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): March 6, 2023

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)

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:

Trading
symbolName of each exchange
on which registeredCommon StockVRCAThe 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 March 6, 2023, Verrica Pharmaceuticals Inc. (the "*Registrant*") issued a press release announcing its financial results for the quarter and year ended December 31, 2022. 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 <u>Press Release, dated March 6, 2023</u>

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: March 6, 2023

Verrica Pharmaceuticals Inc.

/s/ P. Terence Kohler Jr.

P. Terence Kohler Jr. Chief Financial Officer



Verrica Pharmaceuticals Reports Fourth Quarter and Full-Year 2022 Financial Results

New Drug Application for VP-102 assigned PDUFA goal date of July 23, 2023

VP-102 has potential to address the approximately six million patients in the U.S. with molluscum contagiosum

Dosing of first patient in Part 2 of Phase 2 study of VP-315 for treatment of basal cell carcinoma expected in 2Q 2023

Raised gross proceeds of \$32.5 million in secondary offering; pro forma cash and cash equivalents to fund planned operations into 1Q 2024

WEST CHESTER, PA – March 6, 2023 (GLOBE NEWSWIRE) – Verrica Pharmaceuticals Inc. ("Verrica" or "the Company") (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced financial results for the fourth quarter and year ended December 31, 2022.

"We continue to execute across all aspects of our business, highlighted by the FDA's recent acceptance of the filing of the resubmission of our NDA for VP-102, which is being developed for the treatment of molluscum contagiosum," said Ted White, Verrica's President and Chief Executive Officer. "Our potentially first-in-class oncolytic peptide immunotherapy, VP-315, for the treatment of basal cell carcinoma also continues to advance, and we remain on track to dose patients in Part 2 of our ongoing Phase 2 trial in the second quarter.

"In parallel with our regulatory and clinical accomplishments, we continue to make progress in our pre-commercial activities as we prepare for a potential U.S. launch of what could potentially be the first FDA-approved therapy for molluscum – a condition afflicting millions of children each year in the U.S. Utilizing our innovative "Buy-and-Bill" commercial model, we believe shelf-stable products for in-office administration such as VP-102 can be efficiently distributed to reach this large and underserved patient population with minimal capital outlay for dermatology practices."

Business Highlights and Recent Developments

VP-102

On February 27, 2023, the U.S. Food and Drug Administration (FDA) assigned a Prescription Drug User Fee Act (PDUFA) of July 23, 2023 for Verrica's New Drug Application (NDA) for VP-102, which is being developed for the treatment of molluscum contagiosum (molluscum). In January, the Company announced that it resubmitted the NDA for VP-102 for the treatment of molluscum to the FDA.

Verrica is seeking conditional approval to market VP-102 in the United States under the brand name YCANTH™. VP-102 is a proprietary drug-device combination product that contains a GMP-controlled formulation of cantharidin delivered via a single-use applicator that allows for precise topical dosing and targeted administration for the treatment of molluscum. If approved, VP-102 would be the first product approved by the FDA to treat molluscum — a common, highly contagious skin disease that affects an estimated six million people in the United States, primarily children.

VP-315

• Verrica expects to initiate Part 2 of its ongoing Phase 2 study in basal cell carcinoma in the second quarter of 2023. Part 2 is designed to confirm the exploratory dose from Part 1 and identify the recommended dosing regimen for Part 3 of the study. Cohorts will be expanded, and dosing evaluated based upon safety and efficacy results. VP-315 is a potentially first-in-class oncolytic peptide immunotherapy in development as a non-surgical treatment option for non-melanoma skin cancers. The Phase 2 trial is a three-part, open-label, multicenter, dose-escalation, proof-of-concept study with a safety run-in designed to assess the safety, pharmacokinetics, and efficacy of VP-315 when administered intratumorally to adults with biopsy-proven basal cell carcinoma. The study is expected to enroll approximately 66 adult subjects with a histological diagnosis of basal cell carcinoma in at least one eligible target lesion.

Financial Results

Fourth Quarter 2022 Financial Results

- Verrica recognized collaboration revenues of \$0.1 million for the three months ended December 31, 2022, which was related to the Collaboration and License Agreement (Torii Agreement) with Torii Pharmaceutical Col, Ltd (Torii). Verrica did not recognize any revenue for the same period in 2021.
- Verrica reported a net loss of \$5.9 million for the fourth quarter of 2022, compared to a \$9.5 million loss for the same period in 2021.
- Research and development expenses were \$3.0 million in the fourth quarter of 2022, compared to \$3.4 million for the same period in 2021.
 The decrease was primarily attributable to a decrease in CMC costs related to Verrica's development of VP-102 for molluscum contagiosum, external genital warts and common warts in 2022.
- General and administrative expenses were \$3.2 million in the fourth quarter of 2022, compared to \$5.1 million for the same period in 2021. The decrease was primarily due to decreased headcount, a decrease in insurance, and other operating costs.

Full Year 2022 Financial Results

- Verrica recognized collaboration revenues related to the Torii Agreement of \$9.0 million for the year ended December 31, 2022 compared to \$12.0 million for 2021. The current period collaboration revenue was related to an \$8.0 million milestone payment and \$1.0 million related to Torii's purchase of supplies and reimbursement for development activities while the 2021 collaboration revenue was driven by the Torii upfront license milestone payment of \$12.0 million.
- Research and development expenses were \$12.2 million for the year ended December 31, 2022, compared to \$15.9 million for 2021. The decrease was primarily attributable decreased CMC and clinical costs related to Verrica's development of VP-102 for molluscum contagiosum, external genital warts, and common warts in 2022, as well as a decrease of 1.3 million related to payments made to Lytix Biopharma AS (Lytix) upon the achievement of regulatory milestones for VP-315, during 2022 compared to 2021.
- General and administrative expenses were \$17.4 million for the year ended December 31, 2022, compared to \$27.0 million for the same
 period in 2021. The decrease of \$9.6 million was primarily a result of a decrease in expenses related to pre-commercial activities
 for VP-102 and decreases in headcount, insurance, professional fees, and other operating costs.
- Costs of collaboration revenue were \$0.7 million for the year ended December 31, 2022, compared to no costs for the year ended
 December 31, 2021. The costs of collaboration revenue during 2022 consisted of payments for manufacturing supply to support
 development and testing services pursuant to the clinical supply agreement with Torii.
- For the year ended December 31, 2022, net loss on a GAAP basis was \$24.5 million, or \$0.72 per share, compared to a net loss of \$35.1 million, or \$1.30 per share, for the same period in 2021.
- For the year ended December 31, 2022, non-GAAP net loss was \$17.4 million, or \$0.51 per share, compared to a non-GAAP net loss of \$27.6 million, or \$1.02 per share, for the same period in 2021.
- As of December 31, 2022, Verrica had aggregate cash and cash equivalents of \$34.3 million. In February 2023, the Company raised gross proceeds of approximately \$32.5 million in an underwritten offering of its common stock and pre-funded warrants. Including the net proceeds received from this offering and the Company's existing cash and cash equivalents as of December 31, 2022, Verrica believes it has sufficient cash and cash equivalents to support planned operations into the first quarter of 2024.

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, loss on debt extinguishment 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. VP-102 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. Verrica is seeking conditional approval to market VP-102 in the United States under the 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 VP- 315 (formerly LTX-315 and VP-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 approval of VP-102 for the treatment of molluscum, the timing of clinical trial completion for VP-315 and Verrica's cash and cash equivalents being sufficient to support planned operations into the first quarter of 2024. 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, 2022 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 (in thousands except share and per share data)

	Three Months Ended December 31,			Year Ended December 31,					
		2022		2021		2022		2021	
Collaboration revenue	\$	68	\$	_	\$	9,032	\$	12,000	
Expenses:									
Research and development		3,030		3,357		12,198		15,929	
General and administrative		3,189		5,113		17,405		26,979	
Cost of collaboration revenue		62		<u> </u>		725			
Total expenses		6,281		8,470		30,328		42,908	
Loss from operations		(6,213)		(8,470)		(21,296)		(30,908)	
Interest income		287		27		476		123	
Interest expense		_		(1,097)		(2,172)		(4,295)	
Loss on extinguishment of debt		_				(1,437)		_	
Other expense		(6)		<u> </u>		(58)			
Net loss	\$	(5,932)	\$	(9,540)	\$	(24,487)	\$	(35,080)	
Net loss per share, basic and diluted	\$	(0.14)	\$	(0.35)	\$	(0.72)	\$	(1.30)	
Weighted average common shares outstanding, basic and diluted	41	,094,053	2	7,519,053	34	4,163,437	2	7,044,462	

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

	As of December 31,		
	2022	2021	
Cash, cash equivalents and marketable securities	\$ 34,273	\$ 70,354	
Prepaid assets and other assets	4,842	3,974	
Total current assets	39,115	74,328	
PP&E, lease right of use asset, other	5,606	5,797	
Total assets	\$ 44,721	\$ 80,125	
Total liabilities	\$ 4,688	\$ 47,520	
Total stockholders' equity	40,033	32,605	
Total	\$ 44,721	\$ 80,125	

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

	Year Ended December 31, 2022			
	Loss from Operations	Net loss	Net loss per share	
GAAP	\$ (21,296)	\$ (24,487)	\$	(0.72)
Non-GAAP Adjustments:				
Stock-based compensation – Selling, General & Admin (a)	3,525	3,525		
Stock-based compensation – Research & Development (a)	1,460	1,460		
Loss on debt extinguishment		1,437		
Non-cash interest expense (b)		617		
Adjusted	\$ (16,311)	\$ (17,448)	\$	(0.51)

	Year En	Year Ended December 31.			
	Loss from Operations			Net loss per share	
GAAP	\$ (30,908)	\$ (35,080)	\$	(1.30)	
Non-GAAP Adjustments:					
Stock-based compensation – Selling, General & Admin (a)	4,540	4,540			
Stock-based compensation – Research & Development (a)	1,513	1,513			
Non-cash interest expense (b)		1,412			
Adjusted	\$ (24,855)	\$ (27,615)	\$	(1.02)	

- (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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