### 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): April 17, 2020

## Verrica Pharmaceuticals Inc.

(Exact Name of Registrant as Specified in its Charter)

46-3137900 (IRS Employer Identification No.) 001-38529 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 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: Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) П 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: Name of each exchange on which registered The Nasdaq Stock Market LLC Title of each class Common Stock

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  $\ oxtimes$ 

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.  $\boxtimes$ 

#### Item 7.01 Regulation FD Disclosure.

On April 17, 2020, Verrica Pharmaceuticals Inc. ("Verrica" or the "Company") will be updating its corporate 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 8.01 Other Events

On April 15, 2020, Ted White, Verrica's President & CEO, delivered a virtual presentation at the 19th Annual Needham Healthcare Conference. During the presentation, which was webcast, Mr. White provided updated information regarding Verrica's planned clinical trials in light of the COVID-19 pandemic. In particular, Mr. White reported that, given the current conditions related to the Coronavirus, Verrica is monitoring the situation very closely and the Company intends to launch Phase 3 clinical trials to evaluate VP-102 for common warts when conditions are appropriate. In addition, the Company also plans to launch the proposed Phase 2 clinical trial to evaluate VP-103 in subjects with plantar warts when conditions are appropriate. Prior to the pandemic and the widespread adoption of "sheltering in place" and "stay at home" orders, the Company remained on track to initiate Phase 3 trials of VP-102 for common warts in the first half of 2020 and the Phase 2 trial of VP-103 for plantar warts in mid-2020, as previously publicly reported.

Statements contained in this Current Report on Form 8-K regarding the timing of the initiation of Verrica's planned clinical trials constitute "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on Verrica's current beliefs and expectations. 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 relating to the severity, duration and spread of the COVID-19 outbreak, as well as the direct and indirect impacts that the pandemic may have on the conditions to initiate the planned clinical trials, as well as other risks and uncertainties that are described in Verrica's Annual Report on Form 10-K for the year ended December 31, 2019, filled with the U.S. Securities and Exchange Commission on March 13, 2020, and other filings Verrica makes with the U.S. Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this report and are based on information available to Verrica as of the date of this report, 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.

#### Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.

Description

99.1 <u>Company Presentation.</u>

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: April 17, 2020

/s/ A. Brian Davis
A. Brian Davis
Chief Financial Officer



# **Company Overview**

April 2020

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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 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 forwardlooking 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, 2019, filed with the U.S. Securities and Exchange Commission (SEC) on March 13, 2020, 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.





VERRICA PHARMACEUTICALS

## 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.<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-
- 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

#### 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



<sup>(1)</sup> 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**

		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA ACCEPTANCE	NEXT EXPECTED MILESTONE
YCANTH	Molluscum Contagiosum					$\longrightarrow$	PDUFA Goal Date: July 13, 2020
102	Common Warts			$\longrightarrow$			Initiate pivotal Phase 3 trials*
dV	External Genital Warts	•		$\rightarrow$			Topline Phase 2 results in 2H 2020
VP-103	Plantar Warts			$\rightarrow$			Initiate Phase 2 trial*

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

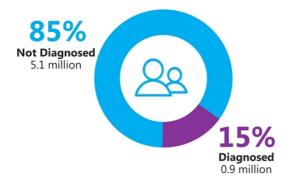


 $<sup>\</sup>mbox{\ensuremath{^{\star}}}\xspace$  Timing for initiating new clinical trials uncertain due to COVID-19 pandemic

## TWO OF THE LARGEST UNMET NEEDS IN DERMATOLOGY

## **Molluscum**

US Prevalence of ~6 million(1) with ~1 million diagnosed annually(2)



### **Common Warts**

US Prevalence of ~22 million(3) with ~1.5 million diagnosed annually(4)



- (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



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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><li>Pain and scarring</li><li>Unsuitable for use in children</li></ul>
Curettage	Using a curette or a surgical instrument with a scoop at the tip to scrape the lesions	<ul><li>Pain and scarring</li><li>Unsuitable for use in children</li></ul>
Laser Surgery	Applying a laser to target and destroy the lesions	<ul><li>Pain, cost and lack of availability</li><li>Unsuitable for use in children</li></ul>
Topical Products	Applying various acids (e.g. salicylic acid), creams or blistering solutions to destroy the lesions	Unproven efficacy
Off-Label Drugs	Retinoids, antiviral medicines, or immune modulating therapies	<ul><li>Limited efficacy</li><li>Side-effects</li></ul>
Natural Remedies	Applying natural oils (e.g. tea tree oil) with antimicrobial properties	<ul><li>Unproven efficacy</li><li>Pain, irritation and allergic reactions</li></ul>
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## THE SOLUTION

# YCANTH™ (VP-102)



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# 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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## **CANTHARIDIN ELICITS A DUAL RESPONSE IN THE SKIN**



## Superficial blistering of lesional skin

Cantharidin is a vesicant, causing the pharmacodynamic response of blistering in the skin. Once applied, cantharidin activates neutral

serine proteases that cause degeneration of the desmosomal plaque and intraepidermal blistering.(1)



Desmosome Cleavage and Blister Formation



## **Elicits Inflammation & Immune Response**

Cantharidin stimulates leukocyte infiltration (e.g., neutrophils, macrophages, B and T cells and eosinophils) and the release of chemokines and cytokines including TNF-a, IL-8 and CXCL-5.(2)



J Invest Dermatol. 1962 Jul;39:39-45.
 J Immunol Methods. 2001 Nov 1;257(1-2):213-20.2

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# SIGNIFICANT CLINICAL PROGRESS OF YCANTH $^{\text{\tiny M}}$ (VP-102) FOR THE TREATMENT OF MOLLUSCUM

	TRIAL AND STATUS	FORMULATION / APPLICATION METHOD	TRIAL DESIGN	TRIAL OBJECTIVES
HASE 3	Pivotal Trial CAMP-1 Complete	VP-102	<ul> <li>N=266</li> <li>Conducted under SPA</li> <li>Randomized, double blind, multi-center, placebo controlled</li> </ul>	<ul> <li>To evaluate the efficacy of dermal application of VP-102 relative to placebo for complete clearance at day 84</li> <li>To assess the safety and tolerability of VP-102</li> </ul>
Ы	Pivotal Trial CAMP-2 Complete	VP-102	<ul> <li>N=262</li> <li>Randomized, double blind, multi-center, placebo controlled</li> </ul>	<ul> <li>To evaluate the efficacy of dermal application of VP-102 relative to placebo for complete clearance at day 84</li> <li>To assess the safety and tolerability of VP-102</li> </ul>
PHASE 2	<b>Innovate Trial</b> Complete	VP-102	<ul><li>Open-label, single-center</li><li>N=33</li></ul>	<ul> <li>To determine possible systemic exposure from a single 24-hour application of VP-102</li> <li>To confirm safety and efficacy with applicator</li> </ul>
	Pilot Trial Complete	Our proprietary formula of cantharidin used in VP-102, applied with the wooden stick part of a cotton-tipped swab	<ul><li>Open-label, single-center</li><li>N=30</li></ul>	To evaluate safety and efficacy and determine optimal treatment duration

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# 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

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## **DEMOGRAPHICS IN PHASE 3 MOLLUSCUM TRIALS**

	VP-102	Vehicle
	(N=311)	(N=216)
Age (years)		
Mean (SD)	7.5 (6.7)	6.8 (5.8)
Median	6.0	6.0
Range	2 – 60	2 – 54
Age Group – no. (%)		
≥2 to 5 yr	138 (44.4)	105 (48.6)
≥6 to 11 yr	139 (44.7)	89 (41.2)
≥12-18 yr	23 (7.4)	17 (7.9)
≥19 yr	11 (3.5)	5 (2.3)
Gender – no. (%)		
Female	155 (49.8)	105 (48.6)
Male	156 (50.2)	111 (51.4)
Race or Ethnic Group – no. (%)		
White	277 (89.1)	201 (93.1)
Black or African American	14 (4.5)	7 (3.2)
Asian	6 (1.9)	1 (0.5)
American Indian/Alaskan Native	0	1 (0.5)
Other	14 (4.5)	6 (2.8)



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## **MOLLUSCUM HISTORY FOR SUBJECTS IN PHASE 3 TRIALS**

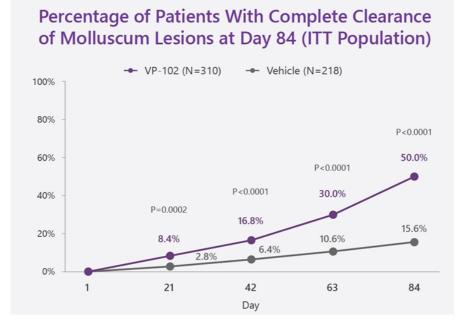
	<b>VP-102</b> (N=311)	<b>Vehicle</b> (N=216)
Baseline Lesion Count	( /	
Mean (SD)	20.5 (23.1)	22.5 (22.3)
Median	12.0	15.5
Range	1 – 184	1 – 110
Time Since Clinical Diagnosis (days)		
Mean (SD)	123.3 (200.7)	126.2 (199.3)
Median	26.0	31.5
Range	1 – 1247	1 – 1302
Age at Diagnosis (years)		
Mean (SD)	7.1 (6.7)	6.5 (5.9)
Median	6.0	5.0
Range	1 – 60	1 – 54
Previous Treatment for Molluscum – no. (%)		
Yes	90 (28.9)	71 (32.9)
Atopic Dermatitis (AD) – no. (%)		
History or Active AD	50 (16.1)	35 (16.2)
Active AD*	23 (7.4)	20 (9.2)

<sup>\*</sup> Active atopic dermatitis was determined by concomitant medication usage of the following medications during the study: topical corticosteroids, topical calcineurin inhibitors, and/or PDE-4 inhibitors. Copyright © 2020 Verrica Pharmaceuticals. All rights reserved.

Note: Slide reflects pooled data from Phase 3 molluscum trials (CAMP-1 and CAMP-2)



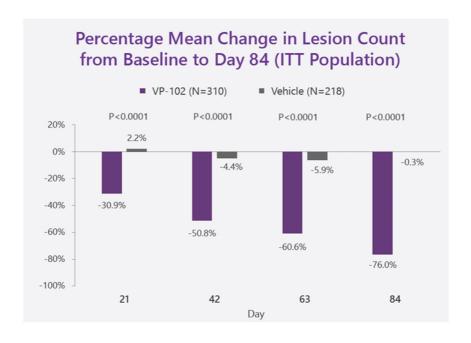
## PHASE 3 STUDIES IN MOLLUSCUM DEMONSTRATE STATISTICALLY SIGNIFICANT EFFICACY ON PRIMARY ENDPOINT OF COMPLETE CLEARANCE





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



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## **SAFETY SUMMARY FOR MOLLUSCUM PHASE 3 TRIALS**

## Incidence of Treatment Emergent Adverse Events (TEAEs) ≥5%

	VP-102 (N=311)	Vehicle (N=216)
At Least One Incidence: N (%)		
Application Site Vesicles	298 (95.8)	63 (29.2)
Application Site Pain	193 (62.1)	36 (16.7)
Application Site Pruritus	169 (54.3)	75 (34.7)
Application Site Scab	147 (47.3)	47 (21.8)
Application Site Erythema	139 (44.7)	58 (26.9)
Application Site Discoloration	100 (32.2)	27 (12.5)
Application Site Dryness	63 (20.3)	31 (14.4)
Application Site Edema	29 (9.3)	10 (4.6)
Application Site Erosion	22 (7.1)	2 (0.9)

## Treatment Emergent Adverse Events (TEAEs) ≥5% by Severity

		VP-102 (N=311)			Vehicle (N=216)	
At Least One Incidence: N (%)	Mild	Moderate	Severe	Mild	Moderate	Severe
Application Site Vesicles	187 (60.1)	100 (32.2)	11 (3.5)	59 (27.3)	4 (1.9)	0
Application Site Pruritus	145 (46.6)	23 (7.4)	1 (0.3)	62 (28.7)	13 (6.0)	0
Application Site Pain	127 (40.8)	59 (19.0)	7 (2.3)	34 (15.7)	2 (0.9)	0
Application Site Scab	120 (38.6)	27 (8.7)	0	44 (20.4)	3 (1.4)	0
Application Site Discoloration	87 (28.0)	12 (3.9)	1 (0.3)	25 (11.6)	2 (0.9)	0
Application Site Erythema	73 (23.5)	65 (20.9)	1 (0.3)	43 (19.9)	15 (6.9)	0
Application Site Dryness	58 (18.6)	5 (1.6)	0	30 (13.9)	1 (0.5)	0
Application Site Edema	21 (6.8)	8 (2.6)	0	7 (3.2)	3 (1.4)	0
Application Site Erosion	20 (6.4)	2 (0.6)	0	2 (0.9)	0	0



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# 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)
Total Discontinuation Rate	6 (1.9)	0 (0)

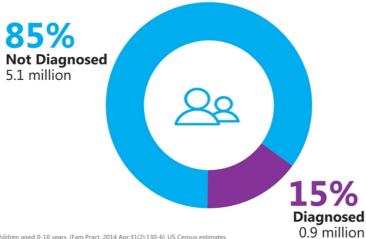






## **REALIZING THE MOLLUSCUM OPPORTUNITY**

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



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.
 IQVIA projected dataset for 12 months ending October 2017

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# 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(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 dermatologi; 20 Company survey of 40 physicians.

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

## **Derms and Ped Derms** (1)



## **KEY REASONS TO USE IF APPROVED**

Efficacy	Precise and pain free application
FDA approval	Convenience of administration

## **Pediatricians** (1)



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

## **KEY REASONS TO USE IF APPROVED**

Efficacy Fits into their current office model

Frustrated with not treating and having no viable options

(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
Medical Directors	7	9.8M
Pharmacy Directors	6	4.2M
IDN Stakeholders	2	6.5M



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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**

- Payers interviewed **recognize a significant unmet need** for molluscum contagiosum and lack of an effective treatment
- Some of the **key concerns** mentioned about the undertreatment of the condition include the **risk of infection**, **scarring**, **or spread of the disease**
- Payers **perceived Ycanth™ (VP-102) to be highly favorable** based on the majority of patients experiencing clearance within 12 weeks
- 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**



## KOL Engagement

Strong established relationships and support



Distribution with supportive HUB services

Dedicated field reimbursement Team



Targeting office based dermatologists and select pediatricians

## Dedicated Institutional Team

Specialists to promote to pediatric dermatologists in academic settings and group practices

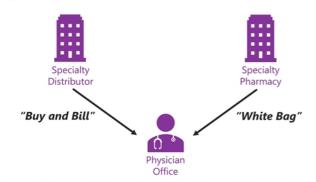
## Disease Awareness

Increase treatment seekers through costefficient consumer advertising

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# YCANTH™ (VP-102) DESIGNED TO BE CLINICIAN ADMINISTERED AND INTEND TO DISTRIBUTE THROUGH SPECIALTY PRODUCT CHANNELS, IF APPROVED



Potential Physician Reimbursement Opportunities			
"Buy and Bill"	"White Bag"		
Office visit	Office visit		
Procedure for lesion destruction	Procedure for lesion destruction		
$Ycanth^{TM} (VP-102) = (ASP + X\%)$			



(1) Verrica intends to file for a product-specific J-code for VP-102

Note: For illustrative purposes only. If approved, actual distribution channels and support services may change as strategy is finalized.

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## PRE-COMMERCIALIZATION ACTIVITIES ONGOING

## **ENGAGEMENT AT KEY CONFERENCES**



WINTER CLINICAL DERMATOLOGY

FALL CLINICAL DERMATOLOGY CONFERENCE®

Poster Presentation







National and Regional Meetings



National and Regional Meetings





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## **DISEASE AWARENESS**

Caregiver MC education through digital and social tools HCP MC education through congresses, speaker programs, and professional journal space

## **OTHER**

Trade distribution channel development

Customer segment insights

Brand strategy, customer segmentation, and targeting

Commercial systems infrastructure







## **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



**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** 

topically to each treatable wart to a maximum of 4 applications

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

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# **DEMOGRAPHICS IN COVE-1 STUDY**

	Cohort 1 VP-102 (N=21)	<b>Cohort 2</b> <b>VP-102</b> (N=35)
Randomized	21	35
Age (years)		
Mean	38	38
Median	37	42
Min, Max	7, 83	12, 67
Gender (N (%))		
Female	11 (52.4%)	22 (62.9%)
Male	10 (47.6%)	13 (37.1%)

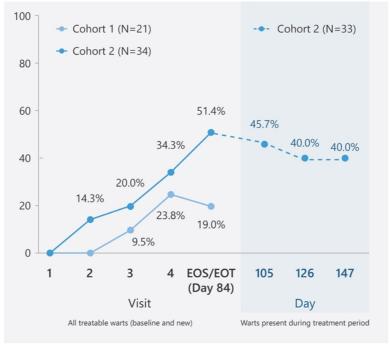


# WART HISTORY FOR SUBJECTS IN COVE-1 STUDY

	<b>Cohort 1</b> <b>VP-102</b> (N=21)	<b>Cohort 2</b> <b>VP-102</b> (N=35)
Time Since Clinical Diagnosis (months)	70.3	15.9
Age at Diagnosis (mean, years)	32.1	36.4
Any Previous Treatments for Common Warts? (Yes)	3 (14.3%)	24 (68.6%)
Wart Number at Baseline (mean)	2.19	1.65

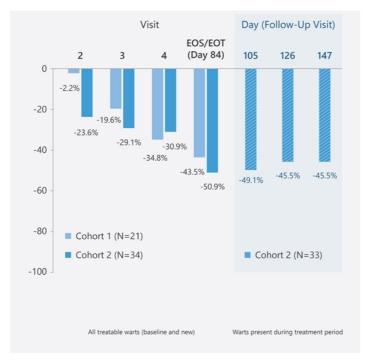


# VP-102 DEMONSTRATED CLINICALLY MEANINGFUL EFFICACY ON PRIMARY ENDPOINT OF COMPLETE CLEARANCE IN COVE-1 STUDY





# VP-102 DEMONSTRATED CLINICALLY MEANINGFUL EFFICACY ON PERCENT CHANGE IN NUMBER OF COMMON WARTS FROM BASELINE IN COVE-1 STUDY





# ADVERSE EVENTS IN COVE-1 STUDY (INCIDENCE≥5%)\*

	Cohort 1 N=21 (To Day 84)	<b>Cohort 2</b> N=34 (To Day 147)
Incidence: N (%)		
Application Site Vesicles	20 (95.2)	27 (79.4)
Application Site Pain	15 (71.4)	26 (76.5)
Application Site Erythema	13 (61.9)	19 (55.9)
Application Site Pruritus	9 (42.9)	16 (47.1)
Application Site Scab	8 (38.1)	20 (58.8)
Application Site Dryness	6 (28.6)	13 (38.2)
Application Site Edema	4 (19.0)	6 (17.6)
Application Site Discoloration	1 (4.8)	8 (23.5)
Application Site Exfoliation	0	4 (11.8)
Application Site Erosion	0	3 (8.8)
Papilloma Viral Infection**	0	3 (8.8)

<sup>\*</sup> Local skin reactions were expected due to the pharmacodynamic action of cantharidin. \*\* Warts reported with verbatim term of 'ring wart' and coded to MeDRA.



# **ADVERSE EVENTS FOR COVE-1 STUDY BY SEVERITY (INCIDENCE≥5%)**

		Cohort 1 N=21 (To Day 84)			Cohort 2 N=34 (To Day 147)	
Incidence: N (%)	Mild	Moderate	Severe	Mild	Moderate	Severe
Application Site Vesicles	18 (85.7)	1 (4.8)	1 (4.8)	16 (47.1)	10 (29.4)	1 (2.9)
Application Site Pain	11 (52.4)	3 (14.3)	1 (4.8)	17 (50)	6 (17.6)	3 (8.8)
Application Site Pruritus	9 (42.9)	0	0	16 (47.1)	0	0
Application Site Erythema	7 (33.3)	5 (23.8)	1 (4.8)	14 (41.2)	5 (14.7)	0
Application Site Scab	6 (28.6)	1 (4.8)	1 (4.8)	18 (52.9)	2 (5.9)	0
Application Site Dryness	6 (28.6)	0	0	12 (35.3)	1 (2.9)	0
Application Site Edema	2 (9.5)	2 (9.5)	0	5 (14.7)	0	1 (2.9)
Application Site Discoloration	1 (4.8)	0	0	6 (17.6)	1 (2.9)	1 (2.9)
Application Site Erosion	0	0	0	0	2 (5.9)	1 (2.9)
Application Site Exfoliation	0	0	0	3 (8.8)	1 (2.9)	0
Papilloma Viral Infection	0	0	0	1 (2.9)	2 (5.9)	0



# **DISCONTINUATION RATES FOR COVE-1**

	Cohort 1 VP-102 (N=21)	Cohort 2 VP-102 (N=35)
Discontinued (total, N(%))	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%)



## **REALIZING THE COMMON WARTS OPPORTUNITY**

US Prevalence of ~22 million in common warts(1) with ~1.5 million diagnosed annually(2)



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







# **CONDYLOMA ACUMINATUM (GENITAL WARTS)**

#### **OVERVIEW**

Caused by human papilloma virus (HPV)

Lesions on the surface of the skin in the genital and perianal regions

Highly contagious and recurrences are common

Treatment options have limitations

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#### **ETIOLOGY AND CLINICAL PRESENTATION**

Transmission

- · Skin to skin contact
- · Spread through sexual contact

Diagnosis & Symptoms

- Can be flat, dome-shaped, keratotic, pedunculated and cauliflower-shaped
- Lesions may occur singularly, in clusters, or as plaques
- Lesions can be itchy, and can cause pain and discomfort



Complications

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

43 VERRICATE PHARMACEUTICALS

## PHASE 2 STUDY (CARE) IN EXTERNAL GENITAL WARTS (EGW)



Study Design

Multi-center, double-blind, placebo-controlled

Dose regimen, efficacy, safety & tolerability

Study comprised of two parts (A and B)
Primary objective of Part A is to identify the two
best dosing regimens for evaluation in Part B



**Endpoints** 

#### Primary

Percent of subjects with complete clearance of all treatable warts at Day 84

#### Secondary

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



**Patients** 

Part A:  $\sim$ 18 subjects 18+ years of age with 2-30 external genital and/or perianal warts for  $\geq$  4 weeks at baseline visit

Part B:  $\sim$ 90 subjects 18+ years of age with 2-30 external genital and/or perianal warts for  $\geq$  4 weeks at baseline visit



**Application** 

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

Part A: To include 3 treatment groups with a 2-hour, 6-hour and 24-hour duration of skin exposure before removal with soap and warm water

Part B: Two selected treatment dosing regimens (duration of skin exposure) based on Part A with follow up period through Day 147

Frequency of administration is every 21 days





Regulatory Exclusivity and Intellectual Property



# VERRICA HAS SEVERAL POTENTIAL WAYS TO MAINTAIN EXCLUSIVITY



Regulatory Exclusivity

5 years of exclusivity for cantharidin as API potentially available upon approval (potential for additional 6 months for pediatric exclusivity where applicable)



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
Our specific formulation, Ycanth™ (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
Single use applicator containing cantharidin formulation (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
Specific design of our commercial applicator (PCT/US2018/036353)	May prevent generics from utilizing a similar applicator
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
Methods for purifying cantharidin and analyzing canth or cantharidin solutions (PCT/US2016/14139)	aridin May force generics to find alternative methodologies to produce GMP cantharidin or determine if their API or drug product is GMP compliant
Methods for complete cantharidin synthesis (PCT/US2015/066487)	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 RECENT AND EXPECTED MILESTONES

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

<sup>\*</sup> Timing for initiating new clinical trials uncertain due to COVID-19 pandemic



#### 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.<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-
- 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

#### 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



<sup>(1)</sup> 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**



## 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

4 Inconvenient and variable

· Application with the wooden stick

part of a cotton-tipped swab can

lead to patients receiving more drug

administration

than necessary

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- 2 Inconsistent purity and lack of controlled product manufacturing
  - · Risk of impurities present such as residual solvents and pesticides

(5) Limited availability

FDA approved product

containing cantharidin(1)

· Illegal to import formulated cantharidin

and academic settings, which require

· Generally not available in hospitals

Only an estimated 7% of 503B compounders produce formulations

#### (3) Lack of reimbursement

· Not FDA approved and therefore not eligible for drug reimbursement







· Inability for physicians to identify where the drug has been applied

(1) Based on 57 503B facilities and 4 compounders of cantharidin per FDA database (January – June 2019)

**VERRICA** 

# MANAGEMENT TEAM WITH EXTENSIVE PRODUCT LAUNCH AND DERMATOLOGY EXPERIENCE



**Ted White**President & Chief
Executive Officer





A. Brian Davis

Chief Financial

Officer



tengion NEOSE



Patrick Burnett MD, PhD Chief Medical Officer







Joe Bonaccorso
Chief Commercial
Officer



Selected Launched Products















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