

**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): May 28, 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.

Item 8.01 Other Events.

On May 28, 2021, Verrica Pharmaceuticals Inc. (the “Company”) issued a press release announcing the extension of the U.S. Food and Drug Administration review period of its New Drug Application for VP-102. The Prescription Drug User Fee Act goal date has been extended by three months to September 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

| Exhibit Number | Exhibit Description |
|-----------------------|---|
| 99.1 | Press Release |
| 104 | Cover Page Interactive Data File (embedded within the 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.

Date: May 28, 2021

/s/ A. Brian Davis

A. Brian Davis

Chief Financial Officer



Verrica Pharmaceuticals Announces Extension of FDA Review Period of its NDA for VP-102 for the Treatment of Molluscum Contagiosum

– Prescription Drug User Fee Act (PDUFA) goal date extended by three months to September 23, 2021 –

WEST CHESTER, PA – May 28, 2021 (GLOBE NEWSWIRE) – Verrica Pharmaceuticals Inc. (“Verrica”) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced that the U.S. Food and Drug Administration (FDA) has extended the review period for the New Drug Application (NDA) for VP-102 for the treatment of molluscum contagiosum (molluscum). The Prescription Drug User Fee Act (PDUFA) goal date has been extended by three months to September 23, 2021.

The FDA extended the PDUFA goal date to allow the Agency to have additional time to review information submitted by Verrica, including its training program and distribution model, in response to comments from the agency regarding the Company’s human factors study. On May 26, 2021, the FDA informed Verrica that the information submitted has been designated a major amendment, which allows FDA to take an additional three months to review the submitted information.

“We remain confident in VP-102 as a potential treatment option for patients with molluscum,” said Ted White, Verrica’s President and Chief Executive Officer. “Importantly, the FDA has recently completed one of the two pre-approval inspections required for approval. We look forward to our continued productive discussions with the FDA as it completes its review of our VP-102 NDA.”

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, with a PDUFA goal date of September 23, 2021, 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)

Molluscum is 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, 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.

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 PDUFA date and potential approval of the NDA for VP-102 and the potential benefits 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, 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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