# 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): November 10, 2020**

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

| Delaware | 001-38529 | 46-3137900 |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| 10 North High Street, Suite 200<br>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:

☐ 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 November 10, 2020, Verrica Pharmaceuticals Inc. (the "***Company***") issued a press release to announce positive topline results from its Phase 2 clinical trial of VP-102 in patients with external genital warts. The Company is also posting an updated version of the Company's corporate presentation on its website. Copies of the press release and presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01 and Exhibits 99.1 and 99.2 hereto, 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

| Exhibit Number | Exhibit Description |
|---|---|
| 99.1 | Press Release dated November 10, 2020. |
| 99.2 | Company Presentation. |
| 104 | Cover Page Interactive Data File (embedded with Inline XBRL document). |

**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.**

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

Date: November 10, 2020

**Verrica Pharmaceuticals Announces Positive Topline Results in Phase 2 Clinical Study of VP-102 in Patients with External Genital Warts (CARE-1)**

*- 35% of subjects treated with VP-102 achieved complete clearance of all treatable genital warts vs 2.4% for vehicle (p=0.0001) -*

*- VP-102 was well-tolerated with no reported serious adverse events related to VP-102 -*

*- Approximately 500,000 to 1 million cases of EGW are newly diagnosed per year in the United States -*

*- Based on positive outcome, Verrica will request an End-of-Phase 2 meeting with the FDA -*

WEST CHESTER, Pa., November 10, 2020 (GLOBE NEWSWIRE) — Verrica Pharmaceuticals Inc. (Verrica) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced positive topline results from its Phase 2 CARE-1 clinical study of VP-102, a novel topical therapy containing a solution of 0.7% (w/v) cantharidin in a proprietary single-use applicator, in external genital warts (EGW). VP-102 achieved positive results on both the primary endpoint of complete clearance of all treatable EGW at Day 84 and the secondary endpoint of the percentage reduction of EGW at Day 84.

“The positive results of the Phase 2 CARE-1 trial suggest that VP-102 has the potential to provide patients and physicians with a well-tolerated and effective option for treatment,” said Gary Goldenberg, MD, Chief Medical Officer of Verrica. “Based on the positive outcome from CARE-1, we intend to request an End-of-Phase 2 meeting with the FDA for the treatment of EGW in the first quarter of 2021.”

”EGW, otherwise known as condyloma acuminata, are one of the most common sexually-transmitted infections in the U.S., often resulting in substantial social stigma, negative impact on quality of life, and an increased risk of HPV-related cervical cancer,” said Neal Bhatia, MD, Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego. “Undertreatment of EGW presents an interdisciplinary public health issue, as patients often seek treatment from a variety of sources including dermatologists, urologists, gynecologists, and primary care physicians. Newer medical therapeutic advances may offer more tolerable and effective approaches to controlling the spread of EGW and therefore can improve outcomes for these patients.”

CARE-1 was a Phase 2, double-blind, vehicle-controlled clinical study of VP-102 to determine the dose regimen, efficacy, safety, and tolerability of VP-102 in subjects with EGW in subjects 18 years of age or older. The study included two sequential parts: Part A and Part B. Part A was conducted in 18 subjects at four research sites. Subjects received treatment with VP-102 to treatable EGW every 21 days for up to four treatments and were told to wash off VP-102 within either 2, 6, or 24 hours of application. Safety results from Part A supported use of VP-102 for both 6-hour and 24-hour treatment exposures in Part B.

Part B was conducted in an additional 87 subjects at nine research sites comparing vehicle to VP-102 applied for either 6 or 24 hours for up to four treatments. The primary analyses were conducted at Day 84. Topline analyses included data from the assessment of EGW at study visits at days 21, 42, 63, and 84.

Study Results and Demographics:

- Subjects presented with a mean wart count of 8.2 with a range of 2 to 30 EGW at baseline. Approximately 50% of subjects had EGW for one year or longer; approximately 23% of subjects had EGW for more than five years.
- Pooled results from the 6- and 24-hour treatment exposures showed 35.1% (20/57) of subjects treated with VP-102 achieved complete clearance of all treatable EGW at Day 84 compared to 2.4% (1/42) of subjects treated with vehicle (p=0.0001).
- For both the 6- and 24-hour treatment exposures, subjects treated with VP-102 achieved statistically significantly larger reductions in percent change from baseline in the number of treatable EGW compared to vehicle at Day 84: 6-hour (p< 0.0001), 24-hour group (p=0.0003).
- VP-102 was well-tolerated. Side effects experienced by the VP-102 treated subjects were consistent with the pharmacodynamic action of cantharidin as a blistering agent. These side effects were primarily mild-to-moderate and included application site vesicles, pain and erythema. No subjects discontinued from the study due to adverse events and there were no serious adverse events reported that were considered related to treatment by the investigator.

In addition to requesting an End-of-Phase 2 meeting with the FDA on next steps for the development of VP-102 for the treatment of EGW, Verrica plans to submit the Phase 2 CARE-1 data for presentation at future medical meetings and for publication in a peer-reviewed medical journal.

**About Genital Warts**

Genital warts (also known as anogenital warts or condyloma acuminatum) are a sexually transmitted viral infection caused by multiple different types of the human papilloma virus (HPV). Approximately 500,000 to 1 million cases of EGW are newly diagnosed per year in the United States, with clinically apparent warts presenting in 1% of the sexually active population (Yanofsky 2012 *Clinical and Aesthetic Dermatol*). HPV is spread through direct skin-to-skin contact, usually during oral, genital, or anal sexual contact with an infected partner. Diagnosis of genital warts is usually made by visual inspection and can be confirmed by biopsy. The four morphologic types of genital warts are cauliflower-shaped, smooth papular, keratotic, and flat. Genital warts cause few symptoms but can occasionally be painful. Conditions known to predispose women to infection with HPV include local trauma, diabetes, and immuno-suppression.

**About Verrica Pharmaceuticals Inc.**

Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. The Company's late-stage product candidate, VP-102, is a potential first-in-class drug-device combination product containing a topical therapy for the treatment of molluscum contagiosum. Verrica submitted an NDA for VP-102 for the treatment of molluscum in September 2019. A Complete Response Letter was received from the FDA regarding the NDA for VP-102 on July 13, 2020. In October 2020, Verrica participated in a Type A meeting with the FDA. Verrica expects to resubmit its New Drug Application for VP-102 for the treatment of molluscum in the first quarter of

2021. If approved, VP-102 will be marketed in the United States under the conditionally accepted brand name YCANTH™. In addition, Verrica has successfully completed a Phase 2 study of VP-102 for the treatment of common warts and a Phase 2 study of VP-102 for the treatment of external genital warts. The Company is also developing VP-103, its third cantharidin-based product candidate, for the treatment of plantar warts. For more information, visit www.verrica.com.

**Forward-Looking Statement**

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 Company's expectations with regard to the potential benefits and clinical development plan for VP-102 for the treatment of EGW, Verrica's interactions and communications with the FDA, and the potential approval of VP-102 to treat EGW, common warts and 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 drug development process and the regulatory approval process, Verrica's reliance on third parties over which it may not always have full control, uncertainties related to the COVID-19 pandemic and other risks and uncertainties that are described in Verrica's Annual Report on Form 10-K for the year ended December 31, 2019, Verrica's Quarterly Report on Form 10-Q for the quarter ended September 30, 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 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.

FOR MORE INFORMATION, PLEASE CONTACT:

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Exhibit 99.

VERRICA™ PHARMACEUTICALS

*Reinventing Skin Science*

# Company Overview

November 2020

# 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, interactions with the FDA, including regarding the CRL Verrica received related to its NDA submission for VP-102 for the treatment of molluscum, 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, 2019, filed with the U.S. Securities and Exchange Commission (SEC) on March 13, 2020, our Quarterly report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 9, 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.

# INVESTMENT HIGHLIGHTS

- **YCANTH™ in Development to Address 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
- **Completed Type A Meeting with FDA for YCANTH™ (VP-102) for the Treatment of Molluscum**
  - Anticipate resubmission of NDA in Q1 2021
- **Positive Phase 3 Results in Molluscum Contagiosum**
  - Achieved statistical significance for primary endpoints in two pivotal trials for YCANTH™ (VP-102)
  - P-value <0.0001 for primary endpoint in both pivotal trials
- **Innovative Product Candidate**
  - Proprietary drug-device combination of formulation and single-use applicator
- **Physician Acceptance**
  - 95% of pediatric dermatologists have used API[3]
- **Dermatology Oncology**
  - Worldwide rights to LTX-315: first-in-class oncolytic peptide injected directly into tumor
  - Positive tumor-specific immune cell responses in multi-indication Phase 1/2 oncology trials
  - Verrica to focus initially on development to treat basal cell and squamous cell carcinomas
  - 5.4 million diagnoses annually in the U.S. of basal and squamous cell skin cancers[4]; patients typically treated with surgery
  - Submission of U.S. IND anticipated during first half of 2021
- **Option Agreement with Torii Pharmaceuticals for Development and Commercialization of VP-102 in Japan**
  - Torii option includes Verrica product candidates for the treatment of molluscum and common warts in Japan
- **Proven Team**
  - Industry-leading, experienced management team with extensive dermatology product launch experience
  - Strengthened clinical and drug development leadership in August 2020

(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.
(4) https://www.cancer.org/cancer/basal-and-squamous-cell-skin-cancer/about/key-statistics.html and Rogers *JAMA Derm* 2015

# OUR PRODUCT PORTFOLIO

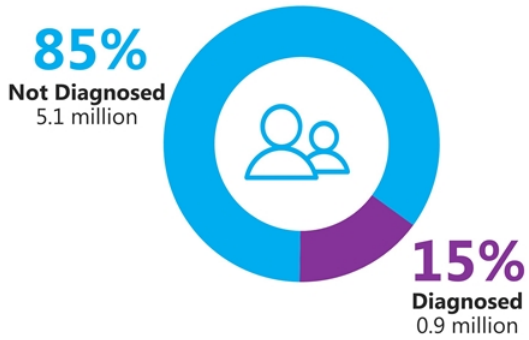
| | | PRE-IND | PHASE 2 | PHASE 3 | NDA | NEXT EXPECTED MILESTONE |
|---|---|---|---|---|---|---|
| YCANTH | Molluscum Contagiosum | | | | | Resubmission of NDA in Q1 2021 |
| VP-102 | Common Warts | | | | | Initiate pivotal Phase 3 trials* |
| | External Genital Warts | | | | | Request End-of-Phase 2 meeting in Q1 2021 |
| VP-103 | Plantar Warts | | | | | Initiate Phase 2 trial* |
| LTX-315 | Non-Melanoma Skin Cancer** | | | | | Submit US IND during 1H 2021 |

* Timing for initiating new clinical trials to be determined
** Initially focused on basal cell and squamous cell carcinomas

# YCANTH™ IN DEVELOPMENT TO ADDRESS 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

# 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



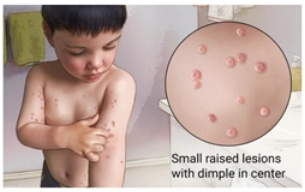
## ETIOLOGY AND CLINICAL PRESENTATION

**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 | LIMITATIONS |
|---|---|---|
| **Cryotherapy** | Freezing the lesions with liquid nitrogen | • Pain and scarring<br>• Unsuitable for use in children |
| **Curettage** | Using a curette or a surgical instrument with a scoop at the tip to scrape the lesions | • Pain and scarring<br>• Unsuitable for use in children |
| **Laser Surgery** | Applying a laser to target and destroy the lesions | • Pain, cost and lack of availability<br>• Unsuitable for use in children |
| **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 | • Limited efficacy<br>• Side-effects |
| **Natural Remedies** | Applying natural oils (e.g. tea tree oil) with antimicrobial properties | • Unproven efficacy<br>• Pain, irritation and allergic reactions |



VERRICA PHARMACEUTICALS

## 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

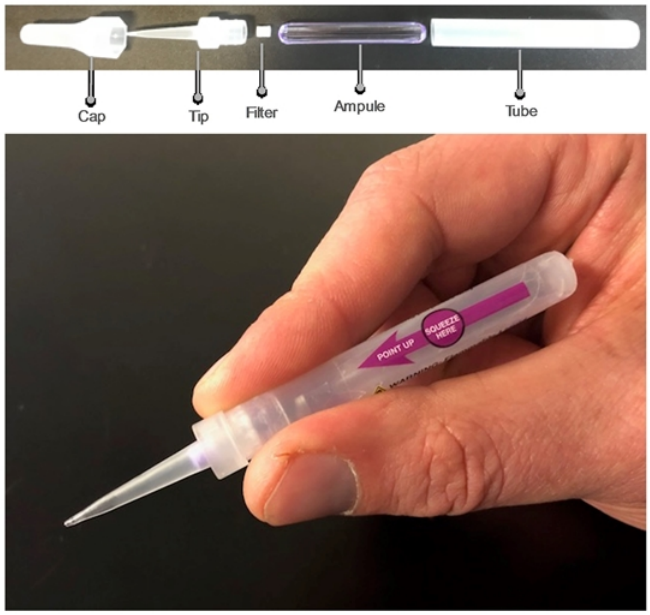
**Single-use applicator** to reduce cross-contamination and allow for more effective application of drug by HCP

**Visualization agent** to identify treated lesions

**Bittering agent** to deter oral ingestion

**Clinician** administered, **In-Office** Procedure





# U.S. REGULATORY STATUS

- NDA for VP-102 for molluscum contagiosum submitted in September 2019
- CRL received July 2020
  - No clinical safety or efficacy issues identified
  - Requests for additional information regarding certain aspects of CMC and Human Factors validation
- Completed Type A Meeting in October 2020
- Next steps
  - Accelerating incorporation of ampule breaking tool
    - Previously planned to incorporate ampule breaking tool post-approval as a potential convenience for healthcare providers
  - Conduct human factors study and obtain additional supportive stability data on the fully assembled device
  - Resubmit NDA (anticipated by end of Q1 2021)

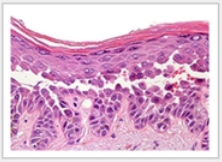
# Molluscum Clinical Evidence

# CANTHARIDIN ELICITS A DUAL RESPONSE IN THE SKIN

## 1 Superficial blistering of lesional skin

Cantharidin is a vesicant, causing the pharmacodynamic response of blistering in the skin.

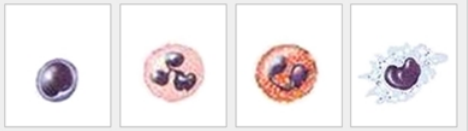
Once applied, cantharidin activates neutral serine proteases that cause degeneration of the desmosomal plaque and intraepidermal blistering.(1)



Desmosome Cleavage and Blister Formation

## 2 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)



Lymphocyte Neutrophil Eosinophil Macrophage

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

# SIGNIFICANT CLINICAL PROGRESS OF YCANTH™ (VP-102) FOR THE TREATMENT OF MOLLUSCUM

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

# 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





VERRICA PHARMACEUTICALS

# DEMOGRAPHICS IN PHASE 3 MOLLUSCUM TRIALS

| | VP-102 (N=311) | Vehicle (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) |





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

# MOLLUSCUM HISTORY FOR SUBJECTS IN PHASE 3 TRIALS

| | VP-102 (N=311) | Vehicle (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) |

* 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.

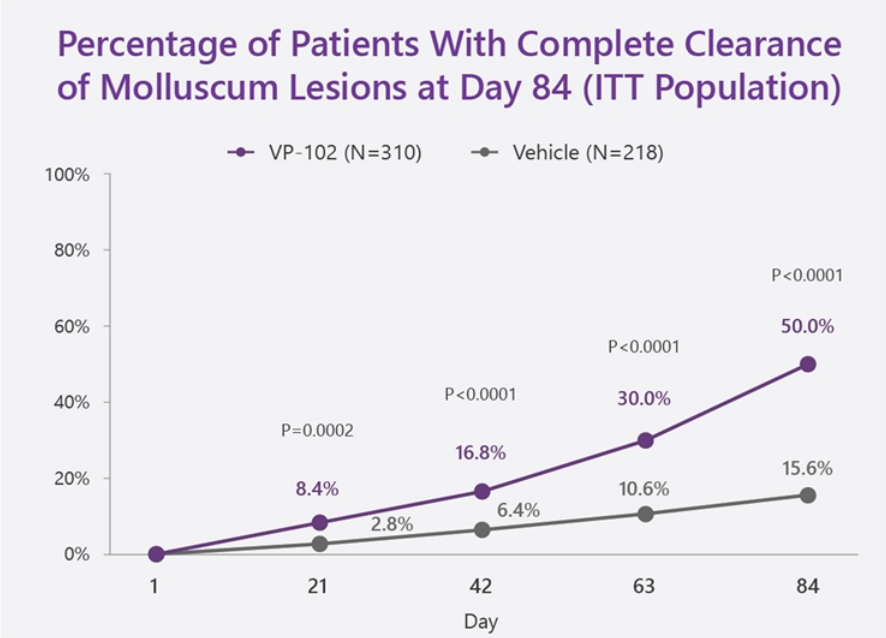


Note: Slide reflects pooled data from Phase 3 molluscum trials (CAMP-1 and CAMP-2)



VERRICA PHARMACEUTICALS

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

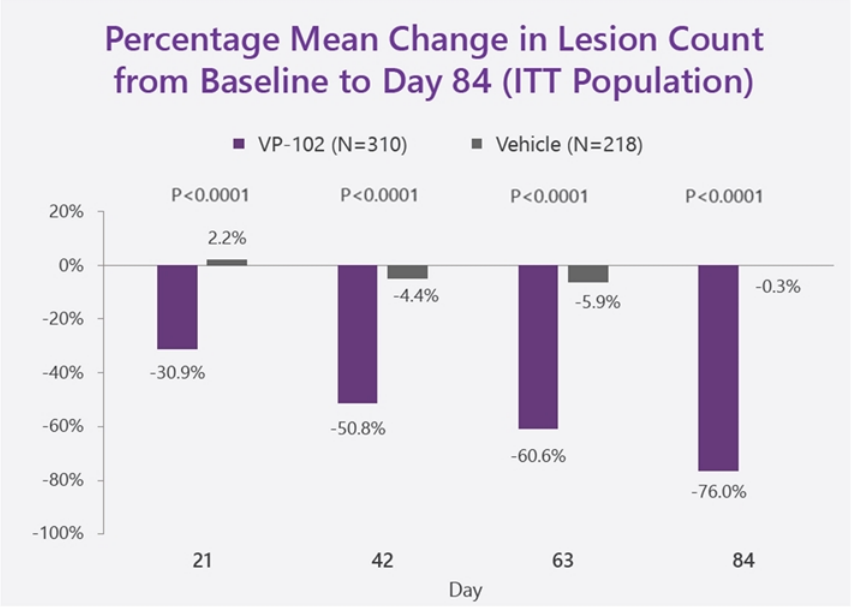







Note: Slide reflects pooled data from Phase 3 molluscum trials (CAMP-1 and CAMP-2)

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








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

# 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 |





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

# 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)** |



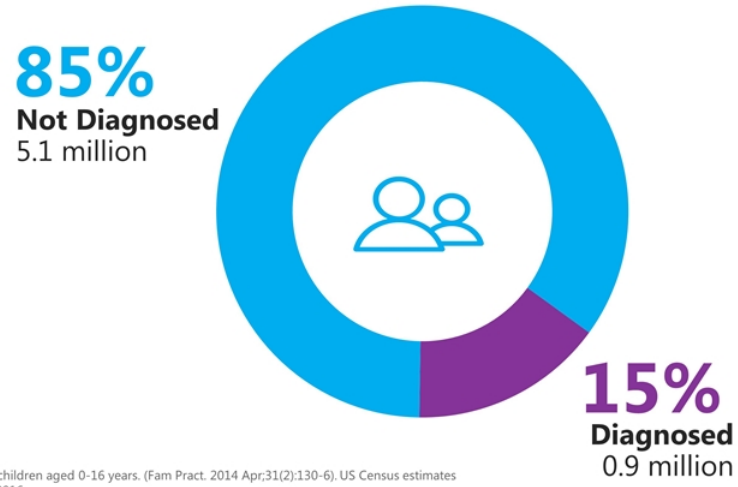


Note: Slide reflects pooled data from Phase 3 molluscum trials (CAMP-1 and CAMP-2)

# MC Commercial Opportunity

# REALIZING THE MOLLUSCUM OPPORTUNITY

US Prevalence of **~6 million in molluscum**[1] with **~1 million diagnosed annually**[2]




(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**[(1)]


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 dermatologists.
(2) Company survey of 40 physicians.

# 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)


### 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 |
|---|---|---|
| **Medical Directors** | 7 | 9.8M |
| **Pharmacy Directors** | 6 | 4.2M |
| **IDN Stakeholders** | 2 | 6.5M |

Source: Third party study commissioned by the Company.



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



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# 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

**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 cost-efficient consumer advertising





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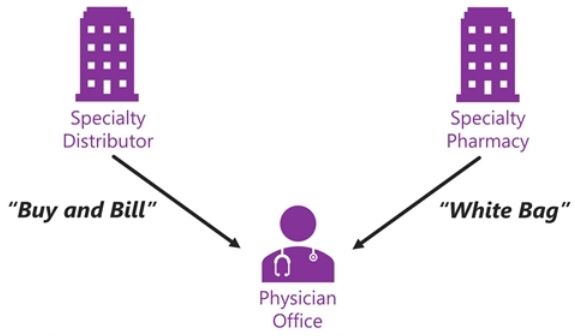
# YCANTH™ (VP-102) DESIGNED TO BE CLINICIAN ADMINISTERED AND INTEND TO DISTRIBUTE THROUGH SPECIALTY PRODUCT CHANNELS, IF APPROVED




| Potential Physician Reimbursement Opportunities | |
|---|---|
| **"Buy and Bill"** | **"White Bag"** |
| Office visit | Office visit |
| Procedure for lesion destruction | Procedure for lesion destruction |
| YCANTH™ (VP-102) = (ASP + X%) | |

**Distribution model will be supported by a patient and HCP services platform (HUB)**

- Benefits investigation/verification to determine coverage
- Full reimbursement support for miscellaneous J-code under medical benefit (1)
- Prior authorization support
- Co-pay/co-insurance assistance

**Dedicated field reimbursement team to support physician offices**

(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.

# PRE-COMMERCIALIZATION ACTIVITIES ONGOING

## Engagement at Premier Venues & Industry Channels

| | | |
|---|---|---|
| The Society for pediatric dermatology | Winter Clinical Dermatology | Fall Clinical Dermatology Conference® Poster Presentation |
| American Academy of Dermatology AAD 1938 | American Academy of Pediatrics National and Regional Meetings | SDPA National and Regional Meetings |
| South Beach Symposium clinical + aesthetic dermatology | MauiDerm The Dermatology Meetings | JAMA Network |

## 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



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# 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
- U.S prevalence of 22 million[1], with 1.5 million[2] diagnosed annually



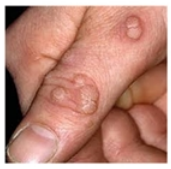
## ETIOLOGY AND CLINICAL PRESENTATION

**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

(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



VERRICA PHARMACEUTICALS

# 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

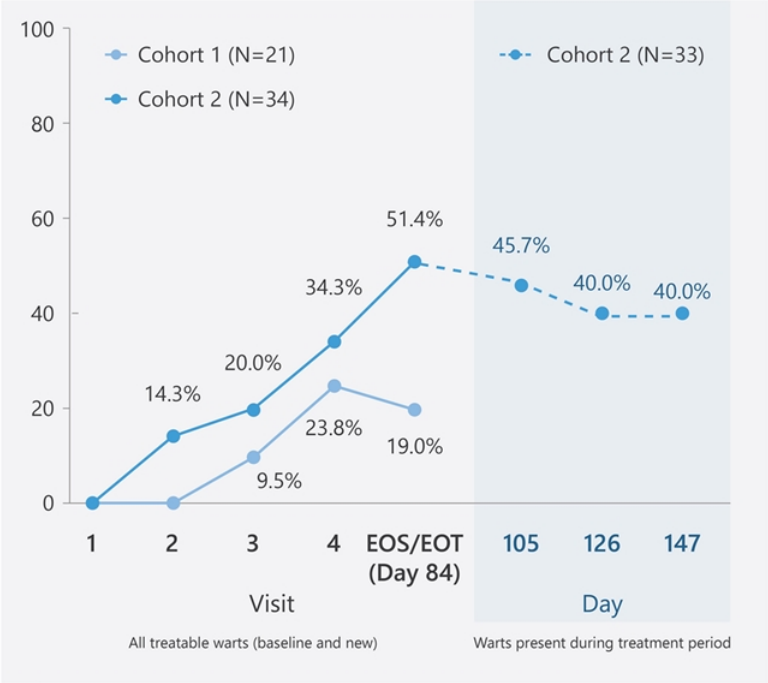
Cohort 1 is treated until clear, Cohort 2 receives one additional treatment at the first visit clearance was observed up to a maximum of 4 total applications

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



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

| | Cohort 1 N=21 (To Day 84) | Cohort 2 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) |

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

# Our Opportunity in External Genital Warts

# 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



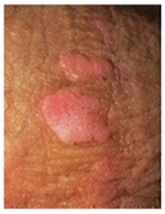
## ETIOLOGY AND CLINICAL PRESENTATION

**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



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# PHASE 2 STUDY (CARE-1) IN EXTERNAL GENITAL WARTS (EGW)

**Study Design**

Multi-center, double-blind, vehicle-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 days 21, 42, and 63

**Patients**

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

Part B: 87 subjects 18+ years of age with 2-30 external genital and/or perianal warts for ≥ 4 weeks at baseline visit

**Application**

Study drug (VP-102) is administered topically to each treatable wart every 21 days until complete clearance for a maximum of 4 treatments

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

Part B: 6- and 24-hour duration of treatment exposure (chosen based on Part A) with follow up period through Day 147

Frequency of administration is every 21 days





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# DEMOGRAPHICS (CARE-1, SAFETY POPULATION)*

| | VP-102 6-hour (N=30) | Vehicle 6-hour (N=24) | VP-102 24-hour (N=27) | Vehicle 24-hour (N=18) |
|---|---|---|---|---|
| **Age** | | | | |
| Mean (SD) | 38.93 (9.9) | 35.83 (7.8) | 34.33 (7.1) | 33.83 (6.3) |
| Min, Max | 26, 59 | 26, 58 | 25, 53 | 25, 43 |
| **Gender, n (%)** | | | | |
| Male | 17 (56.7) | 14 (58.3) | 15 (55.6) | 11 (61.1) |
| Female | 13 (43.3) | 10 (41.7) | 12 (44.4) | 7 (38.9) |
| **Race, n (%)** | | | | |
| White | 24 (80.0) | 13 (54.2) | 24 (88.9) | 12 (66.7) |
| Black or African American | 6 (20.0) | 8 (33.3) | 2 (7.4) | 6 (33.3) |
| American Indian or Alaska Native | 0 (0) | 1 (4.2) | 0 (0) | 0 (0) |
| Other | 0 (0) | 2 (8.3) | 1 (3.7) | 0 (0) |
| **Ethnicity, n (%)** | | | | |
| Hispanic or Latino | 6 (20.0) | 1 (4.2) | 2 (7.4) | 5 (27.8) |
| Not Hispanic or Latino | 24 (80.0) | 23 (95.8) | 25 (92.6) | 13 (72.2) |

*Pooled data from Part A and B



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# BASELINE EGW CHARACTERISTICS (CARE-1, ITT POPULATION)*

| | VP-102 6-hour (N=30) | Vehicle 6-hour (N=24) | VP-102 24-hour (N=27) | Vehicle 24-hour (N=18) |
|---|---|---|---|---|
| **Duration of Warts, No. (%)** | | | | |
| <1 year | 15 (50.0) | 12 (50.0) | 13 (48.1) | 9 (50.0) |
| 1-2 years | 3 (10) | 1 (4.2) | 2 (7.4) | 0 (0.0) |
| >2-5 Years | 4 (13.3) | 5 (20.8) | 8 (29.6) | 3 (16.7) |
| >5 years | 8 (26.7) | 6 (25.0) | 3 (11.1) | 6 (33.3) |
| **Wart Count** | | | | |
| Mean | 8.5 | 6.71 | 9.48 | 7.56 |
| SD | 7.3 | 5.5 | 6.2 | 6.8 |
| Median | 6 | 5 | 9 | 4.5 |
| Min, Max | 2, 30 | 2, 26 | 2, 25 | 2, 28 |
| **Prior Wart Treatment, No. (%)** | | | | |
| Yes | 17 (56.6) | 13 (54.2) | 14 (51.9) | 9 (50) |

*Pooled data from Part A and B



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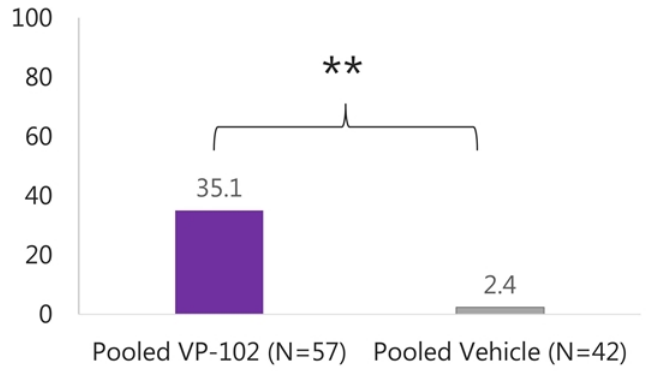
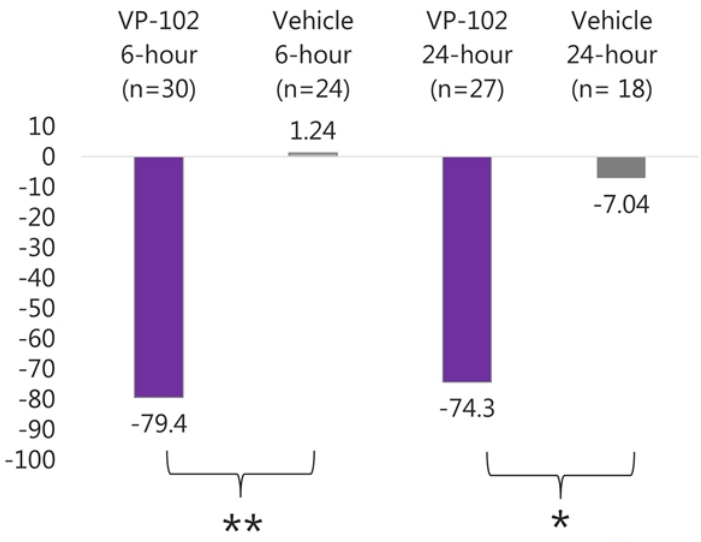
# **EFFICACY** (CARE-1, ITT POPULATION)

Percentage of Subjects with Complete Clearance of all Baseline and New Treatable EGW Lesions•




Mean Percentage Change in EGW Lesions from Baseline




•Pooled data from Part A and B
*P<0.001
**P≤0.0001

# SAFETY: TREATMENT EMERGENT ADVERSE EVENTS ≥ 5% (CARE-1, SAFETY POPULATION)*,□

| TEAEs, N (%) | VP-102 6-hour (N=30) | Vehicle 6-hour (N=24) | VP-102 24-hour (N=27) | Vehicle 24-hour (N=18) |
|---|---|---|---|---|
| **Subjects reporting at least one TEAE** | 29 (100.0) | 15 (68.2) | 28 (100.0) | 9 (45.0) |
| Application site vesicles | 25 (86.2) | 0 (0.0) | 26 (92.9) | 1 (5.0) |
| Application site pain | 20 (69.0) | 3 (13.6) | 19 (67.9) | 4 (20.0) |
| Application site erythema | 14 (48.3) | 3 (13.6) | 19 (67.9) | 1 (5.0) |
| Application site pruritus | 14 (48.3) | 5 (22.7) | 10 (35.7) | 1 (5.0) |
| Application site scab | 13 (44.8) | 1 (4.5) | 14 (50.0) | 0 (0.0) |
| Application site discoloration | 7 (24.1) | 4 (18.2) | 6 (21.4) | 0 (0.0) |
| Application site dryness | 7 (24.1) | 2 (9.1) | 6 (21.4) | 1 (5.0) |
| Application site erosion | 6 (20.7) | 0 (0.0) | 7 (25.0) | 0 (0.0) |
| Application site edema | 3 (10.3) | 1 (4.5) | 7 (25.0) | 1 (5.0) |
| Application site exfoliation | 3 (10.3) | 2 (9.1) | 5 (17.9) | 0 (0.0) |

TEAEs = Treatment Emergent Adverse Events

*Pooled data from Part A and B. No subjects discontinued the study due to AEs.
□No serious adverse events as deemed related to study drug by investigator.

## THE PROBLEM

# Non-Melanoma Skin Cancer



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# NON-MELANOMA SKIN CANCER

## OVERVIEW

Non-melanoma skin cancer includes basal cell and squamous cell carcinoma

Basal cell carcinoma is the most common malignancy in humans[1]

Common treatments are invasive, painful, can cause scarring, and may require destruction of healthy tissue



## ETIOLOGY AND CLINICAL PRESENTATION

**Patient population[1]**

- Estimated 5.4 million diagnoses of basal cell (BCC) and squamous cell (SCC) carcinomas annually
- Increasing age and sun exposure are risk factors

**Diagnosis & Symptoms[2,3]**

- New or changing lesions on sun exposed skin
- Common on the head/neck
- BCC: Pink pearly papules with prominent blood vessels
- SCC: Pink, rough scaly papules, patches, or plaques
- Diagnosis through routine biopsy

**Complications[3,4]**

- Damage to healthy tissue, pain, permanent scarring
- Surgical complications include disfigurement, bleeding and infection
- Metastasis to other areas of the body/organs

(1) Rogers *JAMA Derm* 2015
(2) Combalia *Derm Practic & Concept* 2020
(3) Gruber *StatPearls* 2020
(4) Bailey *Int J of Wom Derm* 2019



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# CURRENT TREATMENTS FOR NON-MELANOMA SKIN CANCER[1-3]

Invasive procedures may lead to permanent scarring, pain, damage to healthy tissue, and recurrence

| | DESCRIPTION | LIMITATIONS |
|---|---|---|
| **Surgical Excision** | Using a scalpel to remove diseased tissue and healthy skin | • Invasive<br>• Can cause scarring/disfigurement, infection, pain |
| **Mohs Surgery** | Used in high risk NMSC or in special sites | • Invasive, may take several rounds<br>• Can cause scarring, disfigurement and pain |
| **Electrodessication and Curettage** | Minor surgical procedure to remove diseased tissue with sharp tool and cauterize the area | • Invasive<br>• Painful<br>• Likely to cause scarring |
| **Topical Agents** | 5-FU, ingenol mebutate, or imiquimod | • May only be efficacious in small, superficial tumors<br>• Local inflammatory reactions, systemic size effects |
| **Oral Therapy** | ERIVEDGE® (vismodegib)[4] | • Approval limited to small subset of BCC and metastatic BCC<br>• Systemic side effects |
| **Oral Therapy** | ODOMZO® (sonidegib)[5] | • Approval limited to small subset of BCC and metastatic BCC<br>• Systemic side effects |

(1) Camilio *Oncoimmunology* 2014
(2) Combalia *Derm Practic & Concept* 2020
(3) Bailey *Int J of Wom Derm* 2019

(4) Per Prescribing Information: a hedgehog pathway inhibitor indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and who are not candidates for radiation.
(5) Per Prescribing Information: a hedgehog pathway inhibitor indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.



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## THE SOLUTION

# LTX-315

# LTX-315 OVERVIEW
## INDUCES IMMUNOGENIC CELL DEATH AND A TUMOR-SPECIFIC IMMUNE RESPONSE[1]

### OVERVIEW

First-in-class oncolytic peptide that is injected directly into a tumor to induce immunogenic cell death

Worldwide license in dermatology oncology[2] from Lytix Biopharma in August 2020

Verrica intends to focus initially on basal cell and squamous cell carcinomas as lead indications

IND submission anticipated during 1H 2021

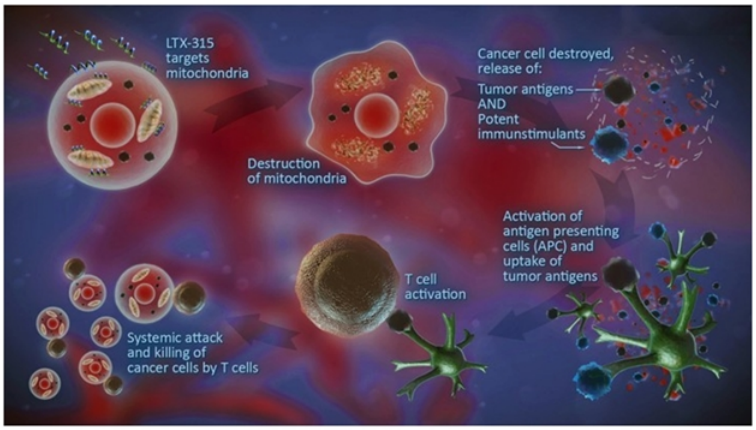
(1) Camilio *Oncoimmunology* 2014
(2) All malignant and pre-malignant dermatological indications, except for metastatic melanoma and metastatic Merkel cell carcinoma

### 1 Kills the Tumor Cells

LTX-315 enters the cells and disturbs cell membranes, causing cell death and release of a patient's tumor specific antigens

### 2 Triggers Immune Responses Targeting Tumor Cells

This allows the immune system to recognize, infiltrate, and attack cancer cells via dendritic cells and cytotoxic T cells



# Regulatory Exclusivity and Intellectual Property

# VERRICA HAS SEVERAL POTENTIAL WAYS TO MAINTAIN EXCLUSIVITY FOR VP-102

**Regulatory Exclusivity**

5 years of exclusivity for cantharidin as API potentially available upon approval (potential for additional 6 months for pediatric exclusivity for common warts and plantar warts indications)

**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 VP-102/103 INTELLECTUAL PROPERTY PORTFOLIO

| | KEY CLAIMS AND PATENT APPLICATIONS | VALUE TO VERRICA |
|---|---|---|
| 1 | Our specific formulation, YCANTH™ (VP-102), key safety additions and novel cantharidin formulations (PCT/US2014/052184) (PCT/US2018/036353) | May prevent generics from copying our ether-free formulation or from making similar formulations |
| | Single use applicator containing cantharidin formulations (PCT/US2014/052184) (PCT/US2018/037808) | 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 |
| 2 | Specific design of our commercial applicator (PCT/US2018/037808) (US 29/607744) | May prevent generics from utilizing a similar applicator<br>Design patent application allowed in the US |
| 3 | Methods of use for cantharidin in the treatment of molluscum (PCT/US2018/037808 and PCT/US2018/036353) (PCT/US2014/052184) | May prevent generics from a similar treatment regimen and label |
| 4 | 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 |
| 5 | Methods for complete cantharidin synthesis (PCT/US2015/066487) (PCT/US2018/054373) | 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**

# OVERVIEW OF LTX-315 INTELLECTUAL PROPERTY PORTFOLIO

| Product | Description | EU | US | JP | Other (*, pending) |
|---|---|---|---|---|---|
| **LTX-315**<br>PCT/EP2009/006744 | Composition-of-matter claims | Granted[1], expires 2029 | Granted, expires 2032 | Granted, expires 2029 | AU, BR*, CA, CN, IN, NZ, KR, RU, SG |
| **LTX-315 T cell clonality**<br>PCT/EP 2017/05229 | Methods-of-use claims | Pending, expires 2037 | Pending, expires 2037 | Pending, expires 2037 | AU*, CN*, KR* |

[1] In force in: UK, Belgium, Denmark, Finland, France, Germany, Italy, Netherlands, Norway, Poland, Spain, Sweden, Switzerland and Turkey

# OUR PRODUCT PORTFOLIO

| | | PRE-IND | PHASE 2 | PHASE 3 | NDA | NEXT EXPECTED MILESTONE |
|---|---|---|---|---|---|---|
| YCANTH | Molluscum Contagiosum | | | | | Resubmission of NDA in Q1 2021 |
| VP-102 | Common Warts | | | | | Initiate pivotal Phase 3 trials* |
| | External Genital Warts | | | | | Request End-of-Phase 2 meeting in Q1 2021 |
| VP-103 | Plantar Warts | | | | | Initiate Phase 2 trial* |
| LTX-315 | Non-Melanoma Skin Cancer** | | | | | Submit US IND during 1H 2021 |

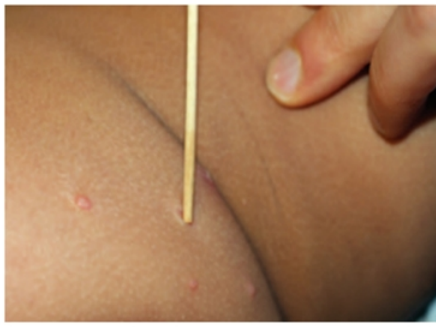
* Timing for initiating new clinical trials to be determined
** Initially focused on basal cell and squamous cell carcinomas

# INVESTMENT HIGHLIGHTS

- **YCANTH™ in Development to Address 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
- **Completed Type A Meeting with FDA for YCANTH™ (VP-102) for the Treatment of Molluscum**
  - Anticipate resubmission of NDA in Q1 2021
- **Positive Phase 3 Results in Molluscum Contagiosum**
  - Achieved statistical significance for primary endpoints in two pivotal trials for YCANTH™ (VP-102)
  - P-value <0.0001 for primary endpoint in both pivotal trials
- **Innovative Product Candidate**
  - Proprietary drug-device combination of formulation and single-use applicator
- **Physician Acceptance**
  - 95% of pediatric dermatologists have used API[3]
- **Dermatology Oncology**
  - Worldwide rights to LTX-315: first-in-class oncolytic peptide injected directly into tumor
  - Positive tumor-specific immune cell responses in multi-indication Phase 1/2 oncology trials
  - Verrica to focus initially on development to treat basal cell and squamous cell carcinomas
  - 5.4 million diagnoses annually in the U.S. of basal and squamous cell skin cancers[4]; patients typically treated with surgery
  - Submission of U.S. IND anticipated during first half of 2021
- **Option Agreement with Torii Pharmaceuticals for Development and Commercialization of VP-102 in Japan**
  - Torii option includes Verrica product candidates for the treatment of molluscum and common warts in Japan
- **Proven Team**
  - Industry-leading, experienced management team with extensive dermatology product launch experience
  - Strengthened clinical and drug development leadership in August 2020

(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.
(4) https://www.cancer.org/cancer/basal-and-squamous-cell-skin-cancer/about/key-statistics.html and Rogers *JAMA Derm* 2015

# 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 manufacturing

- Risk of impurities present such as residual solvents and 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 57 503B facilities and 4 compounders of cantharidin per FDA database (January – June 2019).

# MANAGEMENT TEAM WITH EXTENSIVE PRODUCT LAUNCH AND DERMATOLOGY EXPERIENCE

**Ted White**
President & Chief Executive Officer
NOVARTIS
AQUA an Almirall company

**A. Brian Davis**
Chief Financial Officer
STRONGBRIDGE BIOPHARMA
tengion
NEOSE

**Gary Goldenberg, MD**
Chief Medical Officer
Icahn School of Medicine at Mount Sinai
GOLDENBERG DERMATOLOGY
TEMPLE
WAKE FOREST UNIVERSITY

**Joe Bonaccorso**
Chief Commercial Officer
NOVARTIS
Pierre Fabre

## Selected Launched Products

Diovan valsartan capsules
LAMISIL SINGELDOS
ELIDEL
Hemangeol PROPRANOLOL HYDROCHLORIDE
Acticlate (Doxycycline Hyclate USP) Tablets 75 mg 150 mg





VERRICA PHARMACEUTICALS