

**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): June 26, 2019

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38529
(Commission
File Number)

46-3137900
(IRS Employer
Identification No.)

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

19380
(Zip Code)

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

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

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

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

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

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure

On June 26, 2019, Verrica Pharmaceuticals Inc. (the “Company”) issued a press release reporting positive topline results from the Phase 2 clinical study of VP-102 in patients with common warts, as well as information regarding a conference call to discuss these results and other clinical updates. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. A copy of the presentation that will accompany the conference call is furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K.

The information included in this Item 7.01 of this Current Report on Form 8-K, including the attached Exhibit 99.1 and Exhibit 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Press Release, dated June 26, 2019
99.2	Verrica Pharmaceuticals Inc. Presentation

SIGNATURES

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

Verrica Pharmaceuticals Inc.

Date: June 27, 2019

/s/ Chris Degnan
Chris Degnan
Chief Financial Officer



**Verrica Pharmaceuticals Achieves Positive Topline Results in Phase 2
Clinical Study of VP-102 in Patients with Common Warts**

51% of subjects in Cohort 2 achieved complete clearance of all treatable warts

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

Common warts affect approximately 22 million people in the United States

Based on positive outcome, Verrica to request an 'End of Phase 2' meeting with the FDA

Management to host webcast and conference call tomorrow at 8 a.m. ET

WEST CHESTER, PA – June 26, 2019 (GLOBE NEWSWIRE) – Verrica Pharmaceuticals Inc. (Verrica) (Nasdaq: VRCA), a medical dermatology company committed to the development and commercialization of novel treatments that provide meaningful benefit for people living with skin diseases, today announced positive topline results from its COVE-1 Phase 2 open label clinical study of VP-102 for the treatment of verruca vulgaris, or common warts. COVE-1 included two cohorts that evaluated the safety and efficacy of VP-102, a novel topical therapy containing a solution of 0.7% cantharidin in a proprietary single-use applicator, in subjects with up to six warts. In both cohorts, VP-102 achieved positive results on both the primary endpoint of complete clearance of all treatable warts at Day 84 and the secondary endpoint of the percentage reduction of warts. VP-102 was well-tolerated with no serious adverse events reported.

"This is exciting news for Verrica and our proprietary cantharidin product. Positive Phase 2 data of VP-102 for the treatment of common warts, after the successful Phase 3 results achieved with VP-102 for molluscum contagiosum, further increases our confidence in the broad clinical utility and large market potential of our lead product," said Ted White, President and Chief Executive Officer of Verrica. "We are progressing the development of VP-102 for a broad range of skin diseases. We intend to request an 'End of Phase 2' meeting with the FDA for the treatment of common warts, and remain on track to submit an NDA for the treatment of molluscum contagiosum later this year."

Study Results:

The COVE-1 Phase 2 open label clinical study included two cohorts that evaluated the safety and efficacy of VP-102 in subjects with up to six warts. Cohort 1 was conducted at a single site with 21 subjects age 2 years and older receiving up to 4 treatments with VP-102 at least 14 days between treatments with longer treatment intervals allowed at the discretion of the investigator depending on a specific subject's clinical response. While the study was ongoing, Verrica amended the protocol to allow varying treatment intervals in Cohort 1 at the discretion of the investigator in order to identify the optimal treatment dosing regimen and added a second cohort to the study.

Cohort 2 was conducted at four sites with 35 subjects age 12 years and older receiving up to 4 treatments with VP-102 every 21 days. Paring of warts, a technique commonly used by dermatologists to prepare the wart for treatment, was allowed in Cohort 2 to remove any adherent thick scale from a wart prior to application of study drug. The primary analysis was conducted at Day 84 with an additional period of follow-up through Day 147. Topline analysis included data from the assessment of warts at study visits over 12 weeks. Results showed 51% of subjects (18 of 35) treated with VP-102 in Cohort 2 achieved complete clearance of all treatable warts at Day 84. Secondary endpoints included the percent change from baseline in the number of treatable warts and VP-102 achieved a 51% reduction in the number of warts (28 of 55 warts) compared to baseline by Day 84.

Consistent with the results from the Phase 3 clinical trials in molluscum, VP-102 was also well-tolerated with side effects that were primarily mild-to-moderate. The most frequently reported adverse events were application site reactions that are well-known, reversible side effects related to the mechanism of action of cantharidin, a blistering agent, which is the active ingredient in VP-102. There were no serious adverse events reported.

"Behind acne, warts are the most common dermatological complaint and our treatment options are limited as there are no FDA-approved treatments," said Scott T. Guenther, MD, FAAD, founder of the Dermatology Center of Indiana and lead investigator for the COVE-1 study. "Further, common warts are very persistent and difficult to treat, which is frustrating to patients. The data results on the complete clearance of treatable warts and the percentage of wart reduction in this Phase 2 study is very meaningful and highlight the potential of VP-102 as an important new option for people with common warts."

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 common warts, Verrica plans to submit this data for presentation at future medical meetings and for publication in a peer-reviewed medical journal.

Verrica Conference Call

Management will conduct a conference call at 8 a.m. ET tomorrow, June 27, 2019, to discuss the results. The conference call will be webcast and can be accessed by logging on to the "Investors" section of the Verrica website, www.verrica.com, prior to the event.

The webcast will also be available via the following link: <https://edge.media-server.com/m6/p/ju8namrg>. A replay of the webcast will be archived on the Company's website for 30 days following the call.

To participate on the live call, please dial 866-688-9534 (domestic) or 409-216-0837 (international), and reference conference ID 7183118 prior to the start of the call.

About Common Warts

Common warts (*verruca vulgaris*) are skin growths caused by a contagious viral skin infection, most commonly on the fingers or hands. The human papilloma virus (HPV), the causative agent in common warts, is transmitted by touch. The virus enters the skin and causes skin growths by inducing the skin cells to multiply rapidly. Common warts are benign, but treatment is recommended to prevent the spread of infection and relieve the patient's physical and psychological discomfort.

About Verrica Pharmaceuticals Inc.

Verrica Pharmaceuticals Inc. is a medical dermatology company committed to the development and commercialization of novel treatments that provide meaningful benefit for people living with skin diseases. The company's late-stage product candidate, VP-102, is a potential first-in-class topical therapy for the treatment of molluscum contagiosum and common warts. Molluscum is a highly contagious viral skin infection affecting approximately six million people, primarily children, in the United States, and common warts are contagious skin growths affecting 22 million people. There are currently no FDA-approved treatments for molluscum or common warts. Following positive topline results from two pivotal Phase 3 trials, a New Drug Application for VP-102 for the treatment of molluscum is planned for the second half of 2019. Verrica is planning to meet with the FDA to determine next steps on the development of VP-102 for common warts following positive Phase 2 results. An additional Phase 2 trial is planned in external genital warts. A second product candidate, VP-103, is in pre-clinical development for plantar warts. For more information, visit www.verrica.com.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe”, “expect”, “may”, “plan”, “potential”, “will”, and similar expressions, and are based on Verrica’s current beliefs and expectations. These forward-looking statements include expectations regarding the potential further advancement of VP-102 for the treatment of common warts, submission of a NDA in the second half of 2019 for VP-102 for the treatment of molluscum and the large market potential of VP-102. 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, and other risks and uncertainties that are described in Verrica’s Annual Report on Form 10-K for the year ended December 31, 2018, filed with the U.S. Securities and Exchange Commission on March 7, 2019, 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.

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**Topline Results from
COVE-1:
Phase 2 Clinical Trial of
VP-102 in Patients with
Common Warts**

June 27, 2019

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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 forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. The forward-looking statements in this presentation involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the drug development process and the regulatory approval process, our reliance on third parties over which we may not always have full control, and other risks and uncertainties that are described in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the U.S. Securities and Exchange Commission (SEC) on March 7, 2019, and our other filings made with the SEC. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. There can be no assurance that the opportunity will meet your investment objectives, that you will receive a return of all or part of such investment. Investment results may vary significantly over any given time period. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. We recommend that investors independently evaluate specific investments and strategies.

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

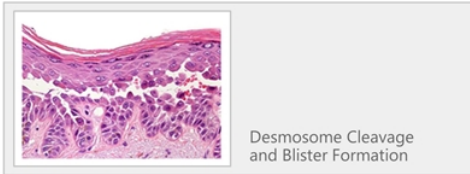
CANTHARIDIN HAS A PROVEN DUAL MECHANISM OF ACTION

1 Targeted Destruction of Infected Skin Leads to Lesion Clearance

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

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

Since acantholysis is intraepidermal, healing occurs without scarring.



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

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

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

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



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

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

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

DEMOGRAPHICS IN COVE-1 STUDY

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

WART HISTORY FOR SUBJECTS IN COVE-1 STUDY

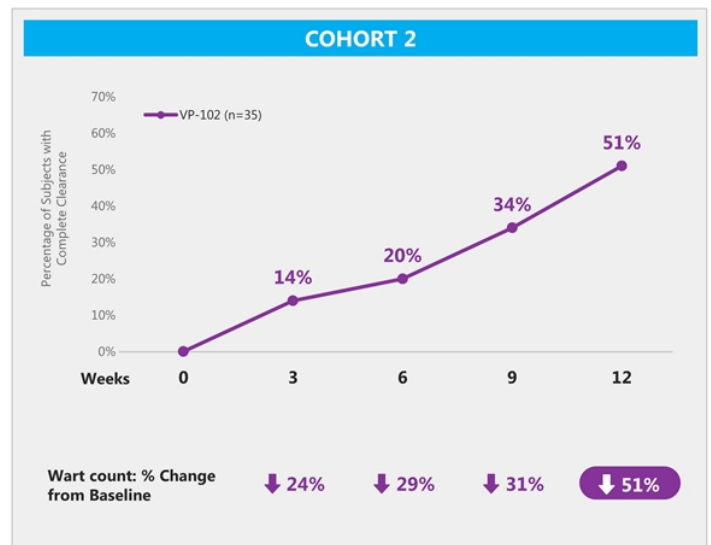
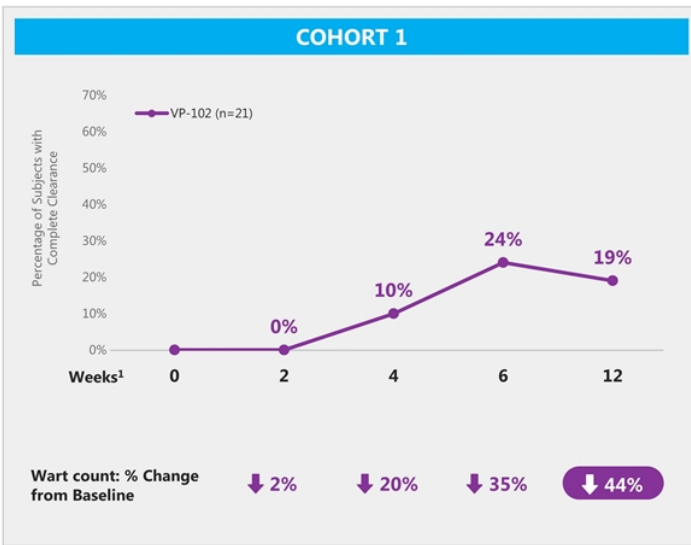
Cohort 1

	VP-102 (N=21)
Time Since Clinical Diagnosis (months)	
Mean	70.3
Age at Diagnosis	
Mean	32.1
Any Previous Treatment for Common Warts?	
Yes	3 (14.3%)
Wart number at Baseline	
Mean	2.19

Cohort 2

	VP-102 (N=35)
Time Since Clinical Diagnosis (months)	
Mean	15.9
Age at Diagnosis	
Mean	36.4
Any Previous Treatment for Common Warts?	
Yes	24 (68.6%)
Wart number at Baseline	
Mean	1.65

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



(1) Cohort 1 was amended to allow varying treatment intervals beyond every 14 days depending on a specific subject's clinical response

SAFETY SUMMARY FOR COVE-1 STUDY

COHORT 1

	VP-102 (N=21) n (%)
Subjects with at least one...	
TEAE (Treatment Emergent AE)	20 (95.2)
Mild TEAE	20 (95.2)
Moderate TEAE	9 (42.9)
Severe TEAE	2 (9.5)
TEAE related to drug	20 (95.2)
Serious TEAE	0 (0)
TEAE leading to discontinuation	0 (0)
Local Skin Reaction TEAE	20 (95.2)
TEAE of Papilloma Viral Infection	0 (0)

AE= Adverse Event

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COHORT 2

	VP-102 (N=34) n (%)
Subjects with at least one...	
TEAE (Treatment Emergent AE)	32 (94.1)
Mild TEAE	32 (94.1)
Moderate TEAE	19 (55.9)
Severe TEAE	4 (11.8)
TEAE related to drug	32 (94.1)
Serious TEAE	0 (0)
TEAE leading to discontinuation	0 (0)
Local Skin Reaction TEAE	32 (94.1)
TEAE of Papilloma Viral Infection	3 (8.8)

ADVERSE EVENTS IN COVE-1 STUDY

PREFERRED TERM NAME	Cohort 1 (N= 21)	Cohort 2 (N=34)
	n (%)	n (%)
Application site vesicles	20 (95.2)	27 (79.4)
Application site pain	20 (95.2)	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)	19 (55.9)
Application site discoloration	1 (4.8)	8 (23.5)
Application site dryness	6 (28.6)	14 (41.2)

AEs occurring in >20% of subjects in any arm

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REALIZING THE COMMON WARTS OPPORTUNITY

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










22M
Prevalence in
U.S.



1.5M
Patients Diagnosed
Annually

(1) 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

SIGNIFICANT RECENT AND EXPECTED CLINICAL MILESTONES

DATE	EVENT
 1Q 2018	Received go ahead from FDA to initiate two Phase 3 trials in molluscum, including SPA on pivotal trial
 1Q 2018	Initiated Phase 3 trials for molluscum and Phase 2 trial for common warts
 3Q 2018	Completed enrollment in two pivotal Phase 3 trials in molluscum
 1Q 2019	Positive topline results from two pivotal Phase 3 trials in molluscum
 2Q 2019	Positive topline results from Phase 2 trial in common warts
 2Q 2019	Initiate Phase 2 trial in external genital warts
 2H 2019	VP-102 NDA submission in molluscum
 2H 2019	VP-103 IND submission in plantar warts
 1Q 2020	Initiate pivotal trials in common warts

SUMMARY & PATH FORWARD

- VP-102 exhibited a clinically meaningful proportion of subjects demonstrating complete clearance of all treatable warts with a treatment regimen of up to 4 applications administered every 21 days
- VP-102 was well-tolerated, with no serious adverse events reported
- No FDA approved treatments are currently available for common warts, a contagious viral infection of the skin affecting an estimated 22 million people in the United States
- Based on positive outcome, Verrica to request an 'End of Phase 2' meeting with the FDA