

**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): February 17, 2021**

**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.

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**Item 8.01 Other Events.**

On February 17, 2021, Verrica Pharmaceuticals Inc. (the “Company”) issued a press release announcing that its resubmitted New Drug Application (“NDA”) for VP-102 has been accepted for filing by the U.S. Food and Drug Administration (“FDA”) and that the Prescription Drug User Fee Act goal date assigned by the FDA for this NDA is June 23, 2021.

A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits**

| <u>Exhibit Number</u> | <u>Exhibit Description</u>                                   |
|-----------------------|--|
| 99.1                  | <a href="#">Press Release</a>                                |
| 104                   | Cover Page Interactive Data File (formatted as inline XBRL). |

**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.

Date: February 17, 2021

**Verrica Pharmaceuticals Inc.**

/s/ A. Brian Davis

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A. Brian Davis

Chief Financial Officer



## **Verrica Pharmaceuticals Announces FDA Filing Acceptance of Resubmitted New Drug Application for VP-102 for the Treatment of Molluscum Contagiosum**

*- PDUFA goal date assigned is June 23, 2021 –*

*- VP-102 (cantharidin 0.7% Topical Solution) could potentially be the first FDA-approved treatment for molluscum contagiosum, a highly contagious viral skin infection affecting approximately 6 million people in the United States, primarily children -*

WEST CHESTER, PA – Feb. 17, 2021 (GLOBE NEWSWIRE) – Verrica Pharmaceuticals Inc. (“Verrica”) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced that its resubmitted New Drug Application (NDA) for VP-102 (cantharidin 0.7% Topical Solution), a proprietary topical therapy for the treatment of molluscum contagiosum (molluscum), has been accepted for filing by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) goal date assigned by the FDA for this NDA is June 23, 2021.

Verrica previously submitted an NDA for VP-102 for the treatment of molluscum in September 2019. As previously announced, the FDA issued a Complete Response Letter requesting additional Chemistry, Manufacturing and Controls (CMC) information as well as Human Factors validation in July 2020. Verrica resubmitted the NDA for VP-102 for the treatment of molluscum on December 23, 2020.

“This is an exciting time for Verrica as we work with the FDA to continue to move VP-102 through the regulatory process,” said Ted White, President and Chief Executive Officer, Verrica. “We believe that VP-102 is well-positioned to become the first FDA-approved product for the treatment of molluscum and could potentially bring relief to the millions of children diagnosed with this highly contagious disease.”

The NDA is based on positive results from two identical Phase 3 randomized, double-blind, multicenter clinical trials (CAMP-1 and CAMP-2) that evaluated the safety and efficacy of VP-102 compared to placebo in patients two years of age and older diagnosed with molluscum. In both trials, a clinically and statistically significant number of patients treated with VP-102 met the primary endpoint of complete clearance of all treatable molluscum lesions.

VP-102 was well-tolerated in both trials, with no serious adverse events reported in VP-102-treated subjects.

## **About VP-102**

Verrica's lead product candidate, VP-102, is a proprietary drug-device combination product that contains a GMP-controlled formulation of cantharidin (0.7% w/v) delivered via a single-use applicator that allows for precise topical dosing and targeted administration. VP-102 is currently under U.S. Food and Drug Administration (FDA) review and could potentially be the first product approved by the FDA to treat molluscum contagiosum—a common, highly contagious skin disease that affects an estimated six million people in the United States, primarily children. 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.

## **About Molluscum Contagiosum (Molluscum)**

There are currently no FDA-approved treatments for molluscum, a highly contagious viral skin disease that affects approximately six million people — primarily children — in the United States. Molluscum is caused by a pox virus that produces distinctive raised, skin-toned-to-pink-colored lesions that can cause pain, inflammation, itching and bacterial infection. It is easily transmitted through direct skin-to-skin contact or through fomites (objects that carry the disease like toys, towels or wet surfaces) and can spread to other parts of the body or to other people, including siblings. The lesions can be found on most areas of the body and may carry substantial social stigma. Without treatment, molluscum can last for an average of 13 months, and in some cases, up to several years.

## **About Verrica Pharmaceuticals Inc.**

Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. Verrica's late-stage product candidate, VP-102, is in development to treat molluscum contagiosum (molluscum), common warts and external genital warts, three of the largest unmet needs in medical dermatology. Verrica is also developing VP-103, its second cantharidin-based product candidate, for the treatment of plantar warts. The Company has also entered a worldwide license agreement with Lytix Biopharma AS to develop and commercialize LTX-315 for dermatologic oncology conditions. For more information, Visit [www.verrica.com](http://www.verrica.com).

## **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 Company's expectations with regard to the potential approval of the NDA for VP-102 and the potential benefits and potential commercialization of VP-102 for the treatment of molluscum, if

approved. 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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