

**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): March 2, 2020**

**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))

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock	VRCA	The Nasdaq Stock Market LLC

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 March 2, 2020, Verrica Pharmaceuticals Inc. (the "**Company**") will be updating its company overview presentation on its website, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) 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	<a href="#">Company Presentation.</a>

**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: March 2, 2020

/s/ A. Brian Davis

A. Brian Davis  
Chief Financial Officer



# Company Overview

March 2020

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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 information in this presentation, including without limitation the forward-looking statements contained herein, 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 drug development process and the regulatory approval process, our reliance on third parties over which we may not always have full control, and other risks and uncertainties that are described in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the U.S. Securities and Exchange Commission (SEC) on March 7, 2019, and our other filings made 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**  
novel  
dermatology  
products



# INVESTMENT HIGHLIGHTS

## ★ Two of the Largest Unmet Needs in Dermatology

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

## ★ July 13, 2020 PDUFA Date for Ycanth™ (VP-102) for the Treatment of Molluscum Contagiosum

## ★ Positive Phase 3 Results in Molluscum Contagiosum

- Achieved statistical significance for primary endpoints in our Phase 3 CAMP-1 and CAMP-2 pivotal trials for Ycanth™ (VP-102)
- P-value <0.0001 for primary endpoint in both pivotal trials



## Positive Topline Phase 2 Results in Common Warts

- VP-102 achieved positive results on both the primary endpoint of complete clearance of all treatable warts at Week 12 (Day 84) and the secondary endpoint of the percentage reduction of warts

## ★ Innovative Product Candidate

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

## ★ Physician Acceptance

- 95% of pediatric dermatologists have used API<sup>(3)</sup>

## ★ Barriers to Competition

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

## ★ Proven Team

- Industry-leading, experienced management team with extensive clinical development and product launch experience

(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.

# OUR PRODUCT PORTFOLIO

YCANTH

VP-102

VP-103

	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA ACCEPTANCE	NEXT EXPECTED MILESTONE
<b>Molluscum Contagiosum</b>						PDUFA Goal Date: July 13, 2020
<b>Common Warts</b>						Initiate pivotal Phase 3 trials in 1H 2020
<b>External Genital Warts</b>						Topline Phase 2 results in 2H 2020
<b>Plantar Warts</b>						Initiate Phase 2 trial Mid 2020

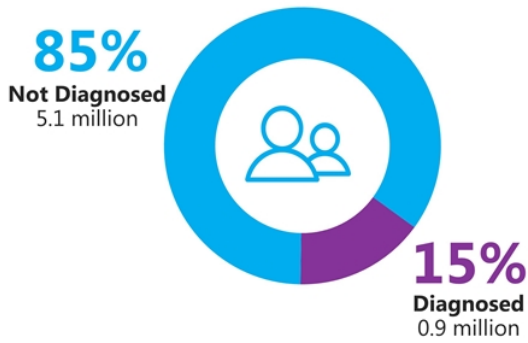
**We retain exclusive, royalty-free rights to our product candidates across all indications globally**



# TWO OF THE LARGEST UNMET NEEDS IN DERMATOLOGY

## Molluscum

US Prevalence of ~**6 million**<sup>(1)</sup> with  
~**1 million diagnosed annually**<sup>(2)</sup>



## Common Warts

US Prevalence of ~**22 million**<sup>(3)</sup> with  
~**1.5 million diagnosed annually**<sup>(4)</sup>



(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) IQVIA projected dataset for 12 months ending October 2017

(3) 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

(4) IQVIA Anonymous Longitudinal Patient Level Data (APLD) for 12 months ending September 2018

## **THE PROBLEM**

# **Molluscum Contagiosum**



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

## **THE SOLUTION**

# **YCANTH™**

**(VP-102)**



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

**GMP-controlled new formulation** of 0.7% w/v cantharidin

- Consistent and shelf-stable

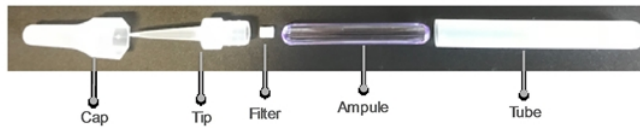
**Single-use applicator** to reduce cross-contamination and allow for more effective application of drug by HCP

**Visualization agent** to identify treated lesions

**Bittering agent** to deter oral ingestion

**Clinician administered, In-Office Procedure**

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# Molluscum Clinical Evidence



# WE HAVE SUCCESSFULLY COMPLETED 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



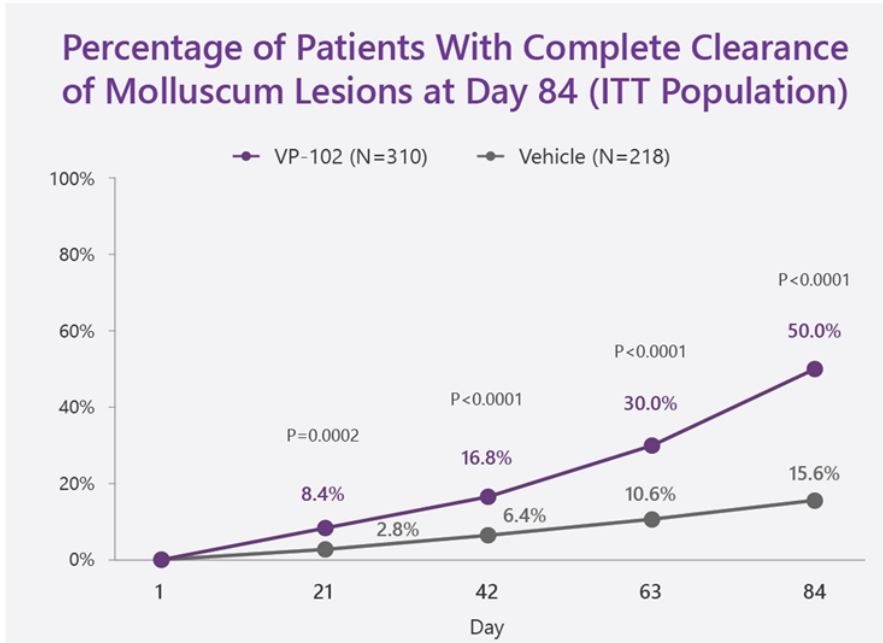
## Application

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

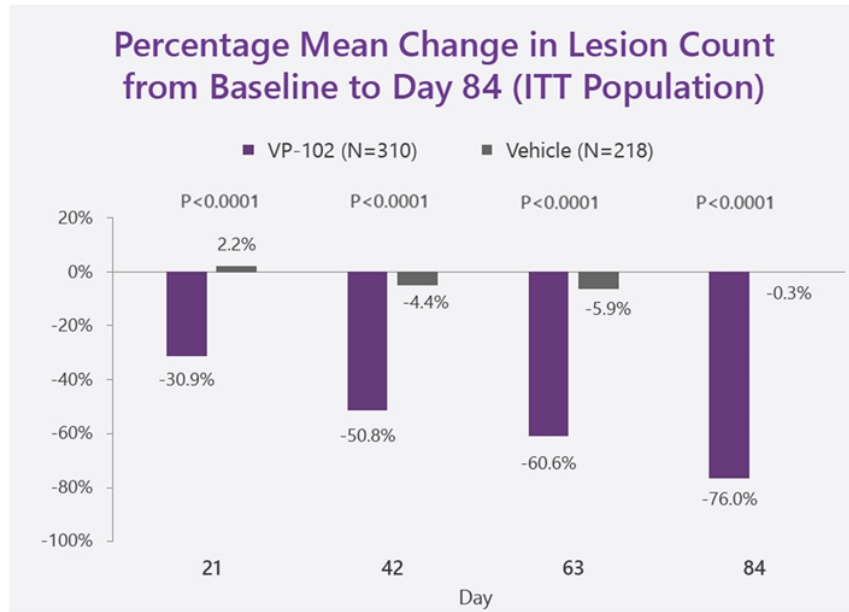
VP-102 or placebo will be left on for 24 hours before removal with soap and warm water



# PHASE 3 STUDIES IN MOLLUSCUM DEMONSTRATE STATISTICALLY SIGNIFICANT EFFICACY ON PRIMARY ENDPOINT OF COMPLETE CLEARANCE



# PHASE 3 STUDIES IN MOLLUSCUM DEMONSTRATE STATISTICALLY SIGNIFICANT EFFICACY ON PERCENT REDUCTION OF LESIONS



# PHASE 3 DISCONTINUATION RATES DUE TO TREATMENT-RELATED ADVERSE EVENTS

N (%)	VP-102 (N=311)	Vehicle (N=216)
Application Site Vesicles	5 (1.6)	0 (0)
Application Site Pain	3 (1.0)	0 (0)
Application Site Pruritus	1 (0.3)	0 (0)
Contact Dermatitis	1 (0.3)	0 (0)
<b>Total Discontinuation Rate</b>	<b>6 (1.9)</b>	<b>0 (0)</b>

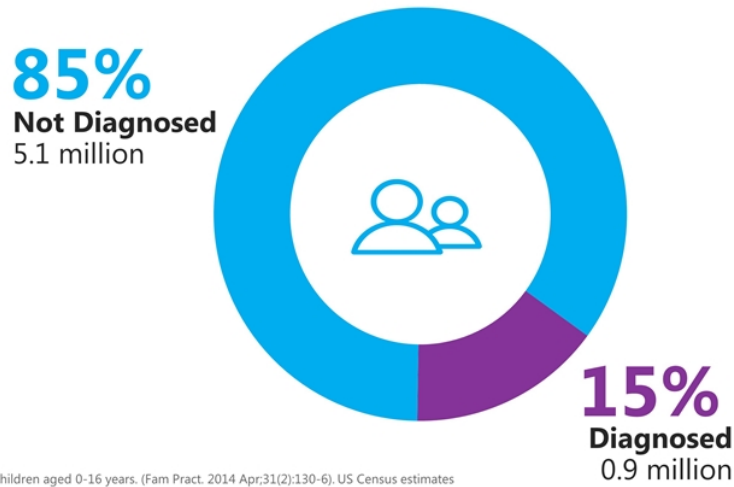
# MC Commercial Opportunity



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# REALIZING THE MOLLUSCUM OPPORTUNITY

US Prevalence of ~6 million in molluscum<sup>(1)</sup> with ~1 million diagnosed annually<sup>(2)</sup>



(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) IQVIA projected dataset for 12 months ending October 2017

# DERMATOLOGISTS ARE FAMILIAR WITH API USED IN YCANTH™ (VP-102) & WOULD USE IF AVAILABLE



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



Physicians reported they **would use Ycanth™ (VP-102) if the cost of the drug was covered**<sup>(2)</sup>

<sup>(1)</sup> 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.

<sup>(2)</sup> Company survey of 40 physicians.

# PHYSICIANS ARE HIGHLY FAVORABLE TO YCANTH (VP-102) PROFILE

## Derms and Ped Derms <sup>(1)</sup>



### KEY REASONS TO USE IF APPROVED

Efficacy	Precise and pain free application
FDA approval	Convenience of administration

## Pediatricians <sup>(1)</sup>



### KEY REASONS TO USE IF APPROVED

Efficacy	Fits into their current office model
Frustrated with not treating and having no viable options	

Scale of 1 (unlikely to use at all) to 7 (highly likely to use)

(1) Physician Qualitative research- one-hour individual interviews [n=30 Pediatricians, 13 Dermatologist, 5 Pediatric Dermatologists]

# INITIAL PAYER RESEARCH SUGGESTS FAVORABLE REIMBURSEMENT LANDSCAPE FOR YCANTH™ (VP-102)

	COHORT SIZE	AVERAGE LIVES COVERED
<b>Medical Directors</b>	7	9.8M
<b>Pharmacy Directors</b>	6	4.2M
<b>IDN Stakeholders</b>	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 YCANTH™ (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 YCANTH™ (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 in Phase 2 trials, **payers anticipate the majority of patients would have access to YCANTH™ (VP-102)** with minimal to no restrictions



Source: Third party study commissioned by the Company.

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# INTEGRATED COMMERCIAL APPROACH WITH MULTIPLE STRATEGIC LEVERS

## Commercial Strategy



# VERRICA HAS SEVERAL POTENTIAL WAYS TO MAINTAIN EXCLUSIVITY



## Regulatory Exclusivity

5.5 years of exclusivity for cantharidin as API potentially available 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 Ycanth™ (VP-102) and potential competitors

Cannot do traditional PK/bioequivalence study (no blood level profile for Ycanth™ (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
<p>1 Our specific formulation, YCANTH™ (VP-102), key safety additions and novel cantharidin formulations (PCT/US2014/052184)</p> <p>2 Single use applicator containing cantharidin formulations (PCT/US2014/052184)</p>	<p>May prevent generics from copying our ether-free formulation or from making similar formulations</p> <p>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</p>
<p>2 Specific design of our commercial applicator (PCT/US2018/036353)</p>	<p>May prevent generics from utilizing a similar applicator</p>
<p>3 Methods of use for cantharidin in the treatment of molluscum (PCT/US2018/037808 and PCT/US2018/036353)</p>	<p>May prevent generics from a similar treatment regimen and label</p>
<p>4 Methods for purifying cantharidin and analyzing cantharidin or cantharidin solutions (PCT/US2016/14139)</p>	<p>May force generics to find alternative methodologies to produce GMP cantharidin or determine if their API or drug product is GMP compliant</p>
<p>5 Methods for complete cantharidin synthesis (PCT/US2015/066487)</p>	<p>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</p>

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

# Our Opportunity in Common Warts



# 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
- Touching of contaminated objects

### 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 SUCCESSFULLY COMPLETED A PHASE 2 STUDY (COVE-1) IN COMMON WARTS



## Study Design

Efficacy, safety & tolerability

Open label study with two cohorts

Cohort 1: one center  
Cohort 2: four centers



## 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  
Change from baseline in number (%) of treatable warts at Day 84



## Patients

Cohort 1: 21 subjects 2+ years of age with common warts, who have not received any type of treatment within the past 14 days

Cohort 2: 35 subjects 12+ 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

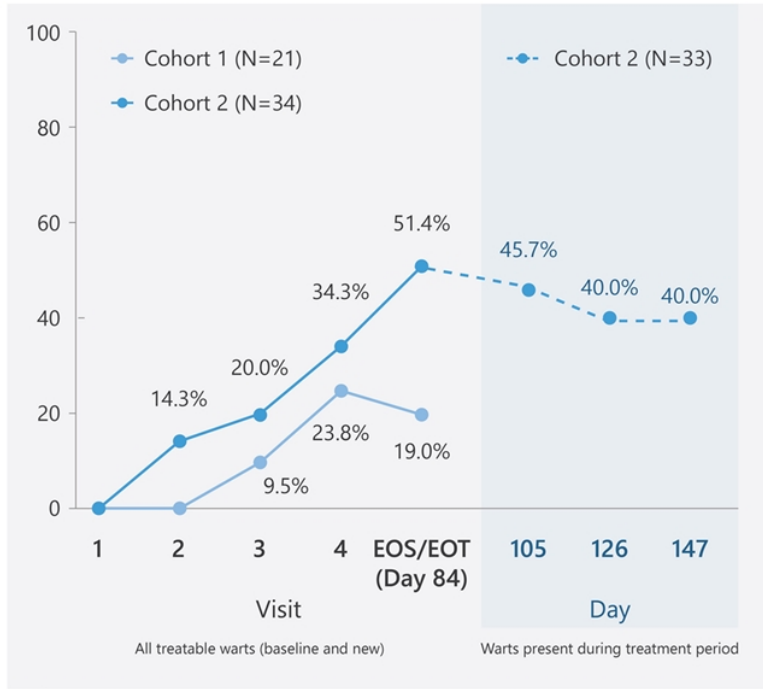
Cohort 1 is treated until clear, Cohort 2 receives one additional treatment at the first visit clearance was observed up to a maximum of 4 total applications

Frequency of administration is at least 14 days (Cohort 1) or 21 days (Cohort 2)

Paring was allowed in Cohort 2

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

# VP-102 DEMONSTRATED CLINICALLY MEANINGFUL EFFICACY ON PRIMARY ENDPOINT OF COMPLETE CLEARANCE IN COVE-1 STUDY














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# DISCONTINUATION RATES FOR COVE-1

	Cohort 1 VP-102 (N=21)	Cohort 2 VP-102 (N=35)
<b>Discontinued (total, N(%))</b>	4 (19.0%)	2 (5.7%)
Lost to follow-up	2 (9.5%)	1 (2.9%)
Withdrawal by subject	2 (9.5%)	0
Protocol violation	0	1 (2.9%)

## SIGNIFICANT RECENT AND EXPECTED MILESTONES

DATE	EVENT
 <b>1Q 2019</b>	Positive topline results from two pivotal Phase 3 trials in molluscum
 <b>2Q 2019</b>	Positive topline results from Phase 2 trial in common warts
 <b>2Q 2019</b>	Initiate Phase 2 trial in external genital warts
 <b>3Q 2019</b>	Ycanth™ (VP-102) NDA submission in molluscum
 <b>4Q 2019</b>	FDA acceptance of Ycanth™ (VP-102) NDA submission in molluscum
 <b>4Q 2019</b>	VP-103 IND submission in plantar warts
 <b>1H 2020</b>	Initiate pivotal Phase 3 trials in common warts
 <b>Mid 2020</b>	Initiate Phase 2 trial in plantar warts
 <b>2H 2020</b>	Ycanth™ (VP-102) PDUFA Goal Date July 13, 2020 in molluscum
 <b>2H 2020</b>	Topline results from Phase 2 trial in external genital warts
 <b>2H 2020</b>	Commercial launch of Ycanth™ (VP-102) for molluscum