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 14, 2024

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.)**

44 West Gay Street, Suite 400 **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 (§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 1.01 Entry into a Material Definitive Agreement.

On May 14, 2024 (the "Amendment Effective Date"), Verrica Pharmaceuticals Inc. (the "Company") entered into an amendment (the Amendment") to the Collaboration and License Agreement (the "Collaboration and License Agreement") dated March 17, 2021, by and between the Company and Torii Pharmaceutical Co., Ltd. ("Torii" and together with the Company, the "Parties").

Pursuant to the Amendment, the Parties will equally split the cost of a global Phase 3 clinical trial of YCANTH (VP-102) for the treatment of common warts (the "Trial"), with Torii paying all of the costs when due and the Company repaying Torii half of the costs (the "Company Portion") as further described below. The Company Portion accrues interest annually at the greater of (i) the one-month Secured Overnight Financing Rate plus 2% and (ii) 6%. Torii has the right to offset the Company Portion plus applicable interest against certain of the milestone-based payments that would otherwise be due to the Company under the terms of the Collaboration and License Agreement. In addition, if Torii has not received payment or other recoupment in full of the Company Portion plus applicable interest within 60 months after the date on which Torii made its first payment for the Trial costs, Torii may invoice the Company for the remained Company Portion plus applicable interest.

If the Trial cannot be conducted in Japan as a result of revocation of regulatory approval or the Company materially breaches either the Collaboration and License Agreement as amended by the Amendment (the "Agreement") or the Warrant (as defined below) and such breach remains uncured for a specified period, Torii is not required to pay for any additional Trial costs and the Company will be required to repay Torii for all Trial costs incurred by Torii, but such repayment will not occur prior to a specified period of time following the expiration of the Company's Credit Agreement with OrbiMed Royalty & Credit Opportunities IV, LP.

The Parties also agreed that if the Company licenses to a third party any of the data generated in connection with Trial (a "License"), the Parties will negotiate in good faith and enter into an agreement whereby the Company will pay Torii at least a low double-digit percentage of the consideration received by the Company under such License.

Pursuant to the Amendment, Torii has the right to terminate the Agreement upon specified prior written notice to the Company, but cannot terminate prior to the earlier of (i) the date of database lock for the Trial or (ii) termination of the Trial. The other termination provisions in the Collaboration and License Agreement remain unchanged.

The foregoing is a summary description of certain terms of the Amendment, is not complete and is qualified in its entirety by reference to the text of the Amendment, which the Company expects to file as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2024.

Item 3.02 Unregistered Sales of Equity Securities.

On the Amendment Effective Date, in connection with the Torii Amendment, the Company issued Torii a warrant (the "Warrant") to purchase up to 500,000 shares of the Company's common stock (the "Exercise Shares") at an exercise price per share of $9.56, which equaled the closing price of the Company's common stock on the trading day before the Amendment Effective Date. The Warrant has a term of ten years (the "Term") and is exercisable only with respect to the Exercise Shares that have vested as of the date of exercise. The Exercise Shares vest as set forth below:

- 166,666 of the Exercise Shares will vest in full on the date during the Term that the first patient is dosed in the Trial.
- 166,666 of the Exercise Shares will vest in full on the date during the Term that the database lock for the Trial occurs.
- 166,668 of the Exercise Shares will vest in full on the date during the Term that the Company submits a New Drug Application (as more fully defined in 21 CFR 314.5, et seq.) with the U.S. Food and Drug Administration for YCANTH (VP-102) for the treatment of common warrants.

The foregoing is a summary description of certain terms of the Warrant, is not complete and is qualified in its entirety by reference to the text of the Warrant, which the Company expects to file as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2024.

The Warrant was issued in reliance upon the exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Rule 506 of Regulation D thereunder.

Item 7.01 Regulation FD Disclosure.

On May 15, 2024, the Company issued a press release announcing the Amendment. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01, 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 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 of Verrica Pharmaceuticals Inc., dated May 15, 2024
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: May 15, 2024

/s/ P. Terence Kohler, Jr.
P. Terence Kohler, Jr.
Chief Financial Officer

Exhibit 99.1

Verrica Pharmaceuticals Announces Amendment to Company's Collaboration and License Agreement with Torii Pharmaceutical Co. Ltd. to Fund Global Pivotal Phase 3 Clinical Trial to Study YCANTH® for the Treatment of Common Warts

Global pivotal Phase 3 clinical trial would be conducted jointly by Verrica and Torii Pharmaceutical; trial expected to begin in the 1st half of 2025

Amendment should benefit both parties from a cost and time to market standpoint; funding structure is expected to have a minimal impact on Verrica's cash position

Common warts is one of the largest and most underserved patient populations in medical dermatology with a prevalence of ~22M in the U.S. and no FDA approved products; Verrica believes common warts represents a multibillion-dollar commercial opportunity; patient opportunity for common warts in the E.U. is believed to be at least equivalent to the U.S.

WEST CHESTER, PA – May 15, 2024 (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 that it has entered into an amendment to its existing licensing agreement with Torii Pharmaceutical Co. Ltd. (Torii), to jointly conduct a global pivotal Phase 3 clinical trial of YCANTH® for the treatment of common warts.

"We are pleased to announce this significant amendment to our license agreement with Torii Pharmaceutical to advance YCANTH into a global pivotal Phase 3 clinical trial for the treatment of common warts," said Ted White, President and Chief Executive Officer of Verrica Pharmaceuticals. "Torii has been an outstanding partner in the development of YCANTH for molluscum contagiosum, and we look forward to our continued collaboration to progress YCANTH through a pivotal global Phase 3 clinical trial for common warts, which represents the single largest and most underserved patient population in all of dermatology. If positive, the data from this global Phase 3 clinical trial would not only potentially allow Verrica to submit a sNDA in the U.S. seeking FDA approval for the use of YCANTH for the treatment of common warts, but may also be utilized by Verrica to seek future marketing authorizations in territories outside the U.S. and Japan, including potentially within the European Union."

In March 2021, Verrica and Torii Pharmaceutical entered into an agreement granting Torii an exclusive license to develop and commercialize Verrica's product candidates for the treatment of molluscum contagiosum and common warts in Japan, including YCANTH (TO-208 in Japan). The terms of the amendment would enable the two parties to equally split the cost of the global Phase 3 clinical trial in common warts, with Torii funding Verrica's portion of the costs as an offset to Torii's future payment obligations to Verrica based on regulatory milestones and

sales of YCANTH for molluscum contagiosum and common warts in Japan. In addition, Torii would make a milestone payment of $8 million to Verrica upon the first patient dosed in Japan in the Phase 3 clinical trial. Initiation of the global study remains subject to feedback from the U.S. FDA and Japan's Pharmaceuticals and Medical Device Agency (PMDA) on the proposed design of the Phase 3 clinical trial.

With a prevalence of approximately 22 million patients in the U.S. alone and no FDA approved therapies, common warts represent one of the largest unmet needs in all of dermatology, which Verrica believes represents a multibillion-dollar commercial opportunity. In the United States, approximately 50% of the patients who seek treatment for common warts are children. If YCANTH is successfully developed, approved and commercialized for the treatment of common warts, Verrica anticipates a high degree of call point overlap and marketing synergies with its molluscum promotion of YCANTH. Verrica further believes that the common wart patient opportunity in the European Union is at least as large as that in the United States.

COVE-1 Phase 2 Data in Common Warts

Verrica has previously announced positive results from the Phase 2 COVE-1 clinical trial that evaluated YCANTH (VP-102) for the treatment of common warts. COVE-1 was an open label clinical trial that evaluated the safety and efficacy of VP-102 in two cohorts of subjects with up to six warts. The primary analysis was conducted at Day 84 with an additional period of follow-up through Day 147. Topline analysis included data from the assessment of warts at study visits over 12 weeks. Results showed that 51% of subjects (18 of 35) treated with VP-102 in Cohort 2 achieved complete clearance of all treatable warts at Day 84. Secondary endpoints included the percent change from baseline in the number of treatable warts and VP-102 achieved a 51% reduction in the number of warts (28 of 55 warts) compared to baseline by Day 84.

About YCANTH (formerly VP-102)

YCANTH 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. YCANTH is currently approved by the FDA to treat molluscum in adult and pediatric patients 2 years of age and older, a common, highly contagious viral skin disease that affects an estimated six million people in the United States, primarily children. Please visit YCANTHPro.com for additional information.

In addition, Verrica has successfully completed a Phase 2 clinical trial of VP-102 for the treatment of common warts and a Phase 2 clinical trial of VP-102 for the treatment of external genital warts.

YCANTH should only be administered by a trained healthcare professional. YCANTH is not for home use.

Important Safety Information

CONTRAINDICATIONS:

None.

WARNINGS AND PRECAUTIONS:

- YCANTH is for topical use only. YCANTH is not for oral, mucosal, or ophthalmic use. Life threatening or fatal toxicities can occur if YCANTH is administered orally. Avoid contact with the treatment area, including oral contact, after treatment. Ocular toxicity can occur if YCANTH comes in contact with eyes. If YCANTH gets in eyes, flush eyes with water for at least 15 minutes.
- Local Skin Reactions: Reactions at the application site may occur, including vesiculation, pruritus, pain, discoloration, and erythema. Avoid application near eyes and mucosal tissue, and to healthy skin. If YCANTH contacts any unintended surface, or healthy skin, immediately remove. If severe local skin reactions occur, remove prior to the recommended 24 hours after treatment.
- YCANTH is flammable, even after drying. Avoid fire, flame or smoking near lesion(s) during treatment and after application until removed.

ADVERSE REACTIONS:

The most common (incidence ≥1%) reactions are the following local skin reactions at the application site: vesiculation, pain, pruritus, scabbing, erythema, discoloration, application site dryness, edema, and erosion. Local skin reactions at the application site were observed in 97% of subjects treated with YCANTH during clinical trials. These local skin reactions are expected and related to the anticipated blistering response of the skin to cantharidin.

DRUG INTERACTIONS:

No studies evaluating the drug interaction potential of cantharidin have been conducted.

USE IN SPECIFIC POPULATIONS:

Pregnancy: There are no available data with use of YCANTH in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Given that systemic exposure to cantharidin following topical administration is low, maternal use is not expected to result in fetal exposure to the drug.

Lactation: Avoid application of YCANTH topical solution to areas with increased risk for potential ingestion by or ocular exposure to the breastfeeding child.

OVERDOSAGE:

Oral ingestion of cantharidin has resulted in renal failure, blistering and severe damage to the gastrointestinal tract, coagulopathy, seizures, and flaccid paralysis.

Please see accompanying full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact Verrica Pharmaceuticals Inc. at 1-877-VERRICA (1-877-837-7422), or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Local skin reactions are expected and should be reported if they are severe.

About Common Warts

Common warts (verruca vulgaris) are skin growths caused by a contagious viral skin infection, most commonly on the fingers or hands. The human papilloma virus (HPV), the causative agent in common warts, is transmitted by touch. The virus enters the skin and causes skin growths by inducing the skin cells to multiply rapidly. Common warts are benign, but treatment is recommended to prevent the spread of infection and relieve the patient's physical and psychological discomfort.

About Verrica Pharmaceuticals Inc.

Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. Verrica's product YCANTH (cantharidin), is the first and only commercially available treatment approved by the FDA to treat adult and pediatric patients two years of age and older with molluscum contagiosum, a highly contagious viral skin infection affecting approximately 6 million people in the United States, primarily children. VP-102 is also in development to treat common warts and external genital warts, two of the largest remaining unmet needs in medical dermatology. Verrica is developing VP-103, its second cantharidin-based product candidate, for the treatment of plantar warts. Verrica 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 non-melanoma skin cancers including basal cell carcinoma and squamous cell carcinoma. 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 the Company's expectations with regard to the clinical development and potential regulatory approval of and commercialization of YCANTH™ for the treatment of common warts in the United States and Japan, including Verrica's expectations regarding the timing of the initiation of a Phase 3 clinical trial of YCANTH™ (VP-102) for the treatment of common warts, and the potential to seek marketing authorizations outside of the United States and Japan. 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, and other risks and uncertainties that are described in Verrica's Annual Report on Form 10-K for the year

ended December 31, 2023, 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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