

**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 12, 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.)

**44 W. Gay St., Suite
400 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 2.02 Results of Operations and Financial Condition.

On November 12, 2021, Verrica Pharmaceuticals Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter and nine months ended September 30, 2021. This press release has been furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 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 Registrant’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 12, 2021
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.

Verrica Pharmaceuticals Inc.

Date: November 12, 2021

/s/ P. Terence Kohler Jr.

P. Terence Kohler Jr.
Chief Financial Officer



Verrica Pharmaceuticals Reports Third Quarter 2021 Financial Results

Contract Manufacturer identified in prior CRL receives satisfactory resolution (VAI) of the facility's identified deficiencies from the FDA

Verrica is engaging with the FDA on next steps toward potential approval of VP-102 for the treatment of molluscum contagiosum

WEST CHESTER, PA – November 12, 2021 (GLOBE NEWSWIRE) – Verrica Pharmaceuticals Inc. (“Verrica”) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced financial results for the third quarter ended September 30, 2021.

“We are pleased that the issues identified at the CMO unrelated to VP-102 have been successfully resolved, enabling us to move toward approval,” said Ted White, Verrica’s President and Chief Executive Officer. “We remain confident in VP-102’s commercial potential. There is a high unmet medical need for molluscum treatments—the viral skin disease affects approximately 6 million people a year in the U.S., mostly children, and there are no FDA-approved treatments. We look forward to continuing our dialogue with the FDA on the appropriate path forward for approval of VP-102.”

Mr. White continued: “In addition, we are excited to continue the expansion of our portfolio into dermatologic oncology by advancing LTX-315, an oncolytic peptide, into clinical development for the treatment of basal cell carcinoma. Skin cancer is the most common cancer in the U.S., with 5 million diagnoses of basal and squamous cell carcinomas each year. We recently submitted an IND for LTX-315 and look forward to initiating our Phase 2 trial in basal cell carcinoma in the first quarter of 2022.”

Business Highlights and Recent Developments

- On September 20, 2021, Verrica announced that the U.S. Food and Drug Administration (“FDA”) issued a Complete Response Letter (“CRL”) regarding its New Drug Application (“NDA”) for VP-102 (cantharidin 0.7% Topical Solution) for the treatment of molluscum contagiosum (“molluscum”). According to the CRL, the FDA identified deficiencies at a facility of a contract manufacturing organization (“CMO”), which were not specifically related to the manufacturing of VP-102 but instead raised general quality issues at the facility. The FDA did not identify any clinical, safety or product specific Chemistry, Manufacturing, and Controls (“CMC”) deficiencies related to VP-102. Following the CRL, on September 22, 2021 Verrica received a General Advice Letter from the FDA with recommendations to improve YCANTH’s user interface.

- On November 5, 2021, Verrica was notified that the inspection of the CMO has been classified as “voluntary action indicated” (“VAI”), is now closed and that the VAI classification will not directly negatively impact FDA’s assessment of the Company’s NDA regarding this CMO. With the satisfactory resolution of the facility inspection, Verrica has engaged the FDA to determine the next steps toward the potential approval of VP-102 for the treatment of molluscum.
- In October 2021, the Company submitted an Investigational New Drug Application (“IND”) for LTX-315, a first-in-class oncolytic peptide, for use in basal cell carcinoma. The Company expects to initiate our Phase 2 trial in basal cell carcinoma in the first quarter of 2022.

Financial Results

Third Quarter 2021 Financial Results

- Research and development expenses were \$3.8 million in the third quarter of 2021, compared to \$5.0 million for the same period in 2020. The decrease was primarily attributable to lower CMC (Chemistry, Manufacturing, and Controls) and clinical costs related to Verrica’s development of VP-102 for external genital warts and common warts, partially offset by increased compensation costs.
- General and administrative expenses were \$8.0 million in the third quarter of 2021, compared to \$4.6 million for the same period in 2020. The increase was primarily driven by increased headcount and other expenses related to pre-commercial activities for VP-102, as well as an increase in insurance, professional fees and other operating expenses.
- For the third quarter of 2021, net loss on a GAAP basis was \$12.8 million, or \$0.47 per share, compared to a net loss of \$10.5 million, or \$0.42 per share, for the same period in 2020.
- For the third quarter of 2021, non-GAAP net loss was \$11.0 million, or \$0.40 per share, compared to a non-GAAP net loss of \$9.0 million, or \$0.36 per share, for the same period in 2020.

Year-to-Date September 2021 Financial Results

- Verrica recognized license revenues of \$12.0 million for the nine months ended September 30, 2021 related to the Collaboration and License Agreement with Torii Pharmaceutical Col, Ltd. There were no license revenues recognized in 2020.
- Research and development expenses were \$12.6 million for the nine months ended September 30, 2021, compared to \$13.4 million for the same period in 2020. The decrease was primarily attributable to decreased CMC and clinical costs related to Verrica’s development of VP-102 for molluscum contagiosum, external genital warts, and common warts, partially offset by a one-time \$2.3 million milestone payment to Lytix Biopharma AS upon the achievement of a regulatory milestone for LTX-315.
- General and administrative expenses were \$21.9 million for the nine months ended September 30, 2021, compared to \$14.7 million for the same period in 2020. The increase was primarily a result of expenses related to increased headcount, an increase in insurance, professional fees and other operating costs, and an increase in expenses related to pre-commercial activities for VP-102.

- For the nine months ended September 30, 2021, net loss on a GAAP basis was \$25.5 million, or \$0.95 per share, compared to a net loss of \$29.7 million, or \$1.19 per share, for the same period in 2020.
- For the nine months ended September 30, 2021, non-GAAP net loss was \$19.8 million, or \$0.73 per share, compared to a non-GAAP net loss of \$25.6 million, or \$1.03 per share, for the same period in 2020.
- As of September 30, 2021, Verrica had aggregate cash, cash equivalents, and marketable securities of \$79.5 million. The Company believes that its existing cash, cash equivalents, and marketable securities as of September 30, 2021 will be sufficient to support planned operations into the third quarter of 2022.

Non-GAAP Financial Measures

In evaluating the operating performance of its business, Verrica's management considers non-GAAP loss from operations, non-GAAP net loss and non-GAAP net loss per share. These non-GAAP financial measures exclude stock-based compensation charges and non-cash interest expense that are required by GAAP. Verrica believes that non-GAAP loss from operations, non-GAAP net loss and non-GAAP net loss per share provides useful information to both management and investors by excluding the effect of certain non-cash expenses and items that Verrica believes may not be indicative of its operating performance, because either they are unusual and Verrica does not expect them to recur in the ordinary course of its business, or they are unrelated to the ongoing operation of the business in the ordinary course. non-GAAP loss from operations, non-GAAP net loss and non-GAAP net loss per share should be considered in addition to results prepared in accordance with GAAP, but should not be considered a substitute for, or superior to, GAAP results. Non-GAAP loss from operations, non-GAAP net loss and non-GAAP net loss per share have been reconciled to the nearest GAAP measure in the tables following the financial statements in this press release.

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. If approved, VP-102 would 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. VP-102 would 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, 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 Verrica'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, interactions with the FDA, the clinical development of Verrica's VP-102 for additional indications and Verrica's other product candidates, expectations regarding the initiation of clinical trials for LTX-315, and Verrica's cash, cash equivalents and marketable securities being sufficient to support planned operations into the third quarter of 2022. 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.

VERRICA PHARMACEUTICALS INC.
Statements of Operations
(unaudited, in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
License revenue:	\$ —	\$ —	\$ 12,000	\$ —
Operating expenses:				
Research and development	3,763	4,988	12,572	13,401
General and administrative	8,005	4,649	21,866	14,747
Total operating expenses	11,768	9,637	34,438	28,148
Loss from operations	(11,768)	(9,637)	(22,438)	(28,148)
Interest income	31	69	96	473
Interest expense	(1,092)	(918)	(3,198)	(2,042)
Net loss	\$ (12,829)	\$ (10,486)	\$ (25,540)	\$ (29,717)
Net loss per share, basic and diluted	\$ (0.47)	\$ (0.42)	\$ (0.95)	\$ (1.19)
Weighted average common shares outstanding, basic and diluted	27,516,477	24,988,939	26,884,527	24,972,972

VERRICA PHARMACEUTICALS INC.
Selected Balance Sheet Data
(unaudited, in thousands)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	\$ 79,495	\$ 65,470
Total assets	88,756	74,154
Short term debt	41,348	35,315
Total liabilities	47,904	41,168
Total stockholders' equity	40,852	32,986

VERRICA PHARMACEUTICALS INC.
Reconciliation of Non-GAAP Financial Measures (unaudited)
(in thousands except per share data)

	Three Months Ended September 30, 2021		
	Loss from Operations	Net loss	Net loss per share
GAAP	\$(11,768)	\$(12,829)	\$(0.47)
Non-GAAP Adjustments:			
Stock-based compensation – General & Admin (a)	1,054	1,054	
Stock-based compensation – Research & Development (a)	427	427	
Non-cash interest expense (b)	—	351	
Adjusted	\$ (10,287)	\$ (10,997)	\$ (0.40)

	Three Months Ended September 30, 2020		
	Loss from Operations	Net loss	Net loss per share
GAAP	\$(9,637)	\$ (10,486)	\$ (0.42)
Non-GAAP Adjustments:			
Stock-based compensation – General & Admin (a)	1,079	1,079	
Stock-based compensation – Research & Development (a)	152	152	
Non-cash interest expense (b)	—	269	
Adjusted	\$ (8,406)	\$ (8,986)	\$ (0.36)

	<u>Nine Months Ended September 30, 2021</u>		
	<u>Loss from Operations</u>	<u>Net loss</u>	<u>Net loss per share</u>
GAAP	\$(22,438)	\$(25,540)	\$ (0.95)
Non-GAAP Adjustments:			
Stock-based compensation – General & Admin (a)	3,582	3,582	
Stock-based compensation – Research & Development (a)	1,150	1,150	
Non-cash interest expense (b)	—	1,058	
Adjusted	\$ (17,706)	\$(19,750)	\$ (0.73)
	<u>Nine Months Ended September 30, 2020</u>		
	<u>Loss from Operations</u>	<u>Net loss</u>	<u>Net loss per share</u>
GAAP	\$(28,148)	\$(29,717)	\$ (1.19)
Non-GAAP Adjustments:			
Stock-based compensation – General & Admin (a)	2,938	2,938	
Stock-based compensation – Research & Development (a)	543	543	
Non-cash interest expense (b)	—	596	
Adjusted	\$ (24,667)	\$(25,640)	\$ (1.03)

- (a) The effects of non-cash stock-based compensation are excluded because of varying available valuation methodologies and subjective assumptions. Verrica believes this is a useful measure for investors because such exclusion facilitates comparison to peer companies who also provide similar non-GAAP disclosures and is reflective of how management internally manages the business.
- (b) The effects of non-cash interest charges are excluded. Verrica believes such exclusion facilitates an understanding of the effects of the debt service obligations on the Company's liquidity and comparisons to peer group companies and is reflective of how management internally manages the business.

FOR MORE INFORMATION, PLEASE CONTACT:

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