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 29, 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 **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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 September 13, 2019, Verrica Pharmaceuticals Inc. (the "Company") submitted to the U.S. Food and Drug Administration (the "FDA") a New Drug Application (the "NDA") under section 505(b) of the Federal Food, Drug, and Cosmetic Act for its product candidate VP-102 for the treatment of molluscum. Under the Prescription Drug User Fee Act ("PDUFA"), the FDA set a PDUFA goal date of July 13, 2020. On June 24, 2020, the Company received a notification from the FDA (the "Notification") stating that, as part of its ongoing review of the Company's NDA, the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The FDA stated that the Notification does not reflect a final decision on the information under review.

The Notification does not specify the deficiencies identified by the FDA.

On June 29, 2020, the Company issued a press release announcing its receipt of the Notification. A copy of Company's press release is filed herewith as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Any statements contained in this report 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 the Company's current beliefs and expectations. These forward-looking statements include expectations regarding the potential receipt and timing of the FDA's approval of the NDA, the Company's expectations with regard to its interactions and communications with the FDA, plans, and expectations related to the PDUFA date. 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, the Company'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 the Company's Annual Report on Form 10-K for the year ended December 31, 2019, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and other filings the Company makes with the U.S. Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this report and are based on information available to the Company as of the date of this report, and the Company has no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release issued by the registrant on June 29, 2020.

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 29, 2020

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

Verrica Pharmaceuticals Provides Regulatory Update on VP-102

WEST CHESTER, Pa., June 29, 2020 (GLOBE NEWSWIRE) — Verrica Pharmaceuticals Inc. (“Verrica”) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for viral skin diseases requiring medical interventions, today announced that, on June 24, 2020, the Company received a letter from the U.S. Food and Drug Administration (FDA) as part of the FDA’s ongoing review of the Company’s New Drug Application (NDA) for VP-102 (cantharidin 0.7% topical solution), Verrica’s lead product candidate for the treatment of molluscum contagiosum. The letter states that there are deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time. The letter further states that the notification does not reflect a final decision on the information under review. In a letter dated November 26, 2019, the FDA had assigned a Prescription Drug User Fee Act (“PDUFA”) goal date of July 13, 2020 for completion of its review of the NDA.

The FDA’s letter does not identify any specific items. But, the Company notes that information requests from the FDA during the NDA review have focused on CMC aspects of the drug-device combination. Verrica’s ability to address these CMC-related requests, however, was significantly impacted in large part by the COVID-19 pandemic.

The requests include, but are not limited to, a specific request related to a potential safety issue with the applicator that could arise if the instructions for use were not properly followed. In response, the Company incorporated an additional user feature into the applicator to address that issue. The addition of that user feature, however, has affected human factors testing as well as requiring additional supportive stability data on the fully assembled device incorporating such feature. The Company believes that both its long-term and registration stability data with the ampule and the as-submitted applicator support significant shelf life and stability for VP-102.

The Company anticipates interactions with, and additional communication from, the FDA and intends to work with the FDA to resolve and address any items as quickly as possible.

Notwithstanding the pandemic or the CMC-related requests that have arisen during the review cycle, the Company believes that the positive results from its two double-blind Phase 3 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 indicates that VP-102 remains viable for FDA approval.

About Verrica Pharmaceuticals Inc.

Verrica is a dermatology therapeutics company developing medications for viral skin diseases requiring medical interventions. The Company’s late-stage product candidate, VP-102, is a potential first-in-class topical therapy for the treatment of molluscum contagiosum. An NDA for VP-102 for the treatment of molluscum is currently under review by FDA and, if approved, VP-102 will be marketed in the United States under the conditionally accepted brand name YCANTH™. Verrica intends to initiate a Phase 3 program of VP-102 for the treatment of common warts when conditions are appropriate, given the COVID-19 pandemic. In addition, VP-102 is being evaluated in Phase 2 study for the treatment of external genital warts. The Company is also developing VP-103, its second cantharidin-based product candidate, and intends to launch a Phase 2 study in subjects with plantar warts when conditions are appropriate. 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 potential receipt and timing of the FDA’s approval of the NDA, the Company’s expectations with regard to its interactions and communications with the FDA, plans and expectations related to the PDUFA date, the potential benefits and potential approval and commercialization of YCANTH™ for the treatment of molluscum, and the clinical development of product candidates for additional indications, including common warts, external genital warts and plantar warts. 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 March 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:

Investors:

A. Brian Davis
Chief Financial Officer
484.453.3300 ext. 103
info@verrica.com

Luke Brown
Solebury Trout
646.378.2944
lbrown@troutgroup.com

Media:

Joshua R. Mansbach
Solebury Trout
646.378.2964
jmansbach@troutgroup.com