

# **Company Overview**

April 2020



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# **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<sup>™</sup> (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

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



<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.

<sup>(2)</sup> 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

# **OUR PRODUCT PORTFOLIO**



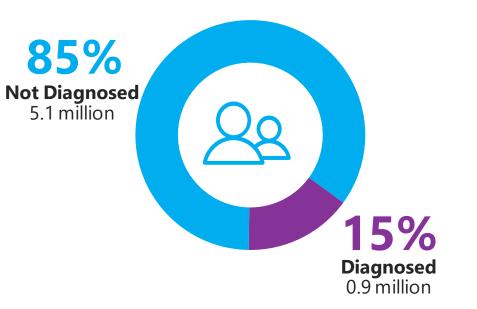
We retain exclusive, royalty-free rights to our product candidates across all indications globally



## TWO OF THE LARGEST UNMET NEEDS IN DERMATOLOGY

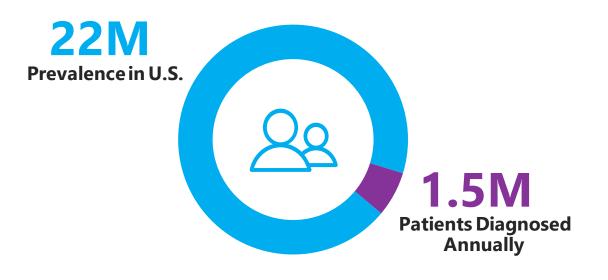
### Molluscum

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

### **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

### DESCRIPTION

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>

LIMITATIONS





## **THE SOLUTION**

# YCANTH™ (VP-102)



## YCANTH<sup>™</sup> (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







# Molluscum Clinical Evidence

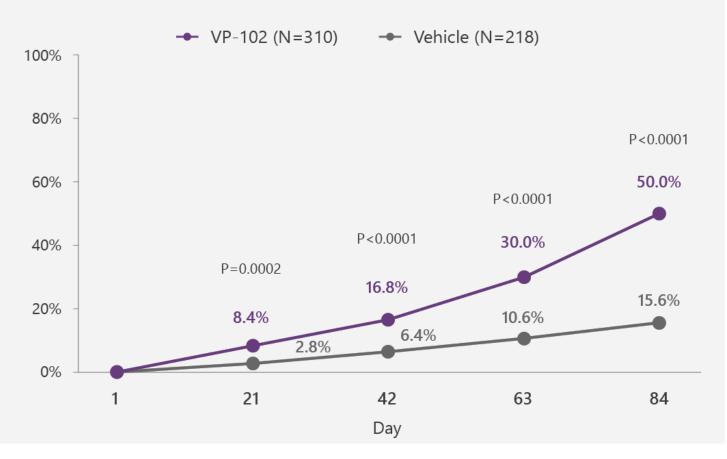
## WE HAVE SUCCESSFULLY COMPLETED TWO PIVOTAL PHASE 3 TRIALS (CAMP-1 & CAMP-2) IN MOLLUSCUM

EXAMPLE IN Trial Design A double-blinded, multicenter, placebo	AMP-1 conducted under DA Special Protocol ssessment (SPA) 12-week study period
Endpoints       Primary:       Percent of subjects with complete clearance of molluscum at Day 84       Secondary         Safety & to	subjects with complete clearance at week 3, 6, and 9
<b>Population</b> Subjects 2+ years of age with MC lesions who have not Enrollment complete with 266 subjects for CAMP-1 and	t received any type of treatment within the past 14 days d 262 subjects for CAMP-2
<b>Application</b> 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

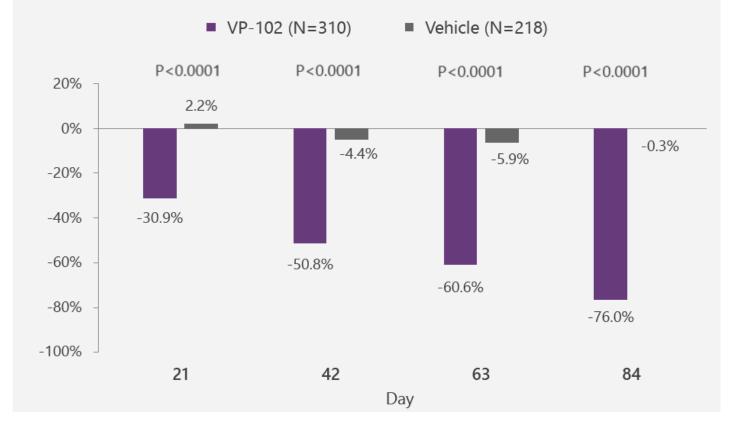
Percentage of Patients With Complete Clearance of Molluscum Lesions at Day 84 (ITT Population)



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

## Percentage Mean Change in Lesion Count from Baseline to Day 84 (ITT Population)





## 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)

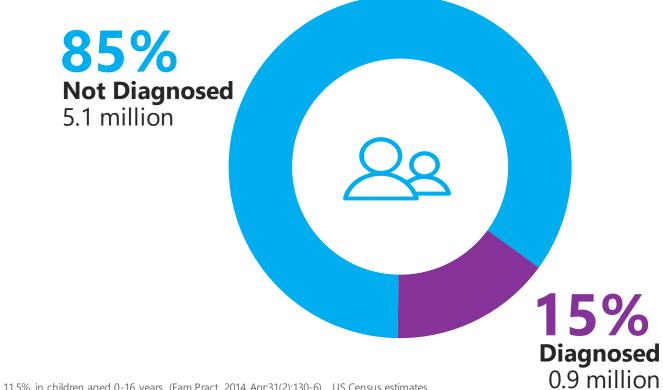




# MC Commercial Opportunity

# **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.

(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<sup>™</sup> (VP-102) if the cost of the drug was covered<sup>(2)</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.
 Company survey of 40 physicians.



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

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

13 5.6

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

EfficacyPrecise and pain free applicationFDA approvalConvenience of administration

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



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



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



Source: Third party study commissioned by the Company.

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

## Key Takeaways

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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<sup>™</sup> (VP-102) to be highly favorable** based on the majority of patients experiencing clearance within 12 weeks







Source: Third party study commissioned by the Company.

## INTEGRATED COMMERCIAL APPROACH WITH MULTIPLE STRATEGIC LEVERS

## **Commercial Strategy**



KOL Engagement

> Strong established relationships and support

Buy and Bill or Specialty Pharmacy

Distribution with supportive HUB services

Dedicated field reimbursement Team Specialized Sales 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



## VERRICA HAS SEVERAL POTENTIAL WAYS TO MAINTAIN EXCLUSIVITY

A BUT	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 systemsLimited 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 <sup>™</sup> (VP-102) and potential competitors (VP-102) )	valence ood level May require new clinical studies with new formulation and new delivery



# **OVERVIEW OF INTELLECTUAL PROPERTY PORTFOLIO**

#### **KEY CLAIMS AND PATENT APPLICATIONS**

VALUE TO VERRICA

Any patents issued from our appli	cations are projected to expire between 2034 and 2039,
<ul><li>Methods for complete cantharidin synthesis (PCT/US2015/066487)</li></ul>	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
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
<ul> <li>Methods of use for cantharidin in the treatment</li> <li>of molluscum (PCT/US2018/037808 and PCT/US2018/036353)</li> </ul>	May prevent generics from a similar treatment regimen and label
Specific design of our commercial applicator (PCT/US2018/036353)	May prevent generics from utilizing a similar applicator
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
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

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

#### **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

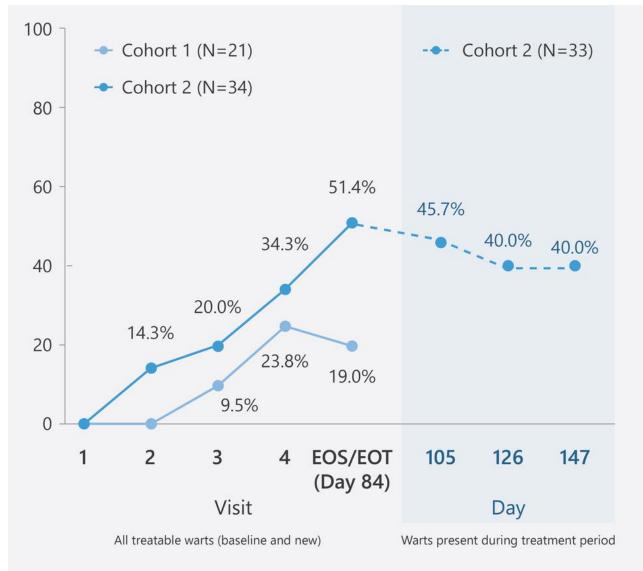
- Scarring may occur
  - Dyspigmentation of affected areas
  - Bacterial superinfection of lesions
  - Irritation, pain, and redness of surrounding skin



## 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	<b>Primary</b> Percent of subjects with complete clearand all treatable warts (baseline and new) at D	ce of of all treatable wa	s achieving complete clearance rts at Visits 2, 3, and 4 eline in number (%) of treatable
<u>8</u>	Patients	Cohort 1: 21 subjects 2+ years of age with con not received any type of treatment within the Cohort 2: 35 subjects 12+ years of age with co not received any type of treatment within the	past 14 days ommon warts, who have	
	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 at least 14 days (Cohort 1) o days (Cohort 2) Paring was allowed in Coho	or 21 for 24 hours before removal with soap

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



## **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%)



# 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
$\bigcirc$	1H 2020	Initiate pivotal Phase 3 trials in common warts
$\bigcirc$	Mid 2020	Initiate Phase 2 trial 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

