
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 12, 2018

Verrica Pharmaceuticals Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38529
(Commission
File Number)

46-3137900
(IRS Employer
Identification No.)

10 North High Street, Suite 200
West Chester, PA
(Address of Principal Executive Offices)

19380
(Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 7.01 Regulation FD Disclosure.

On September 12, 2018, Verrica Pharmaceuticals Inc. (the "Company") issued a press release announcing positive results from its Phase 2 clinical trial of VP-102 for the treatment of molluscum contagiosum and the completion of enrollment of its Phase 3 clinical trials of VP-102 for the treatment of molluscum contagiosum. The full text of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In addition, on September 12, 2018, the Company will make available an updated version of the Company's corporate presentation on the Company's website. A copy of the updated corporate presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibits 99.1 and 99.2) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated September 12, 2018
99.2	Company Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Verrica Pharmaceuticals Inc.

Date: September 12, 2018

/s/ Chris Degnan

Chris Degnan
Chief Financial Officer



Verrica Announces Successful Phase 2 Innovate Trial and Complete Enrollment of Phase 3 Trials of VP-102 in Molluscum Contagiosum Ahead of Schedule

Innovate trial results reaffirm Phase 3 protocol design

No serious adverse events (SAEs) reported during the Innovate trial

Phase 3 pivotal trials for molluscum contagiosum fully enrolled and topline results now expected in 1Q 2019

WEST CHESTER, PA –September 12, 2018 (GLOBE NEWSWIRE) – Verrica Pharmaceuticals Inc. (Verrica) (Nasdaq: VRCA), a pharmaceutical company focused on identifying, developing and commercializing innovative pharmaceutical products for the treatment of skin diseases with significant unmet needs, today announced positive results from its Phase 2 Innovate clinical trial of VP-102 (study VP-102-103). VP-102 is a proprietary drug-device combination containing a novel topical solution of 0.7% cantharidin currently under development for the treatment of molluscum contagiosum (molluscum). Verrica also announced the early completion of enrollment for its Phase 3 pivotal trials for molluscum with topline results now expected in the first quarter of 2019.

Innovate is an open label, single-center trial with the primary objective 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 into either the exposure group (n=17) or the 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 median reduction in molluscum lesions of 98% 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. The safety profile observed during the trial was favorable overall and no SAEs were reported.

“We were pleased to observe a favorable safety profile of VP-102 and clinically meaningful efficacy as assessed by complete clearance and substantial reduction in molluscum lesion counts over a 12-week period,” stated Patrick Burnett, M.D., Ph.D., Chief Medical Officer of Verrica. “The complete clearance rate for the Innovate trial exceeds the assumptions for powering in the current VP-102 Phase 3 clinical trials and reaffirms our confidence in the ongoing Phase 3 program.”

Additionally, Verrica announced the earlier than expected completion of enrollment of its Phase 3 clinical trials, CAMP-1 (study VP-102-101) and CAMP-2 (study VP-102-102), two randomized, double-blind, multicenter, placebo-controlled trials of VP-102 for the treatment of molluscum. The primary objective of the trials is to evaluate the efficacy of dermal application of VP-102 relative to placebo, 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 (visit 5).

"The rate in which we enrolled our Phase 3 pivotal trials speaks to the significant underserved patient population," commented Ted White, President and Chief Executive Officer of Verrica. "We remain committed to making VP-102 the standard of care for the treatment of molluscum, a disease with currently no FDA-approved treatments, and look forward to reporting our pivotal topline results in the first quarter of next year."

About Molluscum Contagiosum

Molluscum contagiosum, or molluscum, is a highly contagious, primarily pediatric, 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. There are currently no approved drugs for molluscum.

About VP-102

Verrica is currently advancing its lead product VP-102, a proprietary topical drug device combination therapy containing a novel topical solution of 0.7% cantharidin, for the treatment of molluscum and verruca vulgaris (common warts). Verrica is also currently evaluating and prioritizing other potential indications for VP-102 and the company's proprietary topical solutions of cantharidin.

About Verrica Pharmaceuticals Inc.

Verrica is a pharmaceutical company focused on identifying, developing and commercializing innovative pharmaceutical products for the treatment of skin diseases with significant unmet needs. The company's lead product candidate, VP-102, is currently being evaluated in two Phase 3 clinical trials for the treatment of molluscum and in a Phase 2 clinical trial for the treatment of common warts.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe", "expect", "may", "plan", "potential", "will", and similar expressions, and are based on Verrica's current beliefs and expectations. These forward-looking statements include expectations regarding the potential clinical development of Verrica's product candidates and the availability of data from Verrica's clinical trials, including the timing of topline results from the Phase 3 pivotal trials for molluscum. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Verrica's reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in Verrica's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, filed with the U.S. Securities and Exchange Commission (SEC) on August 7, 2018, and Verrica's other Periodic Reports filed with the SEC. Any forward-looking statements speak only as of the date of this press release and are based on information available to Verrica as of the date of this release, and Verrica assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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Company Overview

September 2018

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DISCLAIMER

Certain information contained in this presentation and statements made orally during this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and Verrica's own internal estimates and research. While Verrica believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. While Verrica believes its internal research is reliable, such research has not been verified by any independent source.

This presentation contains forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. All statements other than statements of historical facts contained in this presentation, including statements regarding future results of operations and financial position, business strategy, current and prospective product candidates, planned clinical trials and preclinical activities, product approvals, degree of market acceptance of approved products, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product candidates, are forward-looking statements. The words "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this presentation represent our views as of the date of this presentation. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. The forward-looking statements in this presentation involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, our reliance on third parties over which we may not always have full control, and other risks and uncertainties that are described in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, filed with the U.S. Securities and Exchange Commission (SEC) on August 7, 2018, and our other Periodic Reports filed with the SEC. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. There can be no assurance that the opportunity will meet your investment objectives, that you will receive a return of all or part of such investment. Investment results may vary significantly over any given time period. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. We recommend that investors independently evaluate specific investments and strategies.

Developing
innovative
dermatology
products



INVESTMENT HIGHLIGHTS

★ Two of the Largest Unmet Needs in Dermatology

- Prevalence of ~6 million in molluscum contagiosum⁽¹⁾ and ~22 million in common warts in the U.S.⁽²⁾
- No FDA approved drugs to treat molluscum or warts

★ Late-Stage

- Enrollment complete in two pivotal Phase 3 trials in molluscum; topline results expected 1Q 2019

★ Favorable Tolerability

- No SAEs in Phase 2 trials for the treatment of molluscum

★ Physician Acceptance

- 95% of pediatric dermatologists have used API⁽³⁾

★ Innovative Product

- Drug-device combination of a proprietary formulation and a novel single-use applicator

★ Barriers to Competition

- New chemical entity regulatory exclusivity upon approval
- IP pending on product, including on novel formulation, applicator and methods of use
- Drug-device combination makes a 'true generic' unlikely

★ Proven Team

- Industry-leading, experienced management team

(1) Prevalence in the US of 5.1% to 11.5% in children aged 0-16 years. (Fam Pract. 2014 Apr;31(2):130-6). US Census estimates ~69.4MM children aged 0 to 16 years in 2016.

(2) IMS National Disease and Therapeutic Index (NDTI) Rolling 5 Years Ending June 2016. Nguyen et al. Laser Treatment of Nongenital Verrucae A Systemic Review. JAMA Dermatology. 2016; 152(9): 1025-1033

(3) Based on a survey of 115 dermatologists the results of which have been extrapolated to pediatric dermatologists.

MANAGEMENT TEAM WITH EXTENSIVE PRODUCT LAUNCH AND DERMATOLOGY EXPERIENCE



Ted White
President & Chief Executive Officer



Chris Degnan
Chief Financial Officer



Patrick Burnett
MD, PhD
Chief Medical Officer



Linda Palczuk
Chief Operating Officer



Joe Bonaccorso
Chief Commercial Officer



Selected Launched Products



OUR PRODUCT PORTFOLIO

	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT EXPECTED MILESTONE
VP-102 Molluscum Contagiosum					Topline Phase 3 results in 1Q 2019
Common Warts					Topline Phase 2 results by 1H 2019
Additional Indications⁽¹⁾⁽²⁾					To be determined based on indication
VP-103 Plantar Warts⁽³⁾					IND submission in 2019

We retain exclusive, royalty-free rights to our product candidates across all indications globally

(1) Additional indications under consideration include subungual warts, flat warts, actinic keratosis, genital warts and seborrheic keratosis.
 (2) Phase 2 ready assuming use of the same formulation.
 (3) Phase 2 ready assuming leverage of data from VP-102.

FIRST PRODUCT CANDIDATE IS VP-102, A PROPRIETARY DRUG-DEVICE COMBINATION CONTAINING CANTHARIDIN



History of Publications Leading to De-risked Regulatory Pathway

API has been used for dermatologic diseases for **over 50 years**

Phase 2 trials show a **favorable profile** for complete clearance of molluscum



Favorable Tolerability

No SAEs in two Phase 2 trials for the treatment of molluscum

Active ingredient shown to be **well tolerated** in our clinical trials to date



Familiar to Physicians

95% of pediatric dermatologists have experience with cantharidin⁽¹⁾

40% of dermatologists use cantharidin⁽²⁾

Strong desire for increased access to cantharidin



Favorable CMC and Competitive Position

New chemical entity with regulatory exclusivity upon approval

Novel topical solution

Proprietary single-use device

Unique manufacturing process

(1) Based on a survey of 115 dermatologists the results of which have been extrapolated to pediatric dermatologists.

(2) Pompei D, et al. Cantharidin therapy: Practice patterns and attitudes of health care providers. J Am Acad Dermatol 2013;68:1045-46.

THE PROBLEM

Molluscum Contagiosum



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MOLLUSCUM BACKGROUND

OVERVIEW

Caused by a pox virus

Primarily infects children, with the highest incidence occurring in children <14 years old

Highly contagious

If untreated, lesions persist an average of 13 months, with some cases remaining unresolved for 2+ years

Often leads to anxiety and social challenges for the patients and parents and negatively impacts quality of life

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ETIOLOGY AND CLINICAL PRESENTATION

Transmission

- Skin to skin contact
- Sharing of contaminated objects (e.g., clothing, towels, swimming pool toys)

Diagnosis & Symptoms

- Typically 10 to 30 lesions
- 100+ lesions can be observed
- Lesions may be the only sign of infection and are often painless
- Can be diagnosed with skin biopsy to differentiate from other lesions



Complications

- Skin irritation, inflammation, and re-infection
- Follicular or papillary conjunctivitis if lesions on eyelids
- Cellulitis

CURRENT TREATMENTS FOR MOLLUSCUM ARE NOT FDA APPROVED AND HAVE MANY LIMITATIONS

Broad use limited by unproven efficacy, scarring, lack of availability, safety concerns & pain



Significantly undertreated patient population

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	DESCRIPTION	LIMITATIONS
Cryotherapy	Freezing the lesions with liquid nitrogen	<ul style="list-style-type: none"> • Pain and scarring • Unsuitable for use in children
Curettage	Using a curette or a surgical instrument with a scoop at the tip to scrape the lesions	<ul style="list-style-type: none"> • Pain and scarring • Unsuitable for use in children
Laser Surgery	Applying a laser to target and destroy the lesions	<ul style="list-style-type: none"> • Pain, cost and lack of availability • Unsuitable for use in children
Topical Products	Applying various acids (e.g. salicylic acid), creams or blistering solutions to destroy the lesions	<ul style="list-style-type: none"> • Unproven efficacy
Off-Label Drugs	Retinoids, antiviral medicines, or immune modulating therapies	<ul style="list-style-type: none"> • Limited efficacy • Side-effects
Natural Remedies	Applying natural oils (e.g. tea tree oil) with antimicrobial properties	<ul style="list-style-type: none"> • Unproven efficacy • Pain, irritation and allergic reactions

VP-102'S API HAS A LONG HISTORY OF CLINICAL EVIDENCE



Cantharidin: A Comprehensive Review of the Clinical Literature

Richard Torbeck MD¹, Michael Pan BA²,
Ellen de Moll BA³, Jacob Levitt MD²

¹The University of Toledo College of Medicine, Toledo, Ohio,

²Icahn School of Medicine at Mount Sinai, Department of Dermatology, New York, New York,

³University of Connecticut School of Medicine, Farmington, Connecticut

Safety of Cantharidin: A Retrospective Review of Cantharidin Treatment in 405 Children with Molluscum Contagiosum

Virginia A. Moye, M.P.H.,* Shelley
Catheart, M.D.,** Dean S. Morrell, M.D.**

*University of North Carolina, Chapel Hill, North Carolina,

**Department of Dermatology, University of North Carolina, Chapel Hill, North Carolina



Abundant clinical information indicates that, with careful use under physician direction, toxicities are seen that are not worse than and sometimes less severe than those seen with other destructive modalities in the treatment of molluscum contagiosum and warts. **Cantharidin is considered by some to be a treatment of choice for molluscum contagiosum in young children.**

FDA 2015



Cantharidin has been **used for dermatologic diseases for over 50 years** with the primary indications of removal of warts and MC.”

TORBECK ET AL. 2014



Cantharidin is a **safe treatment** modality for MC and should be considered when symptomatic infection necessitates treatment.”

MOYE ET AL. 2014

HISTORICAL COMPOUNDED CANTHARIDIN PRESENTS A NUMBER OF LIMITATIONS

1 Varying concentration

- Evaporation of volatile solvents leads to concentration increases
- Patients can receive more drug than clinically necessary resulting in excessive blistering

2 Inconsistent purity and lack of controlled product

- Per the FDA, highly variable in purity with impurities such as residual solvents or pesticides

3 Lack of reimbursement

- Not FDA approved and therefore not eligible for drug reimbursement

4 Inconvenient and variable administration

- Application with the wooden stick part of a cotton-tipped swab can lead to patients receiving more drug than necessary
- Inability for physicians to identify where the drug has been applied

5 Limited availability

- Illegal to import formulated cantharidin
- Generally not available in hospitals and academic settings, which require FDA approved product
- Only an estimated 7% of 503B compounders produce formulations containing cantharidin⁽¹⁾

(1) Based on 70 503B facilities and 5 compounders of cantharidin per FDA database.



THE SOLUTION

VP-102



VP-102 IS A PROPRIETARY DRUG-DEVICE COMBINATION OF CANTHARIDIN ADMINISTERED THROUGH OUR SINGLE-USE PRECISION APPLICATOR

GMP-controlled formulation of cantharidin with:

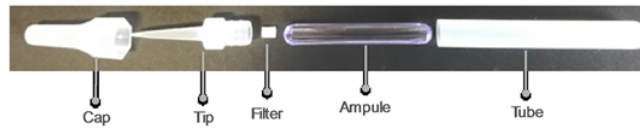
- API that is greater than 99% pure
- Defined pharmaceutical batch process

Long-term, room temperature stability

Visualization agent to see which lesions have been treated

Bittering agent to mitigate oral ingestion by children

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Mechanism of Action and Clinical Evidence



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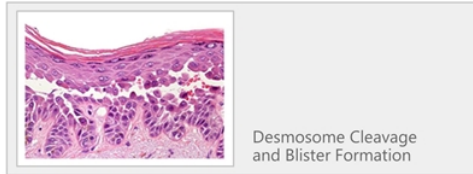
CANTHARIDIN HAS A PROVEN DUAL MECHANISM OF ACTION

1 Targeted Destruction of Infected Skin Leads to Lesion Clearance

Once applied, cantharidin activates neutral serine proteases that cause degeneration of the desmosomal plaque, leading to detachment of tonofilaments from desmosomes.⁽¹⁾

This leads to intraepidermal blistering and nonspecific lysis of the skin, causing the tissues containing the virus to separate from the surrounding skin.

Since acantholysis is intraepidermal, healing occurs without scarring.



(1) J Invest Dermatol. 1962 Jul;39:39-45.

(2) J Immunol Methods. 2001 Nov 1;257(1-2):213-20.2

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2 Elicits Inflammation & Immune Response with Potential to Boost Viral Immune Response

Leukocyte infiltration includes neutrophils, macrophages, B and T cells and eosinophils

Release of chemokines and cytokines including TNF- α , IL-8 and CXCL-5

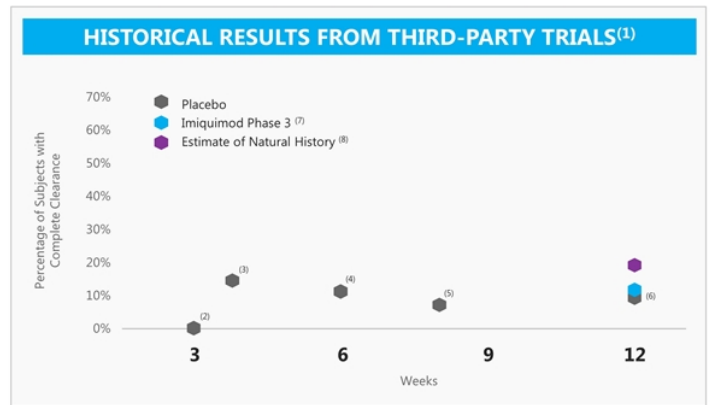
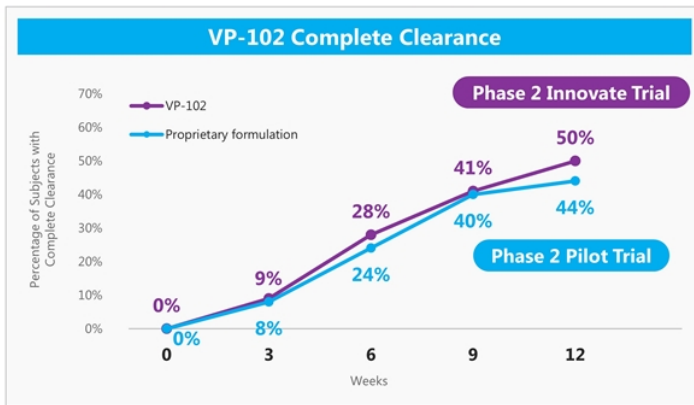
Cantharidin is used in the laboratory as a model for studying leukocyte trafficking and cytokine production.⁽²⁾



SIGNIFICANT CLINICAL PROGRESS OF VP-102 FOR THE TREATMENT OF MOLLUSCUM

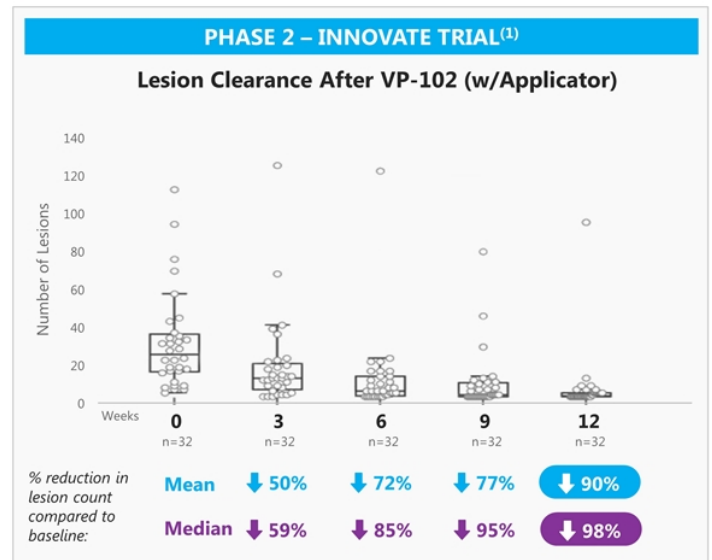
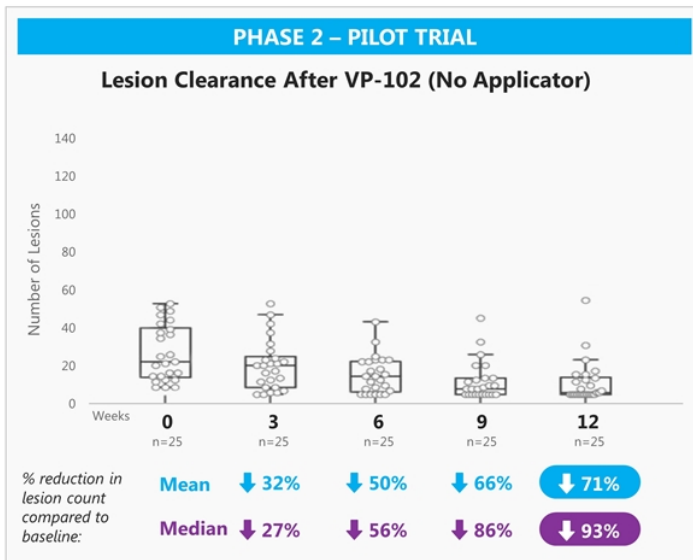
	TRIAL AND STATUS	FORMULATION / APPLICATION METHOD	TRIAL DESIGN	TRIAL OBJECTIVES
PHASE 3	Pivotal Trial CAMP-1 Enrollment Complete	VP-102	<ul style="list-style-type: none"> N=266 Conducted under SPA Randomized, double blind, multi-center, placebo controlled 	<ul style="list-style-type: none"> To evaluate 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
	Pivotal Trial CAMP-2 Enrollment Complete	VP-102	<ul style="list-style-type: none"> N=262 Randomized, double blind, multi-center, placebo controlled 	<ul style="list-style-type: none"> 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 Complete	VP-102	<ul style="list-style-type: none"> Open-label, single-center N=33 	<ul style="list-style-type: none"> To determine possible systemic exposure from a single 24-hour application of VP-102 To confirm safety and efficacy with applicator
	Pilot Trial Complete	Our proprietary formulation of cantharidin used in VP-102, applied with the wooden stick part of a cotton-tipped swab	<ul style="list-style-type: none"> Open-label, single-center N=30 	<ul style="list-style-type: none"> To evaluate safety and efficacy and determine optimal treatment duration

PHASE 2 TRIAL DATA DEMONSTRATES A FAVORABLE PROFILE FOR VP-102 IN MOLLUSCUM CLEARANCE



(1) Historical placebo data from third-party trials with cantharidin; No head-to-head trials have been run against VP-102.
 (2) Burke BE, Baillie J, Olson RD. Essential oil of Australian lemon myrtle (*Backhousia citriodora*) in the treatment of molluscum contagiosum in children. *Biomedicine & Pharmacotherapy* 2004; 58: 245-247.
 (3) Syed TA, Lundin S, Ahmad M. Topical 0.3% and 0.5% podophyloxytoxin cream for self-treatment of molluscum contagiosum in males. *Dermatology* 1994; 189:65-68.
 (4) Garelik J, Schairer D, Hwang H, Viola K, Cohen S. Safety and efficacy of topical cantharidin for the treatment of pediatric molluscum contagiosum: a prospective, randomized, double-blind, placebo-controlled trial. Unpublished.
 (5) Dosal C, Stewart PW, Lin JA, Williams CS, Morrell DS. Cantharidin for the treatment of molluscum contagiosum: a prospective, double-blinded, placebo-controlled trial. *Pediatric Dermatology* 2014;31(4):440-449.
 (6) Theos AU, Cummins R, Silverberg NB, Paller AS. Effectiveness of imiquimod cream 5% for treating childhood molluscum contagiosum in a double-blind, randomized pilot trial. *Cutis* 2004 Aug;74(2):134-8, 141-2.
 (7) FDA Clinical Executive Summary for Imiquimod for Pediatric Molluscum. NDA Submission Number 20723. Submission Code SE8-020. Letter Date September 21, 2006.
 (8) Olsen JR, Gallacher J, Finlay AY, Piquet V, Francis NA. Time to resolution and effect on quality of life of molluscum contagiosum in children in the UK: a prospective community cohort study. *Lancet Infect Dis* 2015;15(2):190-195.
 Natural history point estimates for the percent resolution at Weeks 12 and 18 were derived using the steepest slope of the % resolution versus time (months) curve corresponding to a linear portion between months 8 to 17. This portion of the curve shows the highest rate of resolution and demonstrates 50% of patients resolved the infection over 9 months. This supports point estimates of 17% at 12 weeks and 25% at 18 weeks.

PHASE 2 TRIAL DATA DEMONSTRATES A FAVORABLE PROFILE FOR VP-102 IN MOLLUSCUM CLEARANCE



(1) Trial enrolled 33 subjects into either the exposure group (N=17) or the standard group (N=16) with 32 subjects completing the trial. Exposure group subjects were required to have 21 or more lesions at the baseline visit and standard group subjects had 1 to 20 lesions.

WE HAVE COMPLETED ENROLLMENT IN TWO PIVOTAL PHASE 3 TRIALS (CAMP-1 & CAMP-2) IN MOLLUSCUM



Trial Design

Two identically designed, randomized, double-blinded, multicenter, placebo controlled trials

CAMP-1 conducted under FDA Special Protocol Assessment (SPA)

12-week study period



Endpoints

Primary:
Percent of subjects with complete clearance of molluscum at Day 84

Secondary:
Percent of subjects with complete clearance at week 3, 6, and 9
Safety & tolerability



Population

Subjects 2+ years of age with MC lesions who have not received any type of treatment within the past 14 days
Enrollment complete with 266 subjects for CAMP-1 and 262 subjects for CAMP-2



Application

Study drug (VP-102 or placebo) is administered topically to all treatable lesions every 21 days until clearance or a maximum of 4 applications

VP-102 or placebo will be left on for 24 hours before removal with soap and warm water

Our Opportunity in Common Warts



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VERRUCA VULGARIS (COMMON WARTS)

OVERVIEW

Caused by Human Papilloma virus (HPV)

Infects patients of all ages

Persistent infection, highly refractory

Typically 2-5 lesions

No FDA approved drug for the treatment of common warts

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ETIOLOGY AND CLINICAL PRESENTATION

Transmission

- Skin to skin contact
- Sharing of infected articles of clothing

Diagnosis & Symptoms

- Dome shaped flesh-colored lesions commonly on the hands, fingers, knees or elbows
- Lesions may occur in groups or in a linear pattern
- Lesions can cause considerable pain and discomfort, may spread with skin trauma, and can be itchy



Complications

- Scarring may occur
- Dyspigmentation of affected areas
- Bacterial superinfection of lesions
- Irritation, pain, and redness of surrounding skin

WE HAVE INITIATED A PHASE 2 TRIAL (COVE-1) IN WARTS



Trial Design

Open label, single center

Safety & tolerability

Second cohort to be added via amendment with ~40 additional subjects and a 21-day dosing regimen



Endpoints

Primary

Percent of subjects with complete clearance of all treatable warts (baseline and new) at Day 84

Secondary

Percent of subjects achieving complete clearance of all treatable warts at Visits 2, 3, and 4



Population

Approximately 20 subjects 2+ years of age with common warts who have not received any type of treatment within the past 14 days



Application

Study drug (VP-102) is administered topically to each treatable wart to a maximum of 4 applications or until complete clearance

Frequency of administration is at least 14 days between treatments during a 63 day treatment period

VP-102 will be left on for 24 hours before removal with soap and warm water

Commercial Opportunity



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DERMATOLOGISTS ARE FAMILIAR WITH VP-102'S API & WOULD USE IF AVAILABLE



Physicians who do not use the API of VP-102 **stated inaccessibility as a primary reason why they are not using**⁽¹⁾



Physicians reported they **would use VP-102 if the cost of the drug was covered**⁽²⁾

(1) Pompei DT et al. Cantharidin Therapy: Practice patterns and attitudes of health care providers. *Journal of the American Academy of Dermatology*. 2013; 68(6). Survey of 400 healthcare providers, 87.7% of responders were US based dermatologists.

(2) Company survey of 40 physicians.

INITIAL PAYER RESEARCH SUGGESTS FAVORABLE REIMBURSEMENT LANDSCAPE FOR VP-102

	COHORT SIZE	AVERAGE LIVES COVERED
Medical Directors	7	9.8M
Pharmacy Directors	6	4.2M
IDN Stakeholders	2	6.5M

Source: Third party study commissioned by the Company.

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The 15 Payer Organizations and Plans Represented in the Interviews Cover a Total of **105 Million Commercial & Medicaid Lives**

INITIAL PAYER RESEARCH SUGGESTS FAVORABLE REIMBURSEMENT LANDSCAPE FOR VP-102

Key Takeaways

- 1 Payers interviewed **recognize a significant unmet need** for molluscum contagiosum and lack of an effective treatment
- 2 Some of the **key concerns** mentioned about the undertreatment of the condition include the **risk of infection, scarring, or spread of the disease**
- 3 Payers **perceived VP-102 to be highly favorable** based on the majority of patients experiencing clearance within 12 weeks
- 4 Given the unmet need and favorable clinical outcomes, **payers anticipate the majority of patients would have access to VP-102** with minimal to no restrictions



Source: Third party study commissioned by the Company.

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VERRICA
PHARMACEUTICALS

INTEGRATED COMMERCIAL APPROACH WITH MULTIPLE STRATEGIC LEVERS

Commercial Strategy



PRE-COMMERCIALIZATION ACTIVITIES ONGOING

ENGAGEMENT AT KEY CONFERENCES



Society for Pediatric Dermatology, July

- Advisory Board and Poster Presentation



Summer American Academy of Dermatology, August

FALL CLINICAL DERMATOLOGY CONFERENCE*

Fall Clinical Dermatology, October

- Poster Presentation



American Academy of Pediatrics, November

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LAUNCH OF DISEASE AWARENESS CAMPAIGN



Digital and social research completed to understand content, traffic patterns, and influences



Tools being implemented through rest of year include:



Disease Awareness website "aboutmolluscum.com"



YouTube channel with KOL interview



Professional journal space



Speaker programs

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VERRICA HAS SEVERAL POTENTIAL WAYS TO MAINTAIN EXCLUSIVITY



Regulatory Exclusivity

5.5 years of exclusivity for cantharidin as API possible upon approval (inclusive of potential for 6 months for pediatric indication)



Compounding Pharmacies

If VP-102 is approved, traditional compounding pharmacies will NOT be able to continue compounding cantharidin regularly or in inordinate amounts, except under patient specific circumstances as prescribed by a physician.

The FDA has the authority to regulate compounders. Improper compounding can result in monetary fines plus felony convictions in case of repeat offenses and intent to fraud/mislead.



Manufacturing

VP-102 has the potential to address stability issues with standard packaging and container/closure systems

Limited commercial CMOs with facilities for handling highly potent and highly flammable liquid products

Entered into a supply agreement for naturally-sourced cantharidin; subject to specified minimum annual purchase orders and forecasts, supplier 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



True Generic Unlikely

Unlikely to receive approval under an ANDA due to uniqueness from patent pending protection and significant differences likely between VP-102 and potential competitors

Cannot do traditional PK/bioequivalence study (no blood level profile for VP-102)














May require new clinical studies with new formulation and new delivery approach that shows equivalence without violating any of Verrica's IP

OVERVIEW OF INTELLECTUAL PROPERTY PORTFOLIO

KEY CLAIMS AND PATENT APPLICATIONS	VALUE TO VERRICA
1 Our specific formulation (VP-102), key safety additions and novel cantharidin formulations (PCT/US2014/052184)	May prevent generics from copying our ether-free formulation or from making similar formulations
2 Single use applicator containing cantharidin formulations (PCT/US2014/052184)	May prevent generics from utilizing a single-use applicator for cantharidin that contains both a glass ampule to maintain product stability and a filter placed prior to dispensing tip, which helps increase administration accuracy and prevents direct contact with skin
3 Specific design of our commercial applicator (PCT/US2018/036353)	May prevent generics from utilizing a similar applicator
4 Methods of use for cantharidin in the treatment of molluscum (PCT/US2018/037808 and PCT/US2018/036353)	May prevent generics from a similar treatment regimen and label
5 Methods for purifying cantharidin and analyzing cantharidin or cantharidin solutions (PCT/US2016/14139)	May force generics to find alternative methodologies to produce GMP cantharidin or determine if their API or drug product is GMP compliant
6 Methods for complete cantharidin synthesis (PCT/US2015/066487 and 62/568,004)	Synthetic version would reduce risks of outside contaminants and environmental factors affecting the naturally-sourced API. May prevent generics competing with a synthetic version of cantharidin

Any patents issued from our applications are projected to expire between 2034 and 2039, excluding any patent term adjustment and patent term extensions

SIGNIFICANT EXPECTED MILESTONES

DATE	EVENT
 September 2017	End of Phase 2 Meeting with FDA
 1Q 2018	Received go ahead from FDA to initiate two Phase 3 trials, including SPA on pivotal trial
 1Q 2018	Initiated Phase 3 trials for molluscum and Phase 2 trial for warts
 1Q 2018	Executed purchase order for API that is expected to last through commercial launch
 1Q 2018	Hired COO, CFO, CCO and CMO with significant commercial experience and track record of success
 2Q 2018	Added dermatology veteran Mark Prygocki and KOL Dr. Gary Goldenberg to the Board of Directors
 3Q 2018	Entered into a supply agreement for naturally-sourced cantharidin
 3Q 2018	Completed enrollment in two pivotal Phase 3 trials in molluscum
 1Q 2019	Topline results from two pivotal Phase 3 trials in molluscum
 1H 2019	Topline results from Phase 2 trial in common warts
 2019	VP-102 NDA submission in molluscum
 2019	VP-103 IND submission in plantar warts
 2019	Initiate pivotal trials in common warts

INVESTMENT HIGHLIGHTS

★ Two of the Largest Unmet Needs in Dermatology

- Prevalence of ~6 million in molluscum contagiosum⁽¹⁾ and ~22 million in common warts in the U.S.⁽²⁾
- No FDA approved drugs to treat molluscum or warts

★ Late-Stage

- Enrollment complete in two pivotal Phase 3 trials in molluscum; topline results expected 1Q 2019

★ Favorable Tolerability

- No SAEs in Phase 2 trials for the treatment of molluscum

★ Physician Acceptance

- 95% of pediatric dermatologists have used API⁽³⁾

★ Innovative Product

- Drug-device combination of a proprietary formulation and a novel single-use applicator

★ Barriers to Competition

- New chemical entity regulatory exclusivity upon approval
- IP pending on product, including on novel formulation, applicator and methods of use
- Drug-device combination makes a 'true generic' unlikely

★ Proven Team

- Industry-leading, experienced management team

(1) Prevalence in the US of 5.1% to 11.5% in children aged 0-16 years. (Fam Pract. 2014 Apr;31(2):130-6). US Census estimates ~69.4MM children aged 0 to 16 years in 2016.

(2) IMS National Disease and Therapeutic Index (NDTI) Rolling 5 Years Ending June 2016. Nguyen et al. Laser Treatment of Nongenital Verrucae A Systemic Review. JAMA Dermatology. 2016; 152(9): 1025-1033

(3) Based on a survey of 115 dermatologists the results of which have been extrapolated to pediatric dermatologists.

Appendix



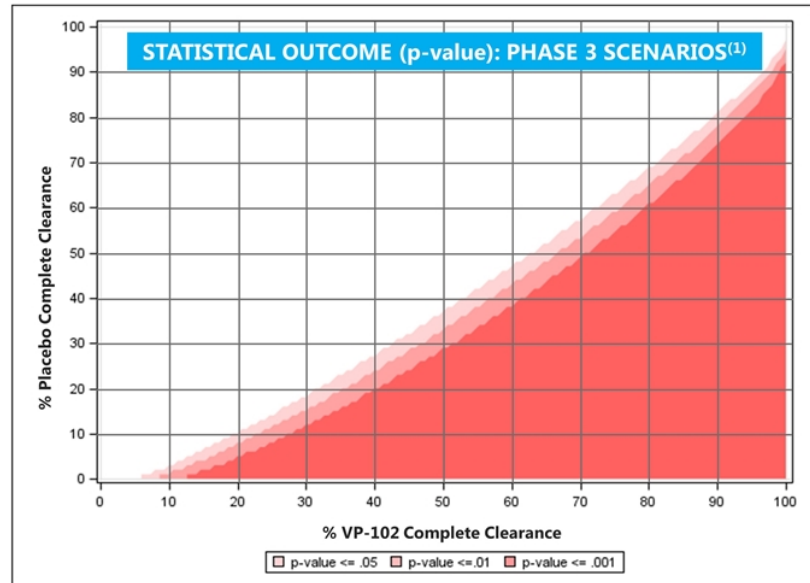
PHASE 3 STATISTICAL POWERING ASSUMPTIONS SUPPORT POSITIVE RESULTS ACROSS A RANGE OF POTENTIAL SCENARIOS

Phase 3 power assumptions:

- Sample size=250 subjects
- Randomization 3:2 (n=150 VP-102, n=100 placebo)
- 44% VP-102 complete clearance rate
- 20% Placebo complete clearance rate
- 10% drop out rate

Assumptions result in >95% power to detect treatment differences in clearance rates with a significance level of 0.05

P-values in graph represent Chi-Square test across different potential Phase 3 outcome scenarios



(1) P-values are from Pearson Chi-Squared test and are valid under the assumed conditions of n=250 subjects (3:2 randomization VP102:placebo)

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Matt Davidson, PhD

Founder
Former Chief Scientific Officer of Verrica



(1)(*)We intend to engage Dr. Lebwohl as principal investigator for future clinical trial(s) in our common warts program.
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