approved drug that produces a clinical difference for an individual patient, as determined by the prescribing practitioner. Registered outsourcing facilities are subject to FDA inspection, and FDA conducts inspections on a risk-based frequency under Section 503B(b)(4) of the FDCA.

Federal and State Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws and regulations restrict business practices in the biopharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products for which we obtain marketing approval. These laws include anti-kickback and false claims laws and regulations, data privacy and security, and transparency laws and regulations, including, without limitation, those laws described below.

The federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and other individuals and entities on the other hand. 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 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.

In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Further, 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 the False Claims Act, which prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim 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, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing 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 respective implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on certain 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 Physician Payments Sunshine Act 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 payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives.

We may also be subject to 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 reporting of information related to drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; as well as 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Coverage and Reimbursement

Market acceptance and sales of any drug products depend in part on coverage and the extent to which adequate reimbursement for drug products will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Coverage and reimbursement for our product also depends on coverage and adequate reimbursement for the procedures using VP-102 for the treatment of molluscum and/or common warts. 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 and/or common warts in the absence of such coverage and adequate reimbursement.

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 customers 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 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, 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 impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Impact of Healthcare Reform on our Business

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 drug product candidates, restrict or regulate post-approval activities, and affect the profitable sale of drug product candidates.

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. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, 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, 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 remain judicial and Congressional 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 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. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends 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 new 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 December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, 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, including the BBA, will remain in effect through 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 unless additional Congressional action is taken. 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, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. Further, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. The likelihood of implementation of these, or any of the other Trump administration reform initiatives is uncertain, particularly in light of the new Biden administration. 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. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

Employees and Human Capital Resources

As of December 31, 2020, we had 29 full-time employees. All of our employees are located in the United States. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Insurance

We currently maintain product liability insurance coverage for our products and clinical trials in amounts consistent with industry standards. However, insurance coverage is becoming increasingly expensive, and we may not be able to obtain or maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability.

Corporate Information

We were incorporated under the laws of the State of Delaware on July 3, 2013. Our principal executive offices are located at 10 North High Street, Suite 200, West Chester, PA 19380 and our telephone number is (484) 453-3300.

Available Information

Our internet website address is www.verrica.com. In addition to the information about us and our subsidiaries contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. Additionally the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov.

ITEM 1A. RISK FACTORS

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 over the next several years and may never achieve or maintain profitability.
  - We may need substantial additional funding to meet our financial obligations and to pursue our business objectives. 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.
  - We have a limited operating history and no history of commercializing products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

- **Risks Related to the Development of Our Product Candidates**
  - Our lead product candidate, VP-102, is being developed for the treatment of molluscum, common warts and external genital 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, common warts, external genital 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 Candidates**
  - 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 VP-102 for the treatment of molluscum and common warts will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these procedures.
  - The market for VP-102 and any other 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 raw material used in VP-102, and if we encounter any extended difficulties in procuring, or creating an alternative for, our raw material in 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 Legal and Regulatory Compliance Matters**
  - We expect to expand our development and regulatory capabilities and 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**
  - We expect to expand our development and regulatory capabilities and 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 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.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage dermatology therapeutics company with limited operating history. Since inception, we have incurred significant net losses. We incurred net losses of $42.7 million and $28.2 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $103.9 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. We have no products approved for commercialization and have never generated any revenue.

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, VP-102, for the treatment of molluscum, including preclinical studies and clinical trials. 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 also developing VP-102 as a treatment for common warts and external genital warts. We also intend to develop our second cantharidin-based product candidate, VP-103, for the treatment of plantar warts and our third product candidate, LTX-315, for the treatment of dermatological oncology indications.

Therefore, we expect to continue to incur significant expenses and operating losses over the next several years. 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 our ongoing clinical programs evaluating VP-102 for the treatment of common warts and external genital warts, as well as initiate and complete additional clinical trials as needed;
- initiate clinical trials evaluating VP-103 for the treatment of plantar warts and LTX-315 for the treatment of dermatological oncology indications;
- pursue regulatory approvals for VP-102 for the treatment of molluscum, and eventually for the treatment of common warts, external genital warts or any other indications we may pursue for VP-102, as well as for VP-103 and LTX-315;

- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including VP-102, VP-103 and LTX-315;
- 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 developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including 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.

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 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 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 may need substantial additional funding to meet our financial obligations and to pursue our business objectives. 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.

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. We expect to continue to incur significant expenses and operating losses over the next several years as we seek marketing approval for VP-102 for the treatment of molluscum, pursue clinical trials and marketing approval for VP-102 for the treatment of common warts, external genital warts and other indications, pursue clinical trials and marketing approval for VP-103 for the treatment of plantar warts, LTX-315 for the treatment of dermatological oncology indications, and advance any of our other product candidates we may develop or otherwise acquire. In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that are not

currently commercially available. If we obtain marketing approval for VP-102 for the treatment of molluscum or common warts or any other product candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing.

As of December 31, 2020, we had cash, cash equivalents and marketable securities of $65.5 million. On March 10, 2020, we entered into (i) a mezzanine loan and security agreement, or the Mezzanine Loan Agreement, with Silicon Valley Bank, as administrative agent and collateral agent, or the Agent, and Silicon Valley Bank and West River Innovation Lending Fund VIII, L.P., as lenders, or the Mezzanine Lenders, pursuant to which the Mezzanine Lenders have agreed to lend the Company up to $50.0 million in a series of term loans, and (ii) a loan and security agreement, or the Senior Loan Agreement, and together with the Mezzanine Loan Agreement, the Loan Agreements, with Silicon Valley Bank, as lender, or the Senior Lender, and together with the Mezzanine Lenders, the Lenders, pursuant to which the Senior Lender has agreed to provide the Company a revolving line of credit of up to $5.0 million. Upon entering into the Loan Agreements, the Company borrowed $35.0 million in term loans from the Mezzanine Lenders. We entered into amendments to the Loan Agreements in October 2020, under which we borrowed an additional $5.0 million in term loans on March 1, 2021.

We believe that our existing cash, cash equivalents, and marketable securities as of December 31, 2020 combined with the $11.5 million up-front payment we are entitled to receive pursuant to the Torii Agreement, will be sufficient to support our planned operations at least through the first quarter of 2022. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. 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 development activities, acquisitions of additional product candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the progress and results of our development programs evaluating VP-102 as a potential treatment for common warts;
- the scope, progress, results and costs of the development programs evaluating VP-102 as a potential treatment for external genital warts and any other indications of VP-102 we may decide to pursue VP-103, and LTX-315;
- the extent to which we develop, in-license or acquire other product candidates and 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 costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for VP-102 for the treatment of molluscum, if approved, and any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize VP-102 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 require additional capital to commercialize VP-102 for the treatment of molluscum, common warts and/or external genital warts, and/or VP-103 for the treatment of plantar warts and/or LTX-315 for the treatment of dermatological oncology indications. If we receive regulatory approval for VP-102, VP-103 or LTX-315 for these indications, 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.

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 have a limited operating history and no history of commercializing products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2013, and our operations to date have been largely focused on raising capital and developing our novel topical solution of cantharidin and our lead product candidate, VP-102, for the treatment of molluscum and common warts, including undertaking preclinical studies and conducting clinical trials. VP-102 is our only product candidate for which we have conducted 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. 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 transition at some point from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We may not be able to generate sufficient cash to service our indebtedness.

We have entered into a Mezzanine Loan Agreement and a Senior Loan Agreement with our Lenders, pursuant to which we have borrowed an aggregate of $40.0 million. Our obligations under the Senior Loan Agreement and the Mezzanine Loan Agreement are secured by, respectively, a first priority perfected security interest and second priority perfected security interest in substantially all of our current and future assets, other than our intellectual property (except rights to payment from the sale, licensing or disposition of such intellectual property). We have also agreed not to encumber our intellectual property assets, except as permitted by the Loan Agreements.

We are subject to a number of affirmative and restrictive covenants pursuant to the Loan Agreements, including covenants regarding maintaining minimum liquidity requirements, achieving minimum product revenues, delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, protection of intellectual property rights, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness or liens, investments and transactions with affiliates, among other customary covenants. Our obligations under the Loan Agreements are subject to acceleration upon the occurrence of specified events of default, including our failure to satisfy our payment obligations under the Loan Agreements, the breach of certain of our other covenants under the Loan Agreements, or the occurrence of a material adverse change, cross defaults to other indebtedness or material agreements, judgment defaults and defaults related to failure to maintain governmental approvals failure of which to maintain could result in a material adverse effect. We are currently 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 Loan Agreements could result in an event of default, which could result in an acceleration of amounts due under the Loan Agreements. 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 the Lenders could seek to enforce security interests in the collateral securing such indebtedness, which would harm our business.

Risks Related to the Development of Our Product Candidates

Our lead product candidate, VP-102, is being developed for the treatment of molluscum, common warts and external genital 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, common warts, external genital 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 products that are approved for commercial sale. We have only one product candidate, VP-102 for which we have conducted clinical trials. 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. Our NDA is presently under review by FDA and there can be no assurance that we will receive approval. In addition to developing VP-102 for the treatment of molluscum, we are also developing VP-102 as a treatment for common warts and external genital warts. In addition, we plan to develop our second cantharidin-based product candidate, VP-103, for the treatment of plantar warts. We also plan to develop our third product candidate, LTX-315, for the treatment of dermatological oncology indications. 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 our cantharidin formula and VP-102 for the treatment of molluscum, common warts and genital warts. Our ability to generate revenue from our product candidates, will depend heavily on their successful development, regulatory approval and eventual commercialization of these product candidates. The success of VP-102, VP-103, LTX-315 or 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 any of our product candidates that receive regulatory approval;
- receipt of timely marketing approvals from applicable regulatory authorities;
- launching commercial sales of products, if approved;
- acceptance of our products, if approved, 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 VP-102 or any other product candidates, if approved;
- the prevalence and severity of adverse events experienced with VP-102 or our other product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative treatments for molluscum and/or common warts or any other indications which we may pursue for VP-102 or any other product candidates;

- our ability to produce VP-102 or any other product candidates on a commercial scale;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our 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-103, LTX-315 or 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 fail 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 data safety monitoring board 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 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. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. 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 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 the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

While we have negotiated a SPA agreement with the FDA relating to one of our Phase 3 clinical trials for VP-102, this agreement does not guarantee approval of VP-102 or any other particular outcome with respect to regulatory review of the study or the product candidate.

We have completed two Phase 3 clinical trials of VP-102 for the treatment of molluscum, one of which was conducted under a SPA with the FDA. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory submission for the product candidate with respect to the indication studied. All agreements and disagreements between the FDA and the sponsor regarding a SPA must be clearly documented in a SPA letter or the minutes of a meeting between the sponsor and the FDA.

However, a SPA agreement does not guarantee approval of a product candidate, and even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, a SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. After a SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

We cannot assure you that our Phase 3 clinical trial conducted under the SPA will be deemed acceptable to the FDA under our SPA agreement or will result in any FDA approval for VP-102. If the FDA revokes or alters its agreement under the SPA, believes that the manner in which the study was conducted was not consistent with the terms of our SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for marketing approval, which could materially adversely affect our business, financial condition and results of operations.

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 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 VP-102 for the treatment of common warts and external genital warts and potentially other dermatological conditions 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 of VP-102 for the treatment of molluscum, common warts and external genital warts, as well as VP-103 for the treatment of plantar warts and LTX-315, for the treatment of dermatological oncology indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for VP-102, VP-103, and LTX-315 that 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 have not obtained regulatory approval for VP-102 or any product candidate and it is possible that neither VP-102 nor any 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 VP-102 or any other product candidate outside of the United States.

Prior to obtaining approval to commercialize VP-102 and any other 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 or foreign marketing application for VP-102 or any future product candidates, 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 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 and 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.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives 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 any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments, including for VP-102, compared to compounded cantharidin;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments, including compounded cantharidin;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for VP-102 and any other potential product candidates;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

In the case of VP-102, the failure of healthcare professionals or patients to perceive the benefits of using VP-102 instead of compounded cantharidin or other alternative therapies, such as curettage or cryotherapy, would adversely affect the commercial success of VP-102, if approved.

If we are unable to establish sales, marketing and distribution capabilities for VP-102 or 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 sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market or co-promote some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and 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 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;

- 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 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 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, 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 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.

We are aware of several other product candidates in earlier stages of development as potential treatments for the indications we intend to target. Veloce Biopharma, Leo Pharma, and Novan have initiated clinical trials with different programs in molluscum. There are a number of other companies developing products for common warts, including Aclaris Therapeutics, or Aclaris. Aclaris has conducted late-stage clinical trials and is pursuing strategic alternatives to further develop and obtain regulatory approval for its product candidate for the treatment of common warts. In addition, other drugs have been and may continue to be used off label as treatment for molluscum, common warts, external genital 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 we receive approval for VP-102, any compounding by licensed pharmacists or licensed physicians under Section 503A would not be legally permitted to include, regularly or in inordinate amounts, the compounding of any drug that is essentially a copy of 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 VP-102, and could be compounded under Section 503A, if there were a difference between the compounded product and 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 VP-102, if approved, where the compounded drug would be considered essentially a copy if it were identical or nearly identical to 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 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 we receive approval for VP-102, if a prescribing practitioner determines that a compounded product prescribed for a specific patient features a change from 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 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, 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 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 VP-102, if approved, in which case compounded drug product that is essentially a copy of 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 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 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 intend to seek NCE exclusivity and/or pediatric exclusivity for VP-102 and future product candidates, and we may be unsuccessful.

As part of our business strategy, we intend to seek NCE exclusivity for VP-102 or 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 VP-102 should, if approved, be eligible for NCE exclusivity and that our planned clinical trials will qualify 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 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 revenue would be adversely affected.

Moreover, even if we obtain NCE exclusivity and/or 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 VP-102 for the treatment of molluscum and common warts 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 VP-102 for the treatment of molluscum and/or common warts 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 and/or common warts 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 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, 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 impact overall physician reimbursement under the Medicare program. 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 VP-102 for the treatment of molluscum and/or common warts, 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.

The market for VP-102 and any other product candidates may not be as large as we expect.

Our lead indications for VP-102 are for molluscum and common warts, both of which are skin diseases that are currently undertreated with no standard of care. If VP-102 is approved for either indication, individuals may continue to decline treatment for molluscum 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 VP-102 and any other 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, common warts and other skin diseases as well as the estimated reimbursement levels for VP-102, if approved. 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, common warts and other skin diseases as well as the estimated reimbursement levels for VP-102, if approved, 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 molluscum, common warts or any other indication. For example, if VP-102 is approved for either molluscum 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 for VP-102 in molluscum, common warts or any other indication we may pursue for VP-102 or for any other product candidate 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 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 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 any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;

- 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 may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. 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.

Risks Related to Our Dependence on Third Parties

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 VP-102 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 our 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 VP-102 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 a third party to supply our raw material used in VP-102, and if we encounter any extended difficulties in procuring, or creating an alternative for, our raw material in VP-102 or any of our other 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 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 VP-102 or any of our other product candidates, whether such cantharidin is naturally sourced or synthetically derived, would impair our business operations.

COVID-19 has adversely impacted and could continue to adversely impact our business.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States. As a direct result of COVID-19, we have decided to delay the initiation of our Phase 3 clinical trials to evaluate VP-102 in subjects with common warts as well as our planned Phase 2 clinical trial to evaluate VP-103 in subjects with plantar warts. As COVID-19 continues to rapidly evolve in the United States, we may experience continued and additional disruptions or impairments that could severely 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;
- delays in review of regulatory filings by regulatory authorities, including but not limited to travel restrictions that may prevent the FDA from being able to conduct any necessary preapproval inspections of our vendors' facilities, as well as our ability to generate responses to the FDA inquiries per the CRL regarding our filed NDA for VP-102;
- delays or limitations in our ability to commercialize VP-102, regardless of regulatory approval, including challenges involving the healthcare providers who would prescribe and administer VP-102, delays in launch preparation activities, or delays in establishing, and subsequently deploying, a commercial field force;

- 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.

We are closely monitoring the pandemic and do not yet know the extent to which COVID-19 may materially impact our business, supply chain, clinical trials and regulatory filings will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We contract with third parties for the manufacture of VP-102 for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of VP-102 or such quantities at an acceptable cost, which could delay, prevent or impair our development 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 of VP-102, or 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 VP-102 or be able to obtain quantities at an acceptable cost or quality, which could 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 of commercial supply of VP-102 or any other product candidates for which we obtain marketing approval. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted prior to approval of our NDA, if at all, and in the future of additional NDAs or comparable marketing application to the FDA or other regulatory authority. We do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We may be unable to establish any agreements with future third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, qualifying and validating such manufacturers may take a significant period of time and reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible increase in costs for the applicator components, raw materials or API in 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 volume requirements, we will need to successfully validate our proposed automated assembly process as designed. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and 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 any 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.

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.

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 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 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 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.

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.

We plan to rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our 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. We currently have one issued patent, and the patent applications that we own may fail to result in other issued patents with claims that cover the product candidates in the United States or in foreign jurisdictions. If this were to occur, early generic competition could be expected against our product candidates in development. There may be relevant prior art relating to our future 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 of our product candidates has 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. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. 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 our 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 our 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 our 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 our 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 future 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 future 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 future patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future 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 our product candidates are limited to specific formulations, preparations and devices, and methods of use and manufacturing processes, and our market opportunity for our 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 our product candidates, is not eligible for patent protection. We seek to obtain patent protection for our manufacturing technology, drug administering technology and our product candidates, including specific formulations, preparations and devices, and methods of use and manufacturing processes. Although the protection afforded by our patent and patent applications may be significant with respect to VP-102, when looking at the ability of the patent and applications to block competition, the protection offered by the patent and 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 future 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 our product candidates so long as the competitors do not infringe any process, use, formulation, preparation or device patents that we have applied for to protect our product candidates, subject to any regulatory exclusivity we may be able to obtain for our product candidates.

The number of patents and patent applications covering products containing the same active ingredient as our 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 our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our product candidates that are different from ours and do not infringe our issued patents covering our product candidates, our device, our manufacturing process or uses of our 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 applied for. 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 VP-102 and any 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 future 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 future 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 patent and 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 VP-102 or any future product candidates, or if we collaborate with additional third parties for the development of VP-102 or any 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 patent or future patents;
- we or future collaborators might not have been the first to make the inventions covered by our patent, 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, 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 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), and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members and, beginning in 2022, will require applicable manufacturers to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives; and
- state and foreign law equivalents of each of the above federal laws; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; state laws that require the reporting of information related to drug prices; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If VP-102 or other product candidates that we may identify are approved and we are found to have improperly promoted off-label uses of those products, 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, 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.

Even if we obtain regulatory approval for VP-102 or any future product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approval for VP-102 or 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. 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 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 VP-102 or any future 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 VP-102 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. 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 remain judicial and Congressional 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 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 December 14, 2018, a Texas U.S. District Court Judge ruled that the

ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, 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, including the BBA, will remain in effect through 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 unless additional Congressional action is taken. 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, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. Further, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. The likelihood of implementation of these, or any of the other Trump administration reform initiatives is uncertain, particularly in light of the new Biden administration. 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. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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 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 VP-102 or other 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. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. 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. 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.

Risks Related to Employee Matters and Managing Our Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

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, A. Brian Davis, 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 potentially implement 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, 2020, we had 29 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 product development, 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.

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.

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:

- the commencement, enrollment or results of our clinical trials of VP-102 for the treatment of common warts and external genital warts and any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for VP-102 for the treatment of molluscum and common warts or any other product candidate we may develop, including VP-103 and LTX-315, 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 VP-102 or any other product candidate;
- 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 6,009,951 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors are elected each year;
- stockholders are not entitled to remove directors other than by a 66 ⅔% 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 "emerging growth company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two 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 a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

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 the earlier of (1) the last day of the fiscal year (a) ending December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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 further implement and maintain proper and effective internal controls to remediate our material weakness, 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.

Commencing with our fiscal year ended December 31, 2019, we began to 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.

In connection with our evaluation of the effectiveness of our disclosure controls and procedures for the year ended December 31, 2019, we have identified a material weakness in our information technology, or IT, general controls, or collectively ITGCs, and related IT-dependent process level controls, which are part of our internal control over financial reporting. Process-level controls that were dependent upon information derived from one of our system was also determined to be ineffective. These deficiencies were the result of an inadequate IT risk assessment process which did not identify the risks associated with ineffective segregation of duties within the IT system. During 2020, we implemented a number of measures to address the material weakness and deficiencies that have been identified and the material weakness has been remediated as of December 31, 2020. See “Item 9A—Management’s Report on Internal Control Over Financial Reporting and –Remediation of Material Weakness.”

We may identify additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. 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, 2020, we had federal and state net operating loss carryforwards of approximately $82.7 million and $84.1 million, respectively. The federal net operating loss carryforwards included in the foregoing totals that were generated 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, the federal net operating losses incurred in 2018 and future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the federal tax law changes. 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 incur increased costs and demands upon management as a result of being a public company.

As a newly public company listed in the United States, we 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 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

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our product candidates could be delayed.

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 and may result in tax obligations in excess of amounts accrued in our financial statements.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We operate in a 4,962 square foot facility in West Chester, Pennsylvania pursuant to a sublease agreement that expires in May 2021.

On July 1, 2019, we entered into a lease for 5,829 square feet of office space located in West Chester, Pennsylvania that is expected to serve as our new headquarters beginning in 2021. The initial term of the lease is seven years with one five-year renewal option and an ongoing right of first offer to lease up to approximately 5,000 square feet of additional space on the same floor of the building. On March 12, 2020 the Company entered into an amendment to that lease agreement. The amendment expands the original premises to include 5,372 square feet of additional office space increasing the total rentable premise to 11,201 square feet of space. The commencement date for the lease was September 1, 2020.

We believe that our existing facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

On July 14, 2020, plaintiff Isaiah Potter, or Potter, filed a putative class action complaint captioned Potter v. Verrica Pharmaceuticals Inc., in the U.S. District Court for the Eastern District of Pennsylvania against the Company and certain of its executive officers, or the Defendants. The complaint alleged that Defendants violated federal securities laws by, among other things, failing to disclose certain supposed safety risks attendant to the VP-102 drug-device and likely delays to regulatory approval of VP-102. The complaint sought unspecified compensatory damages on behalf of Potter and all other persons and entities that purchased or otherwise acquired our securities between September 16, 2019 and June 29, 2020. On December 14, 2020, Potter voluntarily sought to dismiss this case and the parties filed a stipulation of dismissal, which the court granted on December 21, 2020. The case was dismissed with prejudice as to Potter and without prejudice as to the unnamed class members.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASE OF EQUITY SECURITIES

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Pursuant to the Loan Agreements, we are also restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Stockholders

Our common stock is listed on the Nasdaq Global Select Market under the symbol "VRCA". As of March 15, 2021, we had 25,441,113 shares of common stock outstanding held by 32 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Use of Proceeds from Initial Public Offering of Common Stock

Not applicable.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Parties

The following table summarizes repurchases of our common stock during December 2020. There were no purchases during October 2020 or November 2020.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of a Publicly Announced Program	Approximate Dollar Value of Shares that May Yet be Purchased Under the Program
12/1/2020 - 12/31/2020	424,429 (1)	$ 0.0001714	—	$ —

(1) These shares of common stock were repurchased from our former Chief Scientific Officer pursuant to a restricted stock purchase agreement, as amended.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes to those statements included later in this Annual Report. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly in Item 1A. "Risk Factors" and "Special Note Regarding Forward-Looking Statements."

Overview

We are a dermatology therapeutics company committed to the development and commercialization of novel treatments that provide meaningful benefit for people living with skin diseases. Our lead product candidate, VP-102, is a proprietary drug-device combination of our topical solution of cantharidin, a widely recognized, naturally sourced agent to treat topical dermatological conditions, administered through our single-use precision applicator. We are initially developing VP-102 for the treatment of molluscum contagiosum, or molluscum, a highly contagious and primarily pediatric viral skin disease, and common warts. There are currently no products approved by the U.S. Food and Drug Administration, or FDA, nor is there an established standard of care for either of these diseases, resulting in significant undertreated populations in two of the largest unmet needs in dermatology. In addition to patent protection we are seeking, VP-102 has the potential to be the first FDA-approved product for molluscum and for its active pharmaceutical ingredient, or API, to be characterized as a new chemical entity, or NCE, with the five years of non-patent regulatory exclusivity associated with that designation. We believe VP-102 has the potential to qualify for pediatric exclusivity, which would provide for an additional six months of non-patent exclusivity.

In January 2019, we reported positive top-line results from our Phase 3 CAMP-1 and CAMP-2 pivotal trials with VP-102 for the treatment of molluscum. Both clinical trials evaluated the safety and efficacy of VP-102 compared to placebo. In each trial, we observed that a clinically and statistically significant proportion of subjects treated with VP-102 achieved complete clearance of all treatable molluscum lesions compared to subjects treated with placebo. VP-102 was well-tolerated in both trials, with no serious adverse events reported in VP-102 treated subjects. CAMP-1 was conducted under a special protocol assessment, or SPA, agreement with the FDA. Based on the results from these trials, we submitted a new drug application, or NDA, to the FDA for VP-102 for the treatment of molluscum in September 2019. In November 2019, we received notice that the FDA accepted the NDA for filing, with a Prescription Drug User Fee Act, or PDUFA, goal date of July 13, 2020. In July 2020, we received a Complete Response Letter, or CRL, from the FDA for our NDA. The CRL indicated the need for additional information regarding certain aspects of the chemistry, manufacturing and controls, or CMC, processes for the drug/device combination as well as human factors validation. The FDA did not identify any clinical deficiencies. A Type A meeting was held with the FDA in October 2020 to discuss the issues that were identified in the CRL and the resubmission of the NDA for VP-102. We resubmitted our NDA for VP-102 for the treatment of molluscum in December 2020. In February 2021, we received notice that the FDA accepted the resubmitted NDA for filing, with a PDUFA goal date of June 23, 2021.

In June 2019, we announced positive topline results from our COVE-1 Phase 2 open label clinical trial of VP-102 for the treatment of verruca vulgaris, or common warts. Based on feedback from the FDA regarding a potential Phase 3 trial protocol, we are currently evaluating conducting an additional Phase 2 clinical trial of VP-102 for the treatment of common warts.

In addition, we are also developing VP-102 for the treatment of external genital warts. We initiated a Phase 2 clinical trial evaluating the optimal dose regimen, efficacy, safety and tolerability of VP-102 in patients with external genital warts in June 2019. In November 2020, we announced positive topline results from our Phase 2 clinical trial of VP-102 for the treatment of external genital warts. Based on the results of the Phase 2 trial, we requested an end of Phase 2 meeting with the FDA in the first quarter of 2021. In addition, we are conducting necessary drug development activities for VP-103, our second cantharidin-based product candidate, and are evaluating when to initiate a Phase 2 clinical trial for the treatment of plantar warts. We also intend to develop our third product candidate, LTX-315, for the treatment of dermatological oncology indications.

On March 17, 2021, we entered into a collaboration and license agreement, or the Torii Agreement, with Torii Pharmaceutical Co., Ltd., or Torii, 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 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. Pursuant to the Torii Agreement, we are entitled to receive an up-front payment from Torii of $11.5 million. Additionally, we are entitled to receive from Torii an additional $58.0 million in aggregate payments contingent on achievement of specified development, regulatory, and sales milestones, in addition to tiered transfer price payments for supply of product in the percentage range of the mid-30s to the mid-40s of net sales

In August 2020, we entered into an exclusive license agreement with Lytix Biopharma AS, or Lytix, pursuant to which we obtained a worldwide, license for certain technology of Lytix to develop LTX-315 for use in all malignant and pre-malignant dermatological indications, other than metastatic melanoma and metastatic merkel cell carcinoma. We intend to submit an Investigational New Drug Application, or IND, for LTX-315 in the first half of 2021.

Our strategy is to advance VP-102 through regulatory approval and self-commercialize in the United States for the treatment of several skin diseases. We intend to build a specialized sales organization in the United States focused on pediatric dermatologists, dermatologists, and select pediatricians. In the future, we also intend to develop VP-102 for commercialization in additional geographic regions, either alone or together with a strategic partner.

We have been actively monitoring the novel coronavirus, or COVID-19, pandemic and its impact globally. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19. As a direct result of COVID-19, we decided to delay the initiation of our previously planned Phase 3 clinical trials to evaluate VP-102 in subjects with common warts as well as our previously planned Phase 2 clinical trial to evaluate VP-103 in subjects with plantar warts.

Since our inception in 2013, our operations have focused on developing VP-102, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the sale of equity and equity-linked securities and through borrowing under our loan agreement with Silicon Valley Bank.

On June 19, 2018, we completed an IPO of common stock, which resulted in the issuance and sale of 5,750,000 shares of common stock at a public offering price of $15.00 per share, generating net proceeds of $78.4 million after deducting underwriting discounts and other offering costs. On March 10, 2020, we entered into (i) a mezzanine loan and security agreement, or the Mezzanine Loan Agreement, with Silicon Valley Bank, as administrative agent and collateral agent, or the Agent, and Silicon Valley Bank and West River Innovation Lending Fund VIII, L.P., as lenders, or the Mezzanine Lenders, pursuant to which the Mezzanine Lenders have agreed to lend us up to $50.0 million in a series of term loans, and (ii) a loan and security agreement, or the Senior Loan Agreement, and together with the Mezzanine Loan Agreement, the Loan Agreements, with Silicon Valley Bank, as lender, or the Senior Lender, and together with the Mezzanine Lenders, the Lenders, pursuant to which the Senior Lender has agreed to provide us a revolving line of credit of up to $5.0 million. Upon entering into the Loan Agreements, we borrowed $35.0 million in term loans from the Mezzanine Lenders. We entered into amendments to the Loan Agreements in October 2020 under which we borrowed an additional $5.0 million in term loans on March 1, 2021 and we may borrow an additional $10.0 million in term loans subject to (i) FDA approval of our NDA for VP-102 for the treatment of molluscum prior to September 31, 2021, and (ii) compliance with a minimum liquidity covenant.

We believe that our existing cash, cash equivalents and marketable securities as of December 31, 2020, combined with the $11.5 million up-front payment we are entitled to receive pursuant to the Torii Agreement, will be sufficient to support our planned operations at least through the first quarter of 2022.

Since inception, we have incurred significant operating losses. For the years ended December 31, 2020 and 2019, our net loss was $42.7 million and $28.2 million, respectively. As of December 31, 2020, we had an accumulated deficit of $103.9 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue our ongoing clinical programs evaluating VP-102 for the treatment of common warts as well as initiate and complete additional clinical trials, as needed;
- initiate clinical trials evaluating VP-102 for the treatment of external genital warts;
- initiate clinical trials evaluating VP-103 for the treatment of plantar warts, and LTX-315 for the treatment of dermatological oncology indications;
- pursue regulatory approvals for VP-102 for the treatment of molluscum, and eventually for the treatment of common warts, external genital warts or any other indications we may pursue for VP-102, as well as for VP-103 or LTX-315;
- seek to discover and develop additional product candidates;
- ultimately establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including VP-102, VP-103 and LTX-315;
- 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.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A summary of our significant accounting policies appears in the notes to our audited financial statements for the year ended December 31, 2020 included in this Annual Report on Form 10-K. However, we believe that the following accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

Research and Development Costs

Our research and development expenses consist primarily of costs associated with our clinical trials, salaries, employee benefits, and equity-based compensation charges for those individuals involved in ongoing research and development efforts. Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Stock-Based Compensation

We recognize the grant-date fair value of share-based awards issued as compensation as expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Prior to our IPO, the fair value of restricted stock awards was based on a determination by the board of directors of the estimated fair value of the common stock at the date of grant. The fair value of stock options is estimated at the time of grant using the Black-Scholes option pricing model, which requires the use of inputs and assumptions, the most critical of which prior to our IPO was the estimated fair value of our common stock.

Recent Accounting Pronouncements

See Note 2 to our financial statements for a discussion of recent accounting pronouncements and their effect on us.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Subject to certain conditions, as an emerging growth company, we may rely on certain exemptions, including exemptions from (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (1) (a) December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the completion of our initial public offering, (b) the last day of the fiscal year in which we have total annual gross revenues of at least $1.07 billion or (c) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" under the rules of the U.S. Securities and Exchange Commission, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Components of Operating Results

Revenue

We have not generated any revenue since inception.

Operating Expenses

Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing and supply scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial supply and commercial supply, including manufacturing validation batches;
- outsourced professional scientific development services;

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses relating to regulatory activities; and
- laboratory materials and supplies used to support our research activities.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase over the next several years as we increase personnel costs, including stock-based compensation, initiate and conduct clinical trials of VP-102 in patients with common warts, VP-102 in patients with external genital warts, VP-103 in patients with plantar warts, LTX-315 for dermatological oncology indications, and conduct other clinical trials and prepare regulatory filings for our product candidates.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the manufacturing process for our product candidates, the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and administrative functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include market research costs, insurance costs, and professional fees for audit, tax and legal services.

We anticipate that our general and administrative expenses, including payroll and related expenses, will increase in the future as we continue to increase our headcount to support the expected growth in our business, expand our operations and organizational capabilities, and prepare for potential commercialization of VP-102 for the treatment of molluscum, if successfully developed and approved. We also anticipate increased expenses associated with general operations, including costs related to audit, tax and legal services, director and officer insurance premiums, and investor relations costs

Income Taxes

Since our inception in 2013, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year due to our uncertainty of realizing a benefit from those items. As of December 31, 2020, we had federal and state net operating loss carryforwards of approximately $82.7 million and $84.1 million, respectively. The federal net operating loss carryforwards included in the foregoing totals that were generated prior to 2018 (federal of approximately $6.9 million) will begin to expire, if not utilized, by 2033. Utilization of the net operating loss carryforwards may be subject to an annual limitation according to Section 382 of the Internal Revenue Code of 1986, as amended, and similar provisions.

Results of Operations for the Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	For the Year Ended December 31,		
	2020	2019	Change
Operating expenses:			
Research and development	$ 15,673	$ 15,436	$ 237
General and administrative	24,508	14,644	9,864
Total operating expenses	40,181	30,080	10,101
Loss from operations	(40,181)	(30,080)	(10,101)
Other income (expense):			
Interest income	521	1,877	(1,356)
Interest expense	(3,033)	—	(3,033)
Other expense	(1)	(4)	3
Total other (expense) income	(2,513)	1,873	(4,386)
Net loss	$ (42,694)	$ (28,207)	$ (14,487)

Research and Development Expenses

Research and development expenses were $15.7 million for the year ended December 31, 2020, compared to $15.4 million for the year ended December 31, 2019. The increase of $0.2 million was primarily attributable to increased Chemistry, Manufacturing and Controls, or CMC, costs related to our development of VP-102 for molluscum and increased compensation costs, partially offset by decreased clinical costs related to our development of VP-102 for molluscum.

General and Administrative Expenses

General and administrative expenses were $24.5 million for the year ended December 31, 2020, compared to $14.6 million for the year ended December 31, 2019. The increase of $9.9 million was primarily a result of higher stock-based compensation costs, which includes $4.8 million of stock-based compensation expense recorded in December 2020 related to the modification of a stock award to a former executive. The increase was also driven by expenses related to increased headcount, an increase in insurance, professional fees, and other operating costs, and an increase in expenses related to pre-commercial activities for VP-102.

Interest Income

Interest income for the years ended December 31, 2020 and 2019 consisted of interest earned on our cash, cash equivalents and marketable securities. The decrease of $1.4 million was primarily a result of lower interest income due to lower interest rates.

Interest Expense

Interest expense for the year ended December 31, 2020 consisted of interest expense on the Mezzanine Loan Agreement as noted in Note 11 to our financial statements.

Results of Operations for Years Ended December 31, 2019 and 2018

For a discussion and analysis of changes in financial condition and results of operations for the year ended December 31, 2019 as compared to the year ended December 31, 2018, refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 13, 2020.

Liquidity and Capital Resources

Overview

Since our inception, we have not generated any revenue and have incurred net losses and negative cash flows from our operations. We have financed our operations since inception through sales of our convertible preferred stock and the sale of our common stock in our IPO, receiving aggregate gross proceeds of $123.2 million and most recently, $40.0 million of gross proceeds from the Mezzanine Loan Agreement noted below.

As of December 31, 2020, we had cash, cash equivalents and marketable securities of $65.5 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

Indebtedness

On March 10, 2020, or the Effective Date, we entered into (i) the Mezzanine Loan Agreement with the Agent, and the Mezzanine Lenders, pursuant to which the Mezzanine Lenders have agreed to lend us up to $50.0 million in a series of term loans, and (ii) the Senior Loan Agreement with the Senior Lender, pursuant to which the Senior Lender has agreed to provide us with a revolving line of credit of up to $5.0 million. Upon entering into the Loan Agreements, we borrowed $35.0 million in term loans from the Mezzanine Lenders, or the Term A Loan.

On October 26, 2020, we entered into (i) the first amendment to the Mezzanine Loan Agreement, or the Mezzanine Loan Amendment and (ii) the first amendment to the Senior Loan Agreement, or the Senior Loan Amendment with the Lenders, under which we borrowed an additional $5.0 million in term loans on March 1, 2021.

Under the terms of the Mezzanine Loan Agreement, as amended, we may, at our sole discretion, borrow from the Mezzanine Lenders up to an additional $10.0 million in term loans, or the Term B2 Loan. The Term B2 Loan will be available for draw if we receive approval from the FDA of the NDA for VP-102 prior to September 30, 2021 and maintain compliance with the minimum liquidity covenant until the earlier of September 30, 2021 or the occurrence of an event of default.

Under the terms of the Senior Loan Agreement, as amended, we may, at our sole discretion, borrow from the Senior Lender one or more advances on the revolving credit line, or the Revolving Loans, and together with the Term Loans, the Loans) in an aggregate amount not to exceed the lesser of (i) 85% of the aggregate amount then-contained in our eligible accounts receivable and (ii) $5.0 million.

Our obligations under the Senior Loan Agreement and the Mezzanine Loan Agreement, as amended, are secured by, respectively, a first priority perfected security interest and second priority perfected security interest in substantially all of our current and future assets, other than our intellectual property (except rights to payment from the sale, licensing or disposition of such intellectual property). We have also agreed not to encumber our intellectual property assets, except as permitted by the Loan Agreements.

All of the Loans mature on March 1, 2024, or the Maturity Date. The Term Loans will be interest-only through March 31, 2022, followed by 24 equal monthly payments of principal and interest; provided that if we draw the Term B Loan, the Term Loans will be interest-only through September 30, 2022, followed by 18 equal monthly

payments of principal and interest. The Term Loans will bear interest at a floating per annum rate equal to the greater of (i) 7.25% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 2.50%. The Revolving Loans will bear interest at a floating per annum rate equal to the greater of (i) 6.00% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 1.25%.

Under the terms of the Mezzanine Loan Agreement, as amended, we will be required to make a final payment fee of $3,750,000 payable on the earlier of (i) the Maturity Date, (ii) the acceleration of any Term Loans, or (iii) the prepayment of the Term Loans, or the Final Payment. We are recording the final payment fee using the effective interest rate method over the term of the Term Loan with an increase in debt. We may prepay all, or any portion of the Term Loans upon 5 business days advance written notice to the Agent, provided that we will be obligated to pay a prepayment fee equal to (i) $1.5 million if prepaid on or before October 26, 2021, (ii) $1.0 million if prepaid between October 27, 2021 and October 26, 2022, and (iii) $0.5 million if prepaid between October 27, 2022 and October 26, 2023 and (iv) no prepayment fee if prepaid after October 26, 2023, each, a Prepayment Fee.

We may terminate the revolving credit line under the Senior Loan Agreement at any time upon three business days advance written notice to the Senior Lender. If we terminate the revolving credit line prior to the Maturity Date, we must pay to the Senior Lender an early termination fee of $50,000, or the Termination Fee.

Under the Loan Agreements, as amended, we are subject to a number of affirmative and restrictive covenants, including covenants regarding maintaining a specified minimum liquidity ratio, delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, protection of intellectual property rights, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness or liens, investments and transactions with affiliates, and, beginning as of March 31, 2022, achieving minimum levels of trailing six-month net product revenues, among other customary covenants. As of December 31, 2020 we were in compliance with all covenants.

Upon the occurrence of certain events, including but not limited to our failure to satisfy our payment obligations under the Loan Agreements, the breach of certain of our other covenants under the Loan Agreements, or the occurrence of a material adverse change, cross defaults to other indebtedness or material agreements, judgment defaults and defaults related to failure to maintain governmental approvals failure of which to maintain could result in a material adverse effect, the Agent and the Lenders will have the right, among other remedies, to declare all principal and interest immediately due and payable, to exercise secured party remedies, to receive the Final Payment and Termination Fee and, if the payment of principal and interest is due prior to the Maturity Date, to receive the applicable Prepayment Fee. The Loan Agreements also include subjective acceleration clauses that permit the Lenders to accelerate the maturity date under certain circumstances, including a material adverse change in our business, operations, or financial condition or a material impairment of the prospect of repayment of our obligations to the Mezzanine Lenders. Pursuant to the Loan Agreement Amendments, we are subject to a minimum liquidity covenant defined as the balance of the of our unrestricted cash, cash equivalents, and marketable securities in accounts maintained at Silicon Valley Bank being greater than one and one half times our aggregate outstanding obligations to the Mezzanine Lenders.

We believe that without additional financing, it is probable that we will not be in compliance with the minimum liquidity ratio covenant at some point in the next twelve months. In accordance with FASB ASC 470, since the Mezzanine Loan Agreement contains subjective acceleration clauses and assessment that it is probable that the minimum liquidity ratio covenant will not be met, we have classified all outstanding principal and final payment fees as a current liability in the accompanying balance sheet as of December 31, 2020. Even if we are not in compliance with the minimum liquidity covenant and the debt becomes due, we believe that we currently have sufficient funds to meet our operating requirements for at least the next twelve months from the issuance of these financial statements.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2020 and 2019 (in thousands):

	For the Year Ended December 31,	
	2020	2019
Net cash used in operating activities	$ (30,207)	$ (27,408)
Net cash (used in) provided by investing activities	(3,580)	25,955
Net cash provided by financing activities	35,232	423
Net increase (decrease) in cash and cash equivalents	$ 1,445	$ (1,030)

Operating Activities

During the year ended December 31, 2020, operating activities used $30.2 million of cash, primarily resulting from a net loss of $42.7 million and noncash stock-based compensation of $9.8 million. Net cash provided by changes in operating assets and liabilities of $1.6 million consisted primarily of an increase accrued expenses of $1.4 million. The increase in accrued expenses was primarily due to accruals for clinical development and product development activities.

During the year ended December 31, 2019, operating activities used $27.4 million of cash, primarily resulting from a net loss of $28.2 million and noncash stock-based compensation of $3.3 million. Net cash used by changes in operating assets and liabilities of $1.7 million consisted primarily of an increase in prepaid expenses and other assets of $1.6 million. The increase in prepaid expenses and other assets was primarily due to prepayments for clinical development and product development activities and annual insurance policy payments.

Investing Activities

During the year ended December 31, 2020, net cash used in investing activities was related to the purchase of marketable securities of $71.7 million and purchases of property, plant and equipment of $1.5 million, partially offset by the sales and maturities of marketable securities of $69.8 million. During the year ended December 31, 2019, net cash provided by investing activities was related to sales and maturities of marketable securities of $117.7 million partially offset by the purchase of marketable securities of $89.9 million and an increase in long-term deposits of $1.2 million. In addition, $0.7 million was used for the purchase and construction of property and equipment during the year ended December 31, 2019.

Financing Activities

During the ended December 31, 2020, net cash provided by financing activities was $35.2 million, which was primarily related to the proceeds from issuance of debt net of issuance costs of $34.5 million.

During the ended December 31, 2019, net cash provided by financing activities was $0.4 million related to the proceeds from exercise of stock options.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we may need to obtain additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We believe that our existing cash, cash equivalents, and marketable securities as of December 31, 2020, combined with the $11.5 million up-front payment we are entitled to receive pursuant to the Torii Agreement, will be sufficient to support our planned operations at least through the first quarter of 2022. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review of our product candidates;
- the scope, progress, results and costs of our clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to maintain compliance with covenants under our loan agreements;
- the extent to which we acquire or in-license other product candidates and technologies;
- the impact on the timing of our clinical trials and our business due to the COVID-19 pandemic;
- the costs to scale up and secure manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of a product candidate that we do not expect to be commercially available in the near term, if at all. We may need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests of existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to 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.

Contractual Obligations and Commitments

The following table sets forth a summary of our contractual obligations as of December 31, 2020 (in thousands):

	Payments Due by Period				
	Less than 1 Year	1 to 3 Years	3-5 Years	More than 5 Years	Total
Principal payments on debt (1)	$ —	$ 30,625	$ 4,375	$ —	$ 35,000
Interest and lender fees on debt (2)	2,493	4,986	4,185	—	11,664
Operating leases (3)	312	692	715	612	2,331
	$ 2,805	$ 36,303	$ 9,275	$ 612	$ 48,995

(1) Principal payments assume the company maintains compliance with its minimum liquidity covenant to avoid an acceleration of payments.

(2) Interest payable reflects the rate in effect as of December 31, 2020. The interest rate on borrowings under the senior loan agreement is variable and resets monthly. Lender Fees reflect final payment fees due.

(3) Reflects obligations primarily related to our office lease in West Chester, Pennsylvania.

In addition, on August 7, 2020, we entered into an exclusive license agreement, or the Lytix Agreement, with Lytix, pursuant to which we obtained a worldwide, exclusive, royalty-bearing license, with the right to sublicense, for certain technology of Lytix to research, develop, manufacture, have manufactured, use, sell, have sold, offer for sale, import and otherwise commercialize LTX-315 for use in all malignant and pre-malignant dermatological indications, other than metastatic melanoma and metastatic merkel cell carcinoma. Our right to manufacture the active pharmaceutical ingredient is limited to certain instances, and Lytix is obligated to manufacture and supply our clinical and commercial needs for such active pharmaceutical ingredient. We are obligated to use commercially reasonable efforts to develop and to commercialize the product, which development and commercialization will be overseen by a joint steering committee. Lytix has agreed not to pursue any products in the field of dermatology other than LTX-315 for use in metastatic melanoma and metastatic merkel cell carcinoma. Lytix has granted us an exclusive option to negotiate for an exclusive license for use of LTX-315 in additional dermatological indications.

In connection with entering the Lytix Agreement, we made an initial payment of $250,000 and an additional payment of $2.3 million upon the achievement by Lytix of a regulatory milestone. Additionally, we are obligated to pay up to $111.0 million contingent on achievement of specified development, regulatory, and sales milestones, and tiered royalties based on worldwide annual net sales ranging in the low double digits to the mid-teens, subject to certain customary reductions. Our obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of the expiration or abandonment of the last to expire licensed patent covering LTX-315 anywhere in the world and expiration of regulatory exclusivity for LTX-315 in such country. Additionally, all upfront fees and milestone-based payments received by us from a sublicensee will be treated as net sales and will be subject to the royalty payment obligations under the Lytix Agreement, and all royalties received by us from a sublicensee shall be shared with Lytix at a rate that is initially 50% but decreases based on the stage of development of LTX-315 at the time such sublicense is granted.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents and marketable securities, are in the form of U.S. Treasury securities, asset-backed securities, and commercial paper. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. However, due to the short-term nature and low-risk profile of our investment portfolio, we do not expect that an immediate 100 basis point change in market interest rates would have a material effect on the fair market value of our investment portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. In addition, our outstanding debt instruments entered into on March 10, 2020 carry a floating interest rate that is equal to the greater of (i) 7.25% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 2.50%.

We are also exposed to market risk related to changes in foreign currency exchange rates. We contract with vendors that are located outside of the United States, including in China, and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of December 31, 2020, we had minimal or no liabilities denominated in foreign currencies.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended December 31, 2020.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
Verrica Pharmaceuticals Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Verrica Pharmaceuticals Inc. (the Company) as of December 31, 2020 and 2019, the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2017.

Philadelphia, Pennsylvania
March 17, 2021

VERRICA PHARMACEUTICALS INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,686	$ 9,241
Marketable securities	54,784	52,776
Prepaid expenses and other assets	2,180	2,966
Total current assets	67,650	64,983
Property and equipment, net	3,102	2,090
Operating lease right-of-use asset	1,836	111
Other non-current assets	1,566	1,240
Total assets	**$ 74,154**	**$ 68,424**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 348	$ 1,185
Accrued expenses and other current liabilities	3,114	2,036
Operating lease liability	198	130
Deferred revenue	500	—
Current debt, net	35,315	—
Total current liabilities	39,475	3,351
Operating lease liability	1,693	58
Total liabilities	**41,168**	**3,409**
Commitments and Contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value; 200,000,000 authorized as of December 31, 2020 and 2019; 25,546,257 shares issued and 25,441,113 shares outstanding as of December 31, 2020 and 25,912,137 shares issued and 25,786,330 shares outstanding as of December 31, 2019	3	3
Treasury stock, at cost, 105,144 shares as of December 31, 2020 and 2019	—	—
Additional paid-in capital	136,868	126,594
Subscription receivable	—	(410)
Accumulated deficit	(103,886)	(61,192)
Accumulated other comprehensive gain	1	20
Total stockholders' equity	32,986	65,015
Total liabilities and stockholders' equity	**$ 74,154**	**$ 68,424**

The accompanying notes are an integral part of these financial statements.

VERRICA PHARMACEUTICALS INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	For the Year Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 15,673	$ 15,436
General and administrative	24,508	14,644
Total operating expenses	40,181	30,080
Loss from operations	(40,181)	(30,080)
Other income (expense):		
Interest income	521	1,877
Interest expense	(3,033)	—
Other expense	(1)	(4)
Total other (expense)/income	(2,513)	1,873
Net loss	**$ (42,694)**	**$ (28,207)**
Net loss per share, basic and diluted	$ (1.71)	$ (1.13)
Weighted-average common shares outstanding, basic and diluted	24,995,556	24,897,889
Net loss	$ (42,694)	$ (28,207)
Other comprehensive loss:		
Unrealized (loss)/gain on marketable securities	(19)	37
Comprehensive loss	**$ (42,713)**	**$ (28,170)**

The accompanying notes are an integral part of these financial statements.

VERRICA PHARMACEUTICALS INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Stock		Additional PaidIn Capital	Subscription Receivable	Accumulated Deficit	Treasury Stock		Accumulated Other Comprehensive (Loss) Gain	Total Stockholders' Equity
	Shares Issued	Amount				Shares	Cost		
Balance as of December 31, 2018	**25,809,900**	**$ 3**	**$ 122,526**	**$ —**	**$ (33,083)**	**105,144**	**$ —**	**$ (17)**	**$ 89,429**
Stock-based compensation	—	—	3,333	—	—	—	—	—	3,333
Exercise of stock options	74,908	—	423	—	—	—	—	—	423
Subscription receivable (Note 9)	27,329	—	410	(410)	—	—	—	—	—
Adoption of ASU 2018-07 (Note 2)	—	—	(98)	—	98	—	—	—	—
Net Loss	—	—	—	—	(28,207)	—	—	—	(28,207)
Unrealized gain on marketable securities	—	—	—	—	—	—	—	37	37
Balance as of December 31, 2019	**25,912,137**	**3**	**126,594**	**(410)**	**(61,192)**	**105,144**	**—**	**20**	**65,015**
Stock-based compensation	—	—	9,821	—	—	—	—	—	**9,821**
Repurchased and retired common stock	(424,429)	—	—	—	—	—	—	—	**—**
Exercise of stock options	58,549	—	453		—	—	—	—	**453**
Repayment of subscription receivable (Note 9)	—	—	—	410	—	—	—	—	**410**
Net loss	—	—	—	—	(42,694)	—	—	—	**(42,694)**
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(19)	**(19)**
Balance as of December 31, 2020	**25,546,257**	**$ 3**	**$ 136,868**	**$ —**	**$ (103,886)**	**105,144**	**$ —**	**$ 1**	**$ 32,986**

The accompanying notes are an integral part of these financial statements.

VERRICA PHARMACEUTICALS INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	For the Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (42,694)	$ (28,207)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,821	3,333
Accretion of discounts on marketable securities	(138)	(1,063)
Depreciation expense	43	64
Noncash interest expense on debt	940	—
Amortization on operating lease right-of-use asset	186	193
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	786	(1,621)
Accounts payable	(838)	263
Accrued expenses	1,394	(213)
Accounts payable and accrued expenses - related party	—	(38)
Deferred revenue	500	—
Operating lease liability	(207)	(119)
Net cash used in operating activities	(30,207)	(27,408)
Cash flows from investing activities		
Purchases of marketable securities	(71,738)	(89,854)
Sales and maturities of marketable securities	69,849	117,715
Purchases of property, plant and equipment	(1,470)	(682)
Increase in deposits	(221)	(1,224)
Net cash (used in) provided by investing activities	(3,580)	25,955
Cash flows from financing activities		
Proceeds from exercise of stock options	453	423
Proceeds from issuance of debt, net	34,460	—
Debt issuance cost	(91)	—
Repayment of subscription receivable	410	—
Net cash provided by financing activities	35,232	423
Net increase (decrease) in cash and cash equivalents	1,445	(1,030)
Cash and cash equivalents at the beginning of the year	9,241	10,271
Cash and cash equivalents at the end of the year	**$ 10,686**	**$ 9,241**
Supplemental disclosure of noncash investing and financing activities:		
Property and equipment purchases payable or accrued at period end	$ 318	$ 733
Subscription receivable on exercise of options	$ —	$ 410
Right-of-use asset obtained in exchange for lease obligation	$ 1,910	$ —
Change in unrealized gain/(loss) on marketable securities	$ (19)	$ 37
Cash paid for interest	$ 1,875	$ —
Debt issuance costs included in accrued expenses at year end	$ 100	$ —

The accompanying notes are an integral part of these financial statements.

Note 1—Organization and Description of Business Operations

Verrica Pharmaceuticals Inc. (the "Company") was formed on July 3, 2013 and is incorporated in the State of Delaware. The Company is a dermatology therapeutics company committed to the development and commercialization of novel treatments that provide meaningful benefit for people living with skin diseases.

Liquidity and Capital Resources

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2020, the Company had an accumulated deficit of $103.9 million. In March 2020, the Company entered into a Mezzanine Loan Agreement (Note 11), pursuant to which the Company borrowed (i) $35.0 million in March 2020 that remains outstanding as of December 31, 2020 and (ii) $5.0 million on March 1, 2021. On March 17, 2021, the Company entered into the Torii Agreement (Note 13), pursuant to which Torii is obligated to make an upfront payment of $11.5 million. As discussed in Note 12, the Mezzanine Loan Agreement was amended on October 26, 2020 and now includes a minimum liquidity covenant. If the Company is not in compliance with the minimum liquidity ratio covenant, the outstanding debt and any related final payment fees, prepayment fees, and accrued interest become due upon demand. The Company believes that, without additional financing, it is probable that it will not be in compliance with the minimum liquidity ratio covenant at some point in the next twelve months. Even if the Company is not in compliance with the minimum liquidity covenant and the debt becomes due, management believes the Company currently has sufficient funds to meet its operational requirements for at least the next twelve months from the issuance of these financial statements.

Note 2—Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The Company's functional currency is the U.S. dollar.

The Company has been actively monitoring the novel coronavirus ("COVID-19") pandemic and its impact globally. Management believes the financial results for the year ended December 31, 2020 were not significantly impacted by COVID-19. In addition, management believes the remote working arrangements, travel restrictions and any other regulations imposed by various governmental jurisdictions have had limited impact on the Company's ability to maintain internal operations during the year. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19. As a direct result of COVID-19, the Company decided to delay the initiation of its previously planned Phase 3 clinical trials to evaluate VP-102 in subjects with common warts as well as its previously planned Phase 2 clinical trial to evaluate VP-103 in subjects with plantar warts.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's financial statements relate to the valuation of common stock and stock options. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from

other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Cash, Cash Equivalents and Marketable Securities

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and money market mutual funds.

The Company classifies its marketable securities as "available-for-sale", pursuant to *ASC 320, Investments—Debt and Equity Securities*, carries them at fair market value and classifies them as current assets on its balance sheets. There were no marketable securities with a maturity of greater than one year as of December 31, 2020. Unrealized gains and losses on marketable debt securities are recorded as a separate component of accumulated other comprehensive gain or loss included in stockholders' equity.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash, cash equivalents and marketable securities are financial instruments that are potentially subject to concentrations of credit risk. The Company's deposits are in accounts at large financial institutions, and amounts may exceed federally insured limits. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the funds are held. The Company has no financial instruments with off-balance sheet risk of loss.

Property and Equipment

Property and equipment is recorded at cost less accumulated depreciation. Depreciation and amortization is calculated using the straight line method over the expected useful life of the asset, after the asset is placed in service. The Company generally uses the following depreciable lives for its major classifications of property and equipment:

Description	Useful Lives
Equipment	5 years
Leasehold Improvements	Lease term
Office Furniture and Fixtures	3 years

Expenditures associated with upgrades and enhancements that improve, add functionality, or otherwise extend the life of property and equipment are capitalized, while expenditures that do not, such as repairs and maintenance, are expensed as incurred.

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset may not be fully recoverable. If the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount, an impairment loss would be recognized if the carrying value of the asset exceeds its fair value. Fair value is generally determined using discounted cash flows. No impairment losses have been recorded during the years ended December 31, 2020 or 2019.

Research and Development Costs

The Company's research and development expenses consist primarily of costs associated with the Company's clinical trials, salaries, payroll taxes, employee benefits, and equity-based compensation charges for those individuals involved in ongoing research and development efforts. Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Fair Value Measurement

ASC 820, *Fair Value Measurements*, provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions, and other events and circumstances from non-owner sources. For the years ended December 31, 2020 and 2019, comprehensive loss includes net loss and unrealized gain (loss) on marketable securities.

Stock-Based Compensation

The Company accounts for stock-based compensation awards in accordance with *ASC 718, Compensation –Stock Compensation*. The Company uses the Black-Scholes option-pricing model to value its stock option awards. For stock-based awards granted to employees, non-employees and to members of the board of directors for their services, the Company estimates the grant date fair value of each option award and recognizes compensation expense on a straight-line basis over the vesting period of the award.

The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates, and, for grants prior to the Company's IPO, the value of the common stock. The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The fair value of restricted stock awards are based on the closing price of the Company's common stock on the grant date.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes*, which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Net Loss Per Share

Net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share excludes the potential impact of common stock options and unvested shares of restricted stock because their effect would be anti-dilutive due to the Company's net loss. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per common share are the same.

The table below provides potential shares outstanding that were not included in the computation of diluted net loss per common share, as the inclusion of these securities would have been anti-dilutive:

	As of December 31,	
	2020	2019
Shares issuable upon exercise of stock options	2,901,908	1,914,545
Non-vested shares under restricted stock grants	475,000	1,148,859

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework–Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The adoption of this guidance as of January 1, 2020 did not have an impact on the financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles–Goodwill and Other–Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The guidance also requires the entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonably certain renewals. The guidance becomes effective for the Company in the year ending December 31, 2020. The adoption of this guidance as of January 1, 2020 did not have an impact on the financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The

changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. The Company adopted this ASU as of January 1, 2019 and recorded an adjustment to accumulated deficit and additional paid-in capital of $98,000.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous GAAP. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method to apply the new guidance as of January 1, 2019, rather than as of the earliest period presented, and elected the package of practical expedients described above. Based on the analysis, on January 1, 2019, the Company recorded an operating lease right-of-use asset of $304,000 and an operating lease liability of $306,000 and eliminated deferred rent of $2,000. See Note 10 for additional information.

Note 3—Investments in Marketable **Securities**

Investments in marketable securities consisted of the following as of December 31, 2020 and 2019 (in thousands):

	As of December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 11,607	$ 2	$ —	$ 11,609
Commercial paper	41,674	—	(1)	41,673
Asset-backed securities	1,502	—	—	1,502
Total marketable securities	$ 54,783	$ 2	$ (1)	$ 54,784

	As of December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 7,397	$ 3	$ —	$ 7,400
Commercial paper	31,913	7	(1)	31,919
Asset-backed securities	13,446	11	—	13,457
Total marketable securities	$ 52,756	$ 21	$ (1)	$ 52,776

Unrealized gains and losses on marketable debt securities are recorded as a separate component of accumulated other comprehensive gain (loss) included in stockholders' equity. Realized gains (losses) are included in interest income (expense) in the statement of operations and comprehensive loss on a specific identification basis. The Company recorded nominal realized gains and losses during the years ended December 31, 2020 and 2019. The Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value during the years ended December 31, 2020 or 2019.

Accretion of bond discount on marketable securities and interest income on marketable securities is recorded as interest income on the statement of operations and comprehensive loss.

There were no marketable securities with a maturity of greater than one year for either period presented.

The following tables presents fair value by level in accordance with ASC 820 (see Note 2) of the Company's marketable securities (in thousands):

	Fair Value Measurement as of December 31, 2020			
	Level 1	Level 2	Level 3	Total
U.S. treasury securities	$ 11,609	$ —	$ —	$ 11,609
Commercial paper	—	41,673	—	41,673
Asset-backed securities	—	1,502	—	1,502
Total	$ 11,609	$ 43,175	$ —	$ 54,784

	Fair Value Measurement as of December 31, 2019			
	Level 1	Level 2	Level 3	Total
U.S. treasury securities	$ 7,400	$ —	$ —	$ 7,400
Commercial paper	—	31,919	—	31,919
Asset-backed securities	—	13,457	—	13,457
Total	$ 7,400	$ 45,376	$ —	$ 52,776

Note 4—Property and Equipment

Property and equipment, net consisted of (in thousands):

	As of December 31,	
	2020	2019
Office furniture and fixtures	$ 117	$ 48
Machinery and equipment	102	—
Leasehold improvements	101	68
Office equipment	52	31
Construction in process	2,857	2,027
	3,229	2,174
Accumulated depreciation	(127)	(84)
Total property and equipment, net	$ 3,102	$ 2,090

Depreciation expense for the years ended December 31, 2020 and 2019 was $43,000 and $64,200, respectively.

The Company has recorded an asset classified as construction in process associated with the construction of a product packaging line that would be placed into service for commercial manufacturing upon future regulatory product approval.

Note 5—Related Party Transactions

Prior to the completion of the initial public offering ("IPO") of the Company's common stock in June 2018, the Company was controlled by PBM VP Holdings, LLC ("PBM VP Holdings") an affiliate of PBM Capital Group, LLC ("PBM"). Paul B. Manning, who is the Chairman and Chief Executive Officer of PBM and the current chairman of the Company's Board of Directors, and certain entities affiliated with Mr. Manning, continue to be the Company's largest shareholder on a collective basis.

On December 2, 2015, the Company entered into a Services Agreement (the "SA") with PBM. Pursuant to the terms of the SA, which had an initial term of twelve months (and was automatically renewable for successive monthly periods), PBM rendered advisory and consulting services to the Company. Services provided under the SA included certain business development, operations, technical, contract, accounting and back office support services. In consideration for these services, the Company was obligated to pay PBM a monthly management fee. On January 1, 2019, the Company amended the SA with PBM, decreasing the monthly fee to $26,333. On October 1, 2019, the SA was amended to reduce the monthly management fee to $5,000 as a result of a reduction in services provided by PBM.

For the years ended December 31, 2020 and 2019, the Company incurred expenses under the SA of $60,000 and $252,500, respectively, which were primarily included in general and administrative expenses.

As of December 31, 2020 and 2019, the Company had no payables due to PBM and its affiliates.

Note 6—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2020	2019
Compensation and related costs	$ 1,338	$ 1,195
Clinical trials and drug development	611	733
Professional fees	447	89
Construction in process	277	—
Interest expense	219	—
Other accrued expenses and other current liabilities	222	19
Total accrued expenses and other current liabilities	$ 3,114	$ 2,036

Note 7—Commitments and Contingencies

Litigation

On July 14, 2020, plaintiff Isaiah Potter ("Potter") filed a putative class action complaint captioned Potter v. Verrica Pharmaceuticals Inc., in the U.S. District Court for the Eastern District of Pennsylvania against the Company and certain of its executive officers, or the Defendants. The complaint alleged that Defendants violated federal securities laws by, among other things, failing to disclose certain supposed safety risks attendant to the VP-102 drug-device and likely delays to regulatory approval of VP-102. The complaint sought unspecified compensatory damages on behalf of Potter and all other persons and entities that purchased or otherwise acquired our securities between September 16, 2019 and June 29, 2020. On December 14, 2020, Potter voluntarily sought to dismiss this case and the parties filed a stipulation of dismissal, which the court granted on December 21, 2020. The case was dismissed with prejudice as to Potter and without prejudice as to the unnamed class members.

Supply Agreement and Purchase Order

On July 16, 2018, the Company entered into a supply agreement with a supplier of crude cantharidin material. All executed purchase orders for crude cantharidin in the ordinary course of business are expected to be covered under the terms of the supply agreement. Pursuant to the supply agreement, the supplier has agreed that it will not supply cantharidin, any beetles or other raw material from which cantharidin is derived to any other customer in North America, subject to specified minimum annual purchase orders and forecasts by the Company. The supply agreement has an initial five-year term, which is subject to automatic renewal absent termination by either party in accordance with the terms of the supply agreement. Each party also has the right to terminate the supply agreement for other customary reasons such as material breach or bankruptcy.

During 2019, the Company executed a single purchase order pursuant to which the Company agreed to purchase $1.8 million of crude cantharidin material. As of December 31, 2019, the Company had made a prepayment of $1.1 million against this purchase order. The Company received the shipments of material in 2020, and as of December 31, 2020, this purchase order was fulfilled, and the Company has no remaining obligation.

Agreements with Former Chief Scientific Officer

On May 31, 2018, the Company and the former Chief Scientific Officer ("CSO") executed a transition agreement related to his resignation from employment as well as a Consulting Agreement (the "Consulting Agreement") that began upon the closing of the IPO and terminated in 2020.

The Consulting Agreement provided for cash payments to the former CSO of $29,375 per month for the first 12 months of the agreement. After the first 12 months, the former CSO received $300 per hour for each hour of consulting services provided. As of December 31, 2020 and 2019, the Company has no remaining obligation under this Consulting Agreement.

Note 8—Stockholders' Equity

Common Stock

The Company had authorized 200,000,000 shares of common stock, $0.0001 par value per share, as of each of December 31, 2020 and 2019. Each share of common stock is entitled to one vote. Common stock owners are entitled to dividends when funds are legally available and declared by the Board.

Note 9—Stock-Based Compensation

In June 2018, the Board adopted and approved the 2018 Equity Incentive Plan (the "2018 Plan"), which amended and restated the Company's prior 2013 Equity Incentive Plan (the "2013 Plan") and became effective in connection with the IPO. Prior to the effectiveness of the 2018 Plan, the 2013 Plan provided for the grant of share-based awards to employees, directors and consultants of the Company. As a result of the effectiveness of the 2018 Plan, no further grants may be made under the 2013 Plan.

The 2018 Plan provides for the grant of incentive stock options to employees, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of stock awards to employees, including officers, consultants and directors. The 2018 Plan also provides for the grant of performance-based cash awards to employees, including officers, consultants and directors. The Company initially reserved 3,738,199 shares of common stock for issuance under the 2018 Plan, which is the sum of (1) 2,198,198 new shares, plus (2) the number of shares reserved for issuance under the 2013 Plan at the time the 2018 Plan became effective, plus (3) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to the 2013 Plan (such as upon the expiration or termination of a stock award prior to exercise). The number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 each year, for a period of ten years, from January 1, 2019 through January 1, 2028, by 4% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Board. As of December 31, 2020, 1,992,231 shares were available for grant under the 2018 Plan.

Stock Options

The Company's employee and non-employee stock options generally vest as follows: 25% after 12 months of continuous services and the remaining 75% on a ratable basis over a 36-month period from 12 months after the grant date. Stock options granted during the year ended December 31, 2020 have a maximum contractual term of 10 years. The stock options are subject to time vesting requirements through 2024, are nontransferable, and have term expiration dates set to expire through 2030.

The grant date fair value of employee and non-employee stock option awards is determined using the Black-Scholes option-pricing model. The following assumptions were used during the years ended December 31, 2020 and 2019 to estimate the fair value of employee and non-employee stock option awards:

	For the Year Ended December 31,	
	2020	2019
Exercise price	$6.56 - $15.91	$7.95 - $14.65
Risk-free rate of interest	0.27% - 1.67%	1.42% - 2.56%
Expected term (years)	6.0	5.98
Expected stock price volatility	76.71% - 85.97%	72.1% - 78.3%
Dividend yield	—	—
Weighted average grant date fair value	$7.00	$7.84

The following table summarizes the Company's employee and non-employee stock option activity under the 2013 Plan and 2018 Plan for the years ended December 31, 2020 and 2019:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate intrinsic value
Outstanding as of December 31, 2018	1,529,883	$ 8.03		
Options granted	830,918	11.57		
Exercised	(102,237)	8.15		
Forfeited	(344,019)	10.37		
Outstanding as of December 31, 2019	1,914,545	9.14		
Options granted	1,193,956	10.35		
Exercised	(58,549)	7.73		
Forfeited	(125,377)	10.78		
Expired	(22,667)	12.00		
Outstanding as of December 31, 2020	2,901,908	$ 9.57	8.0	$ 7,702,295
Options vested and exercisable as of December 31, 2020	1,148,578	$ 8.50	6.8	$ 4,123,882

The aggregate intrinsic value in the above table is calculated as the difference between fair value of the Company's common stock price and the exercise price of the stock options. The weighted average grant date fair value per share for the employee and non-employee stock options granted during the years ended December 31, 2020 and 2019 was $7.00 and $7.84, respectively. As of December 31, 2020, the total unrecognized compensation related to unvested employee and non-employee stock option awards granted was $10.7 million, which the Company expects to recognize over a weighted-average period of 2.7 years.

The Company utilizes a designated broker to process exercises of stock options. In late December 2019, there was an exercise of 27,329 vested stock options for which the Company did not receive the net proceeds from the designated broker until early January 2020. The net proceeds have been reflected as a stock subscription receivable as of December 31, 2019 in the balance sheet.

Restricted Stock

Pursuant to the Amended and Restated Stock Purchase Agreement (the "Amended and Restated Agreement") between the Company and the former CSO, 848,859 shares held by the former CSO were subject to repurchase by the Company at $0.0001714 per share in the event the former CSO ceased to be a consultant to the

Company. These shares were to be released from the repurchase option on the earliest to occur of (i) a change in control, (ii) regulatory approval of the Company's new drug application for VP-102 for the treatment of molluscum, (iii) commercial sale of products and (iv) a covered termination, as defined in the Amended and Restated Agreement.

In December 2020, the Company and the former CSO amended the agreement whereby 424,430 shares were no longer subject to repurchase and the remaining 424,429 shares were repurchased and retired by the Company at $0.0001714 per share. The Company accounted for the December 2020 amendment as a modification to a share-based payment arrangement whereby the shares no longer subject to repurchase represent a new grant. The value of the new grant was $4.8 million and was recognized immediately. Prior to the December 2020 modification, no compensation expense had been recognized for these nonvested shares as these shares were performance-based and the triggering event was not determined to be probable.

In November 2019 and August 2020, the Company granted 300,000 and 250,000 restricted stock units to its executive officers. The restricted stock units vest 50% upon receipt of regulatory approval of the Company's new drug application for VP-102 for the treatment of molluscum (the "Approval Date") and 50% shall vest on the one year anniversary of the Approval Date subject to the holders' continuous service through each applicable date. No compensation expenses has been recognized for these nonvested restricted stock units as these shares are performance based and the triggering event was not determined to be probable as of December 31, 2020. As of December 31, 2020, the total unrecognized compensation expense related to the restricted stock was $5.6 million.

The following table summarizes restricted stock awards:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested as of December 31, 2018	848,859	$ 0.33
Granted	300,000	15.71
Non-vested as of December 31, 2019	1,148,859	4.35
Granted	250,000	8.17
Forfeitures	(499,429)	2.64
Vested	(424,430)	11.27
Non-vested as of December 31, 2020	475,000	$ 11.74

Stock-based compensation expense, which includes expense for both employees and non-employees, has been reported in the Company's statements of operations for the years ended December 31, 2020 and 2019 as follows (in thousands):

	For the Year Ended December 31,	
	2020	2019
Research and development	$ 813	$ 609
General and administrative	9,008	2,724
Total stock-based compensation	$ 9,821	$ 3,333

Note 10—Leases

Effective January 1, 2019, the Company accounts for its leases under ASC 842, *Leases (Topic 842)*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease, if available, otherwise at the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. Variable lease expenses, if any, are recorded when incurred.

In calculating the right-of-use asset and lease liability, the Company elected to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the guidance as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term.

The Company leases office space in West Chester, Pennsylvania under an agreement classified as an operating lease that expires in May 2021. The Company does not act as a lessor or have any leases classified as finance leases. On July 1, 2019, the Company entered into a lease for 5,829 square feet of office space located in West Chester, Pennsylvania that is expected to serve as the Company's new headquarters. On March 12, 2020 the Company entered into an amendment to the lease agreement. The amendment expands the original premises to include 5,372 square feet of additional office space increasing the total rentable premise to 11,201 square feet of space. For the first six months following the commencement date of September 1, 2020, the base rent is based on the square footage of the original premises. The initial term will expire on September 1, 2027. Base rent over the initial term is approximately $2.4 million, and the Company is also responsible for its share of the landlord's operating expense. At the commencement date of the new lease, the Company recorded a right-of-use asset of $1.9 million and a lease liability of $1.9 million on the balance sheet.

As of December 31, 2020, the Company had an operating lease liability of $1,891,000, of which $198,000 was classified as current, and an operating right-of-use asset of $1,836,000.

The components of lease expense are as follows (in thousands):

	For the Year Ended December 31,	
	2020	2019
Operating lease:		
Operating lease costs	$ 164	$ 211
Short-term lease costs	22	17
Total rent expense	$ 186	$ 228

Maturities of the Company's operating lease, excluding short-term leases as of December 31, 2020 are as follows (in thousands):

2021	$ 312
2022	343
2023	349
2024	355
2025	360
Thereafter	612
Total lease payments	2,331
Less imputed interest	(440)
Total lease liability	$ 1,891

The remaining term of the Company's operating lease was 6.7 years and the discount rate used to measure the present value of the Company's operating lease liability was 6.25% as of December 31, 2020.

Note 11–Debt

On March 10, 2020 (the "Effective Date"), the Company entered into (i) a mezzanine loan and security agreement (the "Mezzanine Loan Agreement") with Silicon Valley Bank, as administrative agent and collateral agent (the "Agent"), and Silicon Valley Bank and West River Innovation Lending Fund VIII, L.P., as lenders (the "Mezzanine Lenders"), pursuant to which the Mezzanine Lenders have agreed to lend the Company up to $50.0 million in a series of term loans, and (ii) a loan and security agreement (the "Senior Loan Agreement", and together with the Mezzanine Loan Agreement, the "Loan Agreements") with Silicon Valley Bank, as lender (the "Senior Lender", and together with the Mezzanine Lenders, the "Lenders"), pursuant to which the Senior Lender has agreed

to provide the Company with a revolving line of credit of up to $5.0 million. Upon entering into the Loan Agreements, the Company borrowed $35.0 million in term loans from the Mezzanine Lenders (the "Term A Loan").

On October 26, 2020, the Company entered into (i) the first amendment to the Mezzanine Loan Agreement (the "Mezzanine Loan Amendment") and (ii) the first amendment to the Senior Loan Agreement (the "Senior Loan Amendment" and together with the Mezzanine Loan Amendment the "Loan Agreement Amendments") with the Lenders, under which the Company borrowed an additional $5.0 million in term loans on March 1, 2021 from the Mezzanine Lenders (the "Term B1 Loan").

Under the terms of the Mezzanine Loan Agreement, as amended, the Company may, at its sole discretion, borrow from the Mezzanine Lenders up to an additional $10.0 million in term loans (the "Term B2 Loan"). The Term B1 Loan and Term B2 Loan, together with the Term A Loan, are referred to herein as the "Term Loans." The Term B2 Loan will be available for draw if the Company receives approval from the FDA of the NDA for VP-102 prior to September 30, 2021 and the Company maintains compliance with the minimum liquidity covenant until the earlier of September 30, 2021 or the occurrence of an event of default.

Under the terms of the Senior Loan Agreement, as amended, the Company may, at its sole discretion, borrow from the Senior Lender one or more advances on the revolving credit line (the "Revolving Loans", and together with the Term Loans, the "Loans") in an aggregate amount not to exceed the lesser of (i) 85% of the aggregate amount then-contained in the Company's eligible accounts receivable and (ii) $5.0 million.

The Company's obligations under the Senior Loan Agreement and the Mezzanine Loan Agreement, as amended, are secured by, respectively, a first priority perfected security interest and second priority perfected security interest in substantially all of the Company's current and future assets, other than its intellectual property (except rights to payment from the sale, licensing or disposition of such intellectual property). The Company has also agreed not to encumber its intellectual property assets, except as permitted by the Loan Agreements.

All of the Loans mature on March 1, 2024 (the "Maturity Date"). The Term Loans will be interest-only through March 31, 2022, followed by 24 equal monthly payments of principal and interest; provided that if the Company draws the Term B Loan, the Term Loans will be interest-only through September 30, 2022, followed by 18 equal monthly payments of principal and interest. The Term Loans will bear interest at a floating per annum rate equal to the greater of (i) 7.25% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 2.50%. The Revolving Loans will bear interest at a floating per annum rate equal to the greater of (i) 6.00% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 1.25%.

Under the terms of the Mezzanine Loan Agreement, as amended, the Company will be required to make a final payment fee of $3,750,000 payable on the earlier of (i) the Maturity Date, (ii) the acceleration of any Term Loans, or (iii) the prepayment of the Term Loans (the "Final Payment"). The Company is recording the final payment fee using the effective interest rate method over the term of the Term Loan with an increase in debt. The Company may prepay all, or any portion of the Term Loans upon 5 business days advance written notice to the Agent, provided that the Company will be obligated to pay a prepayment fee equal to (i) $1.5 million if prepaid on or before October 26, 2021, (ii) $1.0 million if prepaid between October 27, 2021 and October 26, 2022, and (iii) $0.5 million if prepaid between October 27, 2022 and October 26, 2023 and (iv) no prepayment fee if prepaid after October 26, 2023 (each, a "Prepayment Fee").

The Company may terminate the revolving credit line under the Senior Loan Agreement at any time upon three business days advance written notice to the Senior Lender. If the Company terminates the revolving credit line prior to the Maturity Date, it must pay to the Senior Lender an early termination fee of $50,000 (the "Termination Fee").

Under the Loan Agreements, as amended, the Company is subject to a number of affirmative and restrictive covenants, including covenants regarding maintaining a specified minimum liquidity ratio, delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, protection of intellectual property rights, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness or liens, investments and transactions with affiliates, and, beginning as of March 31, 2022, achieving minimum levels of trailing six-month net product revenues, among other customary covenants. As of December 31, 2020 the Company is in compliance with all covenants.

Upon the occurrence of certain events, including but not limited to the Company's failure to satisfy its payment obligations under the Loan Agreements, the breach of certain of its other covenants under the Loan Agreements, or the occurrence of a material adverse change, cross defaults to other indebtedness or material agreements, judgment defaults and defaults related to failure to maintain governmental approvals failure of which to maintain could result in a material adverse effect, the Agent and the Lenders will have the right, among other remedies, to declare all principal and interest immediately due and payable, to exercise secured party remedies, to receive the Final Payment and Termination Fee and, if the payment of principal and interest is due prior to the Maturity Date, to receive the applicable Prepayment Fee. The Loan Agreements also include subjective acceleration clauses that permit the Lenders to accelerate the maturity date under certain circumstances, including a material adverse change in the Company's business, operations, or financial condition or a material impairment of the prospect of repayment of the Company's obligations to the Mezzanine Lenders. Pursuant to the Loan Agreement Amendments, the Company is subject to a minimum liquidity covenant defined as the balance of the of the Company's unrestricted cash, cash equivalents, and marketable securities in accounts maintained at Silicon Valley Bank being greater than one and one half times the Company's aggregate outstanding obligations to the Mezzanine Lenders.

The Company believes that, without additional financing, it is probable that it will not be in compliance with its minimum liquidity ratio covenant at some point in the next twelve months. In accordance with FASB ASC 470, since the Mezzanine Loan Agreement contains subjective acceleration clauses and the assessment that it is probable that the minimum liquidity ratio covenant will not be met, the Company has classified all outstanding principal and final payment fees as a current liability in the accompanying balance sheet as of December 31, 2020.

Upon entering into the Loan Agreement, the Company received proceeds of $35.0 million in term loans and incurred debt discount and issuance costs of $3.3 million. The terms of the Loan Agreements as amended include a final payment fee of $3.8 million, classified as a contra-liability on the balance sheet as of December 31, 2020. The Company incurred additional debt issuance costs related to the revolving credit line of $0.1 million, classified as other non-current assets in the balance sheet as of December 31, 2020. These costs related to the revolving credit line are being amortized to interest expense over the life of the loans using the straight-line method.

For the year ended December 31, 2020, the Company recognized interest expense of $3.0 million, of which $2.1 million was interest on the term loan and $0.9 million, was noncash interest expense related to the amortization of deferred debt issuance costs and accrual of the final payment fee.

The following table summarizes the composition of debt as reflected on the balance sheet as of December 31, 2020 (in thousands):

Gross proceeds	$	35,000
Accrued final payment fee		3,750
Unamortized debt discount and issuance costs		(3,435)
Total short-term debt, net	$	35,315

In the event the Company maintains compliance with its minimum liquidity covenant to avoid an acceleration of payments, the aggregate maturities of debt as of December 31, 2020 are as follows (in thousands):

2021	$	—
2022		13,125
2023		17,500
2024 (1)		4,375
Total	$	35,000

(1) Excludes the final payment fee due at time of maturity.

Note 12–Income Taxes

There is no provision for income taxes as the Company has incurred operating losses since inception and maintains a full valuation allowance against its deferred tax assets.

Differences between the provision (benefit) for income taxes and income taxes at the statutory federal income tax rate are as follows (in thousands):

	For the Year Ended December 31,	
	2020	2019
Tax computed at statutory federal income tax rate	$ (8,966)	$ (5,923)
State taxes, net of federal benefit	(2,938)	(2,312)
Permanent items	1,283	70
R&D credits	(2,405)	—
Other	(2)	(285)
Change in valuation allowance	13,028	8,450
Income tax provision (benefit)	$ —	$ —

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	As of December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryovers	$ 23,881	$ 14,370
Research and development credits	2,405	—
Share-based compensation	2,170	1,128
Lease liabilities	549	54
Accrued compensation	388	321
Other	12	12
Total deferred tax assets	29,405	15,885
Less valuation allowance	(28,863)	(15,835)
Deferred tax asset, net of valuation allowance	542	50
Deferred tax liabilities:		
Right-of-use assets	(532)	(32)
Fixed assets	(10)	(18)
Total deferred tax liabilities	(542)	(50)
Net deferred tax assets	$ —	$ —

The Company has determined, based upon all available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax asset.

As of December 31, 2020, the Company had federal and state net operating loss carryforwards of approximately $82.7 million and $84.1 million, respectively. The federal net operating loss carryforwards included in the foregoing totals that were generated prior to 2018 (federal of approximately $6.9 million) will begin to expire, if not utilized, by 2033. Under the 2017 federal income tax law changes, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. As of December 31, 2020, the Company had federal and state research and development carryforwards of $2.4 million. 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 and tax credit carryforwards may be limited. The Company has not done an analysis to determine whether or not ownership changes have occurred since inception.

As of December 31, 2019, the Company had uncertain tax positions related to federal income tax credits for its research and development activities. The total amount of unrecognized tax benefits was $1.5 million. The Company released the uncertain tax position in 2020 and as of December 31, 2020 has recognized a deferred tax benefit of $2.4 million of federal income tax credits for its research and development activities. The Company will recognize interest and penalties, if any, related to uncertain tax positions in income tax expense. As of December 31,

2020 and 2019, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statement of operations. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

The 2017 and subsequent federal and state tax years for the Company remain open for the assessment of income taxes.

Note 13—License and Collaboration Agreements

In August 2020, the Company entered into an option agreement with Torii Pharmaceutical Co., Ltd. ("Torii") for the development and commercialization of the Company's product candidates for the treatment of molluscum contagiosum and common warts in Japan, including VP-102 (the "Option Agreement"). Torii paid the Company $0.5 million to secure the exclusive option. The $0.5 million is included in deferred revenue as of December 31, 2020 in the balance sheet.

On March 2, 2021, Torii exercised the exclusive option in the Option Agreement. On March 17, 2021, the Company entered into a collaboration and license agreement (the "Torii Agreement") with Torii, pursuant to which the Company granted Torii an exclusive license to develop and commercialize the Company's product candidates that contain a topical formulation of cantharidin for the treatment of molluscum contagiosum and common warts in Japan, including VP-102. Additionally, the Company 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.

Pursuant to the Torii Agreement, the Company is entitled to receive an up-front payment from Torii of $11.5 million. Additionally, the Company is entitled to receive from Torii an additional $58 million in aggregate payments contingent on achievement of specified development, regulatory, and sales milestones, in addition to tiered transfer price payments for supply of product in the percentage range of the mid-30's to the mid-40's of net sales. The transfer payments shall be payable, on a product-by-product basis, beginning on the first commercial sale of such product and ending on the latest of (a) expiration of the last-to-expire valid claim contained in certain licensed patents in Japan that cover such product, (b) expiration of regulatory exclusivity for the first indication for such product in Japan, and, (c) (i) with respect to the first product, ten years after first commercial sale of such product, and, (ii) with respect to any other product, the later of (x) ten years after first commercial sale of the first product and (y) five years after first commercial sale of such product.

The Torii Agreement expires on a product-by-product basis upon expiration of Torii's obligation under the agreement to make transfer price payments for such product. Torii has the right to terminate the agreement upon specified prior written notice to us. Additionally, either party may terminate the agreement in the event of an uncured material breach of the agreement by, or insolvency of, the other party. The Company may terminate the agreement in the event that Torii commences a legal action challenging the validity, enforceability or scope of any licensed patents.

In August 2020, the Company entered into an exclusive license agreement with Lytix Biopharma AS ("Lytix") for the use of licensed technology to research, develop, manufacture, have manufactured, use, sell, have sold, offer for sale, import, and otherwise commercialize products for use in all malignant and pre-malignant dermatological indications, other than metastatic melanoma and metastatic merkel cell carcinoma (the" Lytix Agreement"). As part of the Lytix Agreement, the Company paid Lytix a one-time up-front fee of $0.3 million in 2020. In addition, in February 2021, the Company paid Lytix a one-time $2.3 million payment upon the achievement by Lytix of a regulatory milestone. The $0.3 million was recognized in research and development expense in the statement of operations for the year ended December 31, 2020. The Company is also obligated to pay up to $111.0 million contingent on achievement of specified development, regulatory, and sales milestones, as well as tiered royalties based on worldwide annual net sales ranging in the low double digits to the mid-teens, subject to certain customary reductions. The Company's obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of the expiration or abandonment of the last to expire licensed patent covering LTX-315 anywhere in the world and expiration of regulatory exclusivity for LTX-315 in such country. Additionally, all upfront fees and milestone based payments received by the Company from a sublicensee will be treated as net sales and will be subject to the royalty payment obligations under the Lytix Agreement, and all royalties received by the Company from a sublicensee shall be shared with Lytix at a rate that is initially 50% but decreases based on the stage of development of LTX-315 at the time such sublicense is granted.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K to ensure that the information required to be disclosed by us in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

Management’s Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management utilized the criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) to assess the effectiveness of our internal control over financial reporting as of December 31, 2020.

As disclosed in Part II Item 9A Controls and procedures in our Annual Report on Form 10-K for the year ended December 31, 2019, during the fourth quarter of 2019 management identified a material weakness in our information technology (“IT”) general controls (collectively, “ITGCs”) and related IT-dependent process level controls, which are part of our internal control over financial reporting.

We implemented our previously disclosed remediation plan for the material weakness related to ineffective segregation of duties within this IT system in 2020 by transferring key administrative access to a third-party IT vendor. During the fourth quarter of 2020, we completed our testing of the operating effectiveness of the implemented controls and found them to be effective. As a result, we have concluded the material weakness has been remediated as of December 31, 2020.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting pursuant to Section 404(c) of the Sarbanes Oxley Act of 2002. Because we qualify as an emerging growth company under the JOBS Act, management's report was not subject to attestation by our independent registered public accounting firm.

Remediation of Material Weakness

Our Board of Directors and management take internal control over financial reporting and the integrity of our financial statements seriously. We remediated the deficiency related to ineffective segregation of duties within this IT system in 2020 by transferring key administrative access to a third-party IT vendor.

Changes in Internal Control Over Financial Reporting

Except for the changes noted above regarding the material weakness, there have been no other changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

We will file a definitive Proxy Statement for our 2021 Annual Meeting of Stockholders (the “2021 Proxy Statement”) with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2021 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 is hereby incorporated by reference to the sections of the 2021 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance."

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to the sections of the 2021 Proxy Statement under the captions "Executive Compensation" and "Non-Employee Director Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 is hereby incorporated by reference to the sections of the 2021 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by Item 13 is hereby incorporated by reference to the sections of the 2021 Proxy Statement under the captions "Transactions with Related Persons" and "Independence of the Board of Directors."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference to the sections of the 2021 Proxy Statement under the caption "Ratification of Selection of Independent Auditors."

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

We have filed the following documents as part of this Annual Report:

(a)(1) Financial Statements

The financial statements are included in Item 8. “Financial Statements and Supplementary Data.”

(a)(2) Financial Statement Schedules

All schedules are omitted as information required is inapplicable or the information is presented in the financial statements and the related notes.

(a)(3) Exhibits

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.3 to the Registrant’s Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018)
3.2	Amended and Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.4 to the Registrant’s Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018)
4.1	Description of Verrica Pharmaceuticals Inc. Common Stock (incorporated herein by reference to Exhibit 4.1 to the Registrant’s Annual Report on Form 10-K (File No. 001-38529), filed with the Securities and Exchange Commission on March 13, 2020).
10.1	Amended and Restated Investors’ Rights Agreement by and among the Registrant and certain of its stockholders, dated February 20, 2018 (incorporated herein by reference to Exhibit 10.1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018)
10.2+	2013 Equity Incentive Plan, as amended (incorporated herein by reference to Exhibit 10.2 to the Registrant’s Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018)
10.3+	Form of Stock Option Grant Notice and Stock Option Agreement under 2013 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Registrant’s Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018)
10.4+	2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on June 5, 2018)
10.5+	Form of Stock Option Grant Notice, Stock Option Agreement, Restricted Stock Unit Grant Notice, and Restricted Stock Unit Award Agreement under 2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.5 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on June 5, 2018)
10.6+	Form of Indemnification Agreement with Executive Officers and Directors (incorporated herein by reference to Exhibit 10.6 to the Registrant’s Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018)

10.7	Services Agreement, by and between the Registrant and PBM Capital Group, LLC, dated as of December 2, 2015, as amended on March 29, 2018 (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on May 22, 2018)
10.8+	Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.18 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-225104), filed with the Securities and Exchange Commission on June 5, 2018)
10.9#	Supply Agreement, by and between the Registrant and Funing County Development Brucea Javanica Professional Cooperatives, dated as of July 16, 2018 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38529), filed with the Securities and Exchange Commission on November 7, 2018)
10.10	Second Amendment to Services Agreement, by and between the Registrant and PBM Capital Group, LLC, dated as of January 1, 2019 (incorporated herein by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K (File No. 001-38529), filed with the Securities and Exchange Commission on March 7, 2019).
10.11	Lease Agreement, by and between the Registrant and 44 West Gay LLC, dated as of July 1, 2019 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38529), filed with the Securities and Exchange Commission on July 1, 2019).
10.12+	Employment Agreement, by and between the Registrant and A. Brian Davis, dated as of October 18, 2019 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38529), filed with the Securities and Exchange Commission on November 6,2019).
10.13	Third Amendment to Services Agreement, by and between the Registrant and PBM Capital Group, LLC, dated as of October 1, 2019 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38529), filed with the Securities and Exchange Commission on November 6, 2019).
10.14+	Amended and Restated Employment Agreement, by and between the Registrant and Ted White, dated as of January 10, 2020 (incorporated herein by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-38529), filed with the Securities and Exchange Commission on March 13, 2020).
10.15+	Amended and Restated Employment Agreement, by and between the Registrant and Joe Bonaccorso, dated as of January 10, 2020 (incorporated herein by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K (File No. 001-38529), filed with the Securities and Exchange Commission on March 13, 2020).
10.16*	Loan and Security Agreement, by and between the Company and Silicon Valley Bank, dated as of March 10, 2020 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38529), filed with the Securities and Exchange Commission on May 7, 2020).
10.17*	Mezzanine Loan and Security Agreement, by and among the Company, Silicon Valley Bank and WestRiver Innovation Lending Fund VIII, L.P., dated as of March 10, 2020 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38529), filed with the Securities and Exchange Commission on May 7, 2020).
10.18	First Amendment to Lease Agreement, by and between the Registrant and 44 West Gay LLC, dated as of March 12, 2020 (incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38529), filed with the Securities and Exchange Commission on May 7, 2020).

10.19	Second Amendment to Lease Agreement, by and between the Registrant and 44 West Gay LLC, dated as of April 27, 2020 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38529), filed with the Securities and Exchange Commission on August 5, 2020).
10.20*	Exclusive License Agreement, by and between the Registrant and Lytix Biopharma AS, dated as of August 7, 2020 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38529), filed with the Securities and Exchange Commission on November 9, 2020).
10.21*	First Amendment to Loan and Security Agreement, by and between the Company and Silicon Valley Bank, dated as of October 26, 2020.
10.22*	First Amendment to Mezzanine Loan and Security Agreement, by and among the Company, Silicon Valley Bank and WestRiver Innovation Lending Fund VIII, L.P., dated as of October 26, 2020.
23.1	Consent of KPMG LLP, independent registered public accounting firm
24.1	Power of Attorney (included on signature page)
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32.1^	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to section 906 of The Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Indicates management contract or compensatory plan.

Confidential treatment has been granted with respect to portions of this exhibit (indicated by asterisks) and those portions have been separately filed with the Securities and Exchange Commission.

* Certain portions of this exhibit, indicated by asterisks, have been omitted pursuant to Item 601(b)(10) of Regulation S-K because they are not material and would likely cause competitive harm to the registrant if publicly disclosed.

^ These certifications are being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

VERRICA PHARMACEUTICALS INC.

March 17, 2021

By: /s/ *Ted White*
Ted White
President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Ted White and A. Brian Davis, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Verrica Pharmaceuticals Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Ted White Ted White	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 17, 2021
/s/ A. Brian Davis A. Brian Davis	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 17, 2021
/s/ Paul B. Manning Paul B. Manning	Chairman of the Board of Directors	March 17, 2021
/s/ Sean Stalfort Sean Stalfort	Director	March 17, 2021
/s/ Craig Ballaron Craig Ballaron	Director	March 17, 2021
/s/ Mark Prygocki Mark Prygocki	Director	March 17, 2021
/s/ Lawrence Eichenfield Lawrence Eichenfield	Director	March 17, 2021
/s Diem Nguyen Diem Nguyen	Director	March 17, 2021

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

FIRST AMENDMENT
TO
LOAN AND SECURITY AGREEMENT

This First Amendment to Loan and Security Agreement (this "Amendment") is entered into this 26th day of October, 2020, by and between **SILICON VALLEY BANK** ("Bank") and **VERRICA PHARMACEUTICALS INC.**, a Delaware corporation ("**Borrower**"), whose address is 10 North High Street, Suite 200, West Chester, Pennsylvania 19380.

RECITALS

A. Bank and Borrower have entered into that certain Loan and Security Agreement dated as of March 10, 2020 (as the same may from time to time be amended, modified, supplemented or restated, the "Loan Agreement").

B. Bank has extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that Bank amend the Loan Agreement to (i) modify the financial covenant and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

D. Bank has agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 6.2 (Financial Statements, Reports, Certificates). Sections 6.2(a) and 6.2(b) are amended by inserting the following to appear at the beginning of each such Section:

"at all times following the occurrence of the FDA Event,"

2.2 Section 6.9 (Financial Covenant – Trailing Six (6) Month Net Revenue). Section 6.9 is deleted in its entirety and replaced with the following:

"**6.9 Financial Covenant – Trailing Six (6) Month Net Revenue.** During a Testing Period, Borrower shall achieve (calculated with respect to Borrower only and not on a consolidated basis) for the most recent calendar quarter then-ended and each calendar quarter thereafter if such Testing Period is still in effect, minimum net revenue, generated from the sale of Borrower's products (excluding revenue generated with respect to licensing arrangements), determined in accordance with GAAP, measured on a trailing six (6) month basis, of at least

Trailing Six (6) Month Period Ending	Minimum Revenue
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

With respect to the period ending [***] and each calendar quarter thereafter, the levels of minimum revenue shall be mutually agreed upon between Borrower and Bank, based upon, among other factors, Borrower's Board-approved operating plan and financial projections, which shall be acceptable to Bank, and Bank's then current credit underwriting. With respect thereto, Borrower's failure to agree in writing (which agreement shall be set forth in a written amendment to this Agreement) on or before [***], to any net revenue covenant levels proposed by Bank with respect to any period from [***] through and including [***], shall result in an immediate Event of Default for which there shall be no grace or cure period."

2.3 Section 8.11 (Mezzanine Loan Agreement). Section 8.11 is deleted in its entirety and replaced with the following:

"**8.11 Mezzanine Loan Agreement**. The occurrence of an Event of Default (as defined in the Mezzanine Loan Agreement) under the Mezzanine Loan Agreement (other than Event of Default (as defined in the Mezzanine Loan Agreement) solely under 6.7(b) of the Mezzanine Loan Agreement)."

2.4 Section 13 (**Definitions**). The following term and its definition set forth in Section 13.1 of the Loan Agreement is deleted in its entirety and replaced with the following:

" "**Testing Period**" is, at all times, commencing as of [***], when unrestricted and unencumbered cash (other than Liens in favor of Bank under this Agreement) held in accounts in the name of Borrower maintained with Bank is less than [***] the aggregate principal amount outstanding under the Term B Loan Advances (as defined in the Mezzanine Loan Agreement)."

2.5 Section 13 (Definitions). The Loan Agreement is amended by inserting the following new terms and their respective definitions to appear alphabetically in Section 13.1 thereof:

" "**FDA**" means the United Stated Food and Drug Administration, and any successor thereto."

" "**FDA Event**" means the date on which Borrower has provided Bank with evidence, in Bank's sole but reasonable discretion, that Borrower has received FDA approval of VP-102 for the treatment of Molluscum Contagiosum."

" "**First Amendment Effective Date**" is October 26, 2020."

2.6 Exhibit B (Compliance Certificate). The Compliance Certificate appearing as Exhibit B to the Loan Agreement is deleted in its entirety and replaced with the Compliance Certificate attached as Schedule 1 attached hereto.

3. Limitation of Amendments.

3.1 The amendments set forth in Section 2, above, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Bank may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Bank to enter into this Amendment, Borrower hereby represents and warrants to Bank as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Bank on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Post-Closing Deliverable. Borrower shall deliver to Bank within forty-five (45) days after the First Amendment Effective Date, a duly executed bailee's waiver in favor of Bank, in form and substance acceptable to Bank, for the following location where Borrower maintains property with a third party: [***].

6. Updated Perfection Certificate. Borrower has delivered an updated Perfection Certificate in connection with this Amendment dated as of the date hereof (the "**Updated Perfection Certificate**") which Updated Perfection Certificate shall supersede in all respects that certain Perfection Certificate dated as of March 10, 2020. Borrower hereby acknowledges and agrees that all references in the Loan Agreement to "Perfection Certificate" shall hereinafter be deemed to be references to the Updated Perfection Certificate, as defined herein.

7. Release by Borrower:

A. FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Bank and its present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of

time through and including the date of execution of this Amendment (collectively "Released Claims"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

B. In furtherance of this release, Borrower expressly acknowledges and waives any and all rights under Section 1542 of the California Civil Code, which provides as follows:

> "**A general release** does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party." (Emphasis added.)

C. By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Bank with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

D. This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Bank to enter into this Amendment, and that Bank would not have done so but for Bank's expectation that such release is valid and enforceable in all events.

E. Borrower hereby represents and warrants to Bank, and Bank is relying thereon, as follows:

1 Except as expressly stated in this Amendment, neither Bank nor any agent, employee or representative of Bank has made any statement or representation to Borrower regarding any fact relied upon by Borrower in entering into this Amendment.

2 Borrower has made such investigation of the facts pertaining to this Amendment and all of the matters appertaining thereto, as it deems necessary.

3 The terms of this Amendment are contractual and not a mere recital.

4 This Amendment has been carefully read by Borrower, the contents hereof are known and understood by Borrower, and this Amendment is signed freely, and without duress, by Borrower.

5 Borrower represents and warrants that it is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Borrower shall indemnify Bank, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

8. Integration. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

9. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

10. Effectiveness. This Amendment shall be deemed effective upon (a) the due execution and delivery to Bank of this Amendment by each party hereto, and (b) Borrower's payment to Bank of Bank's legal fees and expenses incurred in connection with this Amendment.

11. Governing Law. The provisions of Section 11 of the Loan Agreement shall apply to this Amendment as if set forth herein, mutatis mutandis.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BANK		**BORROWER**	
SILICON VALLEY BANK		VERRICA PHARMACEUTICALS INC.	
By:	/s/ Tom Gordon	By:	/s/ A. Brian Davis
Name:	Tom Gordon	Name:	A. Brian Davis
Title:	Managing Director	Title:	Chief Financial Officer

Schedule 1

EXHIBIT B

COMPLIANCE CERTIFICATE

TO: SILICON VALLEY BANK Date: _____
FROM: VERRICA PHARMACEUTICALS INC.

The undersigned authorized officer of VERRICA PHARMACEUTICALS INC. ("**Borrower**") certifies that under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (the "**Agreement**"), (1) Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below, (2) there are no Events of Default, (3) all representations and warranties in the Agreement are true and correct in all material respects on this date except as noted below; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, (4) Borrower, and each of its Subsidiaries, has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except as otherwise permitted pursuant to the terms of Section 5.9 of the Agreement, and (5) no Liens have been levied or claims made against Borrower or any of its Subsidiaries, if any, relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Bank. Attached are the required documents supporting the certification. The undersigned certifies that these are prepared in accordance with GAAP consistently applied from one period to the next except as explained in an accompanying letter or footnotes. The undersigned acknowledges that no borrowings may be requested at any time or date of determination that Borrower is not in compliance with any of the terms of the Agreement, and that compliance is determined not just at the date this certificate is delivered. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Agreement.

Please indicate compliance status by circling Yes/No under "Complies" column.

Reporting Covenants	**Required**	**Complies**
Monthly revenue, net profit and cash balance statements with Compliance Certificate	Monthly within 30 days	Yes No
Quarterly financial statements with Compliance Certificate	Within 45 days of quarter end (within 90 days of quarter end for Q4)	Yes No
Annual financial statement with Compliance Certificate (CPA Audited)	FYE within 180 days	Yes No
10-Q Report	Within 45 days of quarter end for 10-Q (within 90 days of quarter end for Q4)	Yes No

Filed 10-Q, 10-K and 8-K	Within 5 days after filing with SEC	Yes No
A/R Agings, A/P Agings & Inventory Reports	At all times following the occurrence of the FDA Event, monthly within 30 days when an Advance is outstanding or has been requested	Yes No
Borrowing Base Reports	At all times following the occurrence of the FDA Event, with each Advance request and monthly within 30 days when an Advance is outstanding	Yes No
Board approved projections	30 days of FYE and as amended/updated	Yes No

Financial Covenants	**Required**	**Actual**	**Complies**
Minimum Revenue*	$ *	$	Yes No

* as set forth in Section 6.9

The following financial covenant analyses and information set forth in Schedule 1 attached hereto are true and accurate as of the date of this Certificate.

The following are the exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions to note.")

VERRICA PHARMACEUTICALS INC.

By: _____
Name: _____
Title: _____

BANK USE ONLY

Received by: _____
AUTHORIZED SIGNER
Date: _____

Verified: _____
AUTHORIZED SIGNER
Date: _____

Compliance Status: Yes No

Schedule 1 to Compliance Certificate

Financial Covenants of Borrower

In the event of a conflict between this Schedule and the Agreement, the terms of the Agreement shall govern.

Dated: _____

I. **Minimum Revenue (Section 6.9)**

Required: During a Testing Period, Borrower shall achieve (calculated with respect to Borrower only and not on a consolidated basis) for the most recent calendar quarter then-ended and each calendar quarter thereafter if such Testing Period is still in effect, minimum net revenue, generated from the sale of Borrower's products (excluding revenue generated with respect to licensing arrangements), determined in accordance with GAAP, measured on a trailing six (6) month basis, of at least:

Trailing Six (6) Month Period Ending	**Minimum Revenue**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Actual:

A. Minimum Revenue $ _____

Is line A equal to or greater than _____*?

** As set forth above.*

_____No, not in compliance _____Yes, in compliance

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

Exhibit 10.22

FIRST AMENDMENT
TO
MEZZANINE LOAN AND SECURITY AGREEMENT

This First Amendment to Loan and Security Agreement (this "**Amendment**") is entered into this 26th day of October, 2020 by and among (a) **SILICON VALLEY BANK**, a California corporation ("**SVB**"), in its capacity as administrative agent and collateral agent ("**Agent**"), (b) **SILICON VALLEY BANK**, a California corporation, as a lender, (c) **WESTRIVER INNOVATION LENDING FUND VIII, L.P.**, a Delaware limited partnership ("**WestRiver**"), as a lender (SVB and WestRiver and each of the other " Lenders" from time to time a party hereto are referred to herein collectively as the "**Lenders**" and each individually as a "**Lender**"), and (d) **VERRICA PHARMACEUTICALS INC.**, a Delaware corporation ("**Borrower**"), whose address is 10 North High Street, Suite 200, West Chester, Pennsylvania 19380.

RECITALS

A. Borrower, Agent and the Lenders have entered into that certain Mezzanine Loan and Security Agreement dated as of March 10, 2020 (as the same may from time to time be amended, modified, supplemented or restated, the "**Loan Agreement**").

B. The Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that the Lenders amend the Loan Agreement to (i) provide for a new term loan, (ii) modify and incorporate new financial covenants, and (iii) make certain other revisions to the Loan Agreement as more fully set forth herein.

D. The Lenders have agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 2.1.1 (Term Loan Advances). Section 2.1.1(a) of the Loan Agreement is amended in its entirety and replaced with the following:

" (a) Availability. Subject to the terms and conditions of this Agreement, upon Borrower's request, the Lenders, severally and not jointly, shall make one (1) term loan advance to Borrower on or about the Effective Date in an original principal amount of Thirty-Five Million Dollars ($35,000,000.00) according to each Lender's Term Loan Commitment as set forth on Schedule 1 hereto (the "**Term A Loan Advance**"). Subject to the terms and conditions of this Agreement, upon Borrower's request, (i) during the First Draw Period, the Lenders, severally and not jointly, shall make one (1) term loan advance available to Borrower in an original principal amount of Five Million Dollars ($5,000,000.00) according to each Lender's Term Loan Commitment as set forth on Schedule 1 hereto (the "**Term B1 Loan Advance**") and (ii) during the

Second Draw Period, the Lenders, severally and not jointly, shall make one (1) term loan advance available to Borrower in an original principal amount of Ten Million Dollars ($10,000,000.00) according to each Lender's Term Loan Commitment as set forth on Schedule 1 hereto (the "**Term B2 Loan Advance**", together with the Term B1 Loan Advance, the "**Term B Loan Advances**"). The Term A Loan Advance and the Term B Loan Advances are hereinafter referred to singly as a "**Term Loan Advance**" and collectively as the "**Term Loan Advances**". After repayment, no Term Loan Advance (or any portion thereof) may be reborrowed."

2.2 Section 2.1.1 (Term Loan Advances). Section 2.1.1(d) of the Loan Agreement is amended in its entirety and replaced with the following:

" (d) Permitted Prepayment. Borrower shall have the option to prepay all, but not less than all, of the Term Loan Advances advanced by the Lenders under this Agreement, provided Borrower (i) delivers written notice to Agent of its election to prepay the Term Loan Advances at least [***] Business Days prior to such prepayment, and (ii) pays to Agent, for the account of the Lenders in accordance with its respective Pro Rata Share, on the date of such prepayment (A) the outstanding principal plus accrued and unpaid interest with respect to the Term Loan Advances, (B) the Final Payment, (C) the Prepayment Premium, and (D) all other sums, if any, that shall have become due and payable with respect to the Term Loan Advances, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts."

2.3 Section 6.7 (Financial Covenants). Section 6.7 is amended in its entirety and replaced with the following:

"**6.7 Financial Covenants**.

(a) Trailing Six (6) Month Net Revenue. During a Testing Period, Borrower shall achieve (calculated with respect to Borrower only and not on a consolidated basis) for the most recent calendar quarter then-ended and each calendar quarter thereafter if such Testing Period is still in effect, minimum net revenue, generated from the sale of Borrower's products (excluding revenue generated with respect to licensing arrangements), determined in accordance with GAAP, measured on a trailing six (6) month basis, of at least:

Trailing Six (6) Month Period Ending	**Minimum Revenue**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

With respect to the period ending [***] and each calendar quarter thereafter, the levels of minimum revenue shall be mutually agreed upon between Borrower, Agent and Lenders, based upon, among other factors, Borrower's Board-approved operating plan and financial projections, which shall be acceptable to Agent and Lenders, and Lenders' then current credit underwriting. With respect thereto, Borrower's failure to agree in writing (which agreement shall be set forth in a written amendment to this Agreement) on or before [***], to any net revenue covenant levels proposed by Agent and Lenders with respect to any period from [***] through and including [***], shall result in an immediate Event of Default for which there shall be no grace or cure period.

(b) Liquidity Ratio. Maintain at all times (calculated with respect to Borrower only and not on a consolidated basis), to be tested as of the last of each month, a Liquidity Ratio of greater than or equal to [***]."

2.4 Section 9.1 (Rights and Remedies). Section 9.1(a) is amended in its entirety and replaced with the following:

" (a) declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations are immediately due and payable without any action by Agent or any Lender); provided that (i) in the case of an Event of Default solely under Section 6.7(a) hereof, the Agent and Lenders shall not be permitted to declare Obligations in respect of the Term A Loan Advance immediately due and payable to the extent not otherwise then due and payable or to exercise any other rights or remedies with respect to the Term A Loan Advance and (ii) in the case of an Event of Default solely under Section 6.7(b) hereof, the Agent and Lenders shall not be permitted to declare Obligations in respect of the Term B Loan Advances immediately due and payable to the extent not otherwise then due and payable or to exercise any other rights or remedies with respect to the Term B Loan Advances;"

2.5 Section 14 (Definitions). The following terms and their respective definitions set forth in Section 14.1 are amended in their entirety and replaced with the following:

" "**Final Payment**" is a payment (in addition to and not in substitution for the regular monthly payments of principal plus accrued interest) equal to Three Million Seven Hundred Fifty Thousand Dollars ($3,750,000.00), due on the earliest to occur of (a) the Term Loan Maturity Date, (b) the payment in full of such Term Loan Advance, (c) as required by Section 2.1.1(d) or 2.1.1(e) or (d) the termination of this Agreement."

" "**Prepayment Premium**" shall be an additional fee, payable to Agent, for the ratable benefit of the Lenders based on their Pro Rata Share, with respect to the Term Loan Advances, in an amount equal to:

(a) for a prepayment of the Term Loan Advances made on or prior to the first (1st) anniversary of the First Amendment Effective Date, One Million Five Hundred Thousand Dollars ($1,500,000.00);

(b) for a prepayment of the Term Loan Advances made after the first (1st) anniversary of the First Amendment Effective Date, but on or prior to the second (2nd) anniversary of the First Amendment Effective Date, One Million Dollars ($1,000,000.00);

(c) for a prepayment of the Term Loan Advances made after the second (2nd) anniversary of the First Amendment Effective Date, but on or prior to the third (3rd) anniversary of the First Amendment Effective Date, Five Hundred Thousand Dollars ($500,000.00); and

(d) for a prepayment of the Term Loan Advances made after the third (3rd) anniversary of the First Amendment Effective Date, [***] ([***])."

" "**Repayment Schedule**" means the period of time equal to twenty-four (24) consecutive months, which shall be reduced to eighteen (18) consecutive months, once the Term B2 Loan Advance is made."

" "**Term Loan Amortization Date**" means April 1, 2022, which shall be extended until October 1, 2022, once the Term B2 Loan Advance is made."

" "**Testing Period**" is, at all times, commencing as of [***], when unrestricted and unencumbered cash (other than Liens in favor of Agent for the ratable benefit of the Lenders under this Agreement) held in accounts in the name of Borrower maintained with SVB is less than [***] the aggregate principal amount outstanding under the Term B Loan Advances."

2.6 Section 14.1 (Definitions). The Loan Agreement is amended by inserting the following new terms and their respective definitions to appear alphabetically in Section 14.1 thereof:

" "**2020 Milestone Event #1**" means delivery by Borrower to Agent, on or prior to March 31, 2021, of evidence satisfactory to Agent and each Lender, in Agent's and each Lender's sole but reasonable discretion, that the FDA has accepted the new drug application resubmission of VP-102 for the treatment of Molluscum Contagiosum on or prior to March 31, 2021."

" "**2020 Milestone Event #2**" " means (i) the 2020 Milestone Event #1 has occurred and (ii) delivery by Borrower to Agent, on or prior to September 30, 2021, of evidence satisfactory to Agent and each Lender, in Agent's and each Lender's sole but reasonable discretion, that (A) Borrower has received FDA approval of VP-102 for the treatment of Molluscum Contagiosum on or prior to September 30, 2021 and (B) Borrower has been in compliance with the Liquidity Ratio financial covenant set forth in Section 6.7(b) hereof, at all times through and including the Funding Date of the Term B2 Loan Advance."

" "**FDA**" means the United States Food and Drug Administration, and any successor thereto."

" "**First Amendment Effective Date**" is October 26, 2020."

" "**First Draw Period**" is the period of time commencing upon the occurrence of the 2020 Milestone Event #1 and continuing through the earlier to occur of (a) March 31, 2021 or (b) an Event of Default."

" "**Liquidity Ratio**" is, calculated with respect to Borrower only and not on a consolidated basis, the ratio of (i) (A) Borrower's unrestricted and unencumbered cash and Cash Equivalents at Bank and Bank's Affiliates, plus (B) the Availability Amount (as defined in the Senior Loan Agreement), to (ii) (A) the aggregate principal amount outstanding under the Revolving Line (as defined in the Senior Loan Agreement), plus (B) the aggregate principal amount outstanding under the Term A Loan Advance."

" "**Second Draw Period**" is the period of time commencing upon the occurrence of the 2020 Milestone Event #2 and continuing through the earlier to occur of (a) September 30, 2021, and (b) an Event of Default."

" "**Term B Loan Advances**" is defined in Section 2.1.1(a)."

" "**Term B1 Loan Advance**" is defined in Section 2.1.1(a)."

" "**Term B2 Loan Advance**" is defined in Section 2.1.1(a)."

2.7 Exhibit B (Compliance Certificate). The Compliance Certificate appearing as Exhibit B to the Loan Agreement is deleted in its entirety and replaced with the Compliance Certificate attached as Schedule 1 attached hereto.

2.8 Schedule 1 (Lenders and Commitments). Lenders and Commitments appearing as Schedule 1 to the Loan Agreement is deleted in its entirety and replaced with the Lenders and Commitments attached as Schedule 2 attached hereto.

3. Limitation of Amendments.

3.1 The amendments set forth in Section 2 above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Agent or the Lenders may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Agent and the Lenders to enter into this Amendment, Borrower hereby represents and warrants to Agent and the Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Agent on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Post-Closing Deliverable. Borrower shall deliver to Agent within [***] days after the First Amendment Effective Date, a duly executed bailee's waiver in favor of Agent and Lenders, in form and substance acceptable to Agent and Lenders, for the following location where Borrower maintains property with a third party: [***].

6. Updated Perfection Certificate. Borrower has delivered an updated Perfection Certificate in connection with this Amendment dated as of the date hereof (the "**Updated Perfection Certificate**") which Updated Perfection Certificate shall supersede in all respects that certain Perfection Certificate dated as of March 10, 2020. Borrower hereby acknowledges and agrees that all references in the Loan Agreement to "Perfection Certificate" shall hereinafter be deemed to be references to the Updated Perfection Certificate, as defined herein.

7. Integration. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

8. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

9. Effectiveness. This Amendment shall be deemed effective upon (a) the due execution and delivery to Agent of this Amendment by each party hereto and (b) Borrower's payment to Agent of Agent's and the Lenders' legal fees and expenses incurred in connection with this Amendment.

10. Governing Law. The provisions of Section 12 of the Loan Agreement shall apply to this Amendment as if set forth herein, mutatis mutandis.

[Signature page follows.]

In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWER:

VERRICA PHARMACEUTICALS INC.

By /s/ A. Brian Davis
Name: A. Brian Davis
Title: Chief Financial Officer

AGENT:

SILICON VALLEY BANK, as Agent

By /s/ Tom Gordon
Name: Tom Gordon
Title: Managing Director

LENDERS:

SILICON VALLEY BANK

By /s/ Tom Gordon
Name: Tom Gordon
Title: Managing Director

WESTRIVER INNOVATION LENDING FUND VIII, L.P.

By /s/ Trent Dawson
Name: Trent Dawson
Title: Chief Financial Officer

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

Schedule 1
EXHIBIT B
COMPLIANCE CERTIFICATE

Date: _____

TO: SILICON VALLEY BANK, as Agent, SVB, and WESTRIVER INNOVATION LENDING FUND VIII, L.P., as Lender

FROM: VERRICA PHARMACEUTICALS INC.

The undersigned authorized officer of VERRICA PHARMACEUTICALS INC. ("**Borrower**") certifies that under the terms and conditions of the Loan and Security Agreement among Borrower, SVB, and WestRiver (the "**Loan Agreement**"), (1) Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below, (2) there are no Events of Default, (3) all representations and warranties in the Agreement are true and correct in all material respects on this date except as noted below; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, (4) Borrower, and each of its Subsidiaries, has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except as otherwise permitted pursuant to the terms of Section 5.8 of the Agreement, and (5) no Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Agent. Attached are the required documents supporting the certification. The undersigned certifies that these are prepared in accordance with GAAP consistently applied from one period to the next except as explained in an accompanying letter or footnotes. The undersigned acknowledges that no borrowings may be requested at any time or date of determination that Borrower is not in compliance with any of the terms of the Agreement, and that compliance is determined not just at the date this certificate is delivered. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Agreement.

Please indicate compliance status by circling Yes/No under "Complies" column.

Reporting Covenants	Required	Complies
Monthly revenue, net profit and cash balance statements with Compliance Certificate	Monthly within 30 days	Yes No
Quarterly financial statements with Compliance Certificate	Within 45 days of quarter end (within 90 days of quarter end for Q4)	Yes No
Annual financial statement with Compliance Certificate (CPA Audited)	FYE within 180 days	Yes No
10-Q Report	Within 45 days of quarter end for 10-Q (within 90 days of quarter end for Q4)	Yes No
Filed 10-Q, 10-K and 8-K	Within 5 days after filing with SEC	Yes No
Board approved projections	30 days of FYE and as amended/updated	Yes No

Financial Covenants	Required	Actual	Complies
Minimum Revenue*	$ *	$	Yes No
Liquidity Ratio	[***]	___[***]	Yes No

* as set forth in Section 6.7(a)

As of the date of this Certificate, the following financial covenant analysis and information set forth in Schedule 1 attached hereto are true and accurate for the period indicated.

Other Matters

Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate. Yes No

The following are the exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions to note.")

VERRICA PHARMACEUTICALS INC.

By: _____

Name: _____

Title: _____

AGENT USE ONLY

Received by: _____
AUTHORIZED SIGNER

Date: _____

Verified: _____
AUTHORIZED SIGNER

Compliance Status: Yes No

Schedule 1 to Compliance Certificate
Financial Covenants of Borrower

In the event of a conflict between this Schedule and the Loan Agreement, the terms of the Loan Agreement shall govern.

Dated: _____

I. Minimum Revenue (Section 6.7(a))

Required: During a Testing Period, Borrower shall achieve (calculated with respect to Borrower only and not on a consolidated basis) for the most recent calendar quarter then-ended and each calendar quarter thereafter if such Testing Period is still in effect, minimum net revenue, generated from the sale of Borrower's products (excluding revenue generated with respect to licensing arrangements), determined in accordance with GAAP, measured on a trailing six (6) month basis, of at least:

Trailing Six (6) Month Period Ending	Minimum Revenue
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Actual:

A. Minimum Revenue $ _____

Is line A equal to or greater than _____*?
** As set forth above.*
_____ No, not in compliance _____ Yes, in compliance

II. Liquidity Ratio (Section 6.7(b))

Required: Maintain at all times (calculated with respect to Borrower only and not on a consolidated basis), to be tested as of the last of each month, a Liquidity Ratio of greater than or equal to [***].

Actual:

A.	Aggregate value of the unrestricted and unencumbered cash and Cash Equivalents of Borrower	$ _____
B.	Availability Amount (as defined in the Senior Loan Agreement)	$ _____
C.	Sum of lines A and B	$ _____
D.	Aggregate principal amount outstanding under the Revolving Line (as defined in the Senior Loan Agreement)	$ _____
E	Aggregate principal amount outstanding under the Term A Loan Advance	$ _____
F	Sum of lines D and E	$ _____
G.	Liquidity Ratio (Line C divided by line F)	_____

Is line G equal to or greater than _____:[***]?

_____ No, not in compliance _____ Yes, in compliance

SCHEDULE 2
SCHEDULE 1
LENDERS AND COMMITMENTS
TERM LOAN COMMITMENTS

Term A Loan Advance

Lender	Term A Loan Advance Commitment	Term A Loan Advance Commitment Percentage
Silicon Valley Bank	$17,500,000.00	50.0%
WestRiver Innovation Lending Fund VIII, L.P.	$17,500,000.00	50.0%
TOTAL	**$35,000,000.00**	**100.0000%**

Term B1 Loan Advance

Lender	Term B1 Loan Advance Commitment	Term B1 Loan Advance Commitment Percentage
Silicon Valley Bank	$2,500,000.00	50.0%
WestRiver Innovation Lending Fund VIII, L.P.	$2,500,000.00	50.0%
TOTAL	**$5,000,000.00**	**100.0000%**

Term B2 Loan Advance

Lender	Term B2 Loan Advance Commitment	Term B2 Loan Advance Commitment Percentage
Silicon Valley Bank	$5,000,000.00	50.0%
WestRiver Innovation Lending Fund VIII, L.P.	$5,000,000.00	50.0%
TOTAL	**$10,000,000.00**	**100.0000%**

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Verrica Pharmaceuticals Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-226153, 333-231265 and 333-237174) on Form S-8 and (No. 333-237171) on Form S-3 of Verrica Pharmaceuticals Inc. of our report dated March 17, 2021, with respect to the balance sheets of Verica Pharmaceuticals Inc. as of December 31, 2020 and 2019, and the related statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of Verrica Pharmaceuticals Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 17, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ted White, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020 of Verrica Pharmaceuticals Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (c) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 17, 2021

/s/ Ted White
Ted White
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, A. Brian Davis, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020 of Verrica Pharmaceuticals Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (c) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 17, 2021

/s/ A. Brian Davis
A. Brian Davis
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350),Ted White, President and Chief Executive Officer of Verrica Pharmaceuticals Inc. (the "Company"), and A. Brian Davis, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2020, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 17th day of March, 2021.

/s/ Ted White
Ted White
President and Chief Executive Officer
(Principal Executive Officer)

/s/ A. Brian Davis
A. Brian Davis
Chief Financial Officer
(Principal Financial Officer)

* This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.