**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 4, 2021**



**Verrica Pharmaceuticals Inc.**

**(Exact Name of Registrant as Specified in its Charter)**



|  |  |  |
| --- | --- | --- |
| **Delaware** | **001-38529** | **46-3137900** |
| **(State or Other Jurisdiction** | **(Commission** | **(IRS Employer** |
| **of Incorporation)** | **File Number)** | **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** | **Name of each exchange** |  |
| **symbol** | **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 March 4, 2021, Verrica Pharmaceuticals Inc. (the “***Registrant***”) issued a press release announcing its financial results for the quarter and year ended December 31, 2020. 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 March 4, 2021](#page4)

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: March 4, 2021 /s/ A. Brian Davis



A. Brian Davis

Chief Financial Officer

**Exhibit 99.1**



**Verrica Pharmaceuticals Reports Fourth Quarter and Full-Year 2020 Financial Results**

*– FDA accepts resubmitted NDA for VP-102 for the treatment of molluscum contagiosum with PDUFA goal date of June 23, 2021 –*

*– Verrica Announces Torii Pharmaceutical Has Exercised Option to Acquire Exclusive License Agreement to Develop and Commercialize VP-102 in*

*Japan Triggering 60-Day Period to Finalize and Execute License Agreement –*

WEST CHESTER, PA – March 4, 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 fourth quarter ended December 31, 2020.

“Over the past year, we worked rapidly to resubmit the NDA for our lead product candidate, VP-102, in molluscum contagiosum, which we recently announced has been accepted for filing and assigned a PDUFA goal date of June 23, 2021,” said Ted White, Verrica’s President and Chief Executive Officer. “We are excited to announce today that Torii Pharmaceutical Co., Ltd. has exercised the option we granted to them in August to develop and commercialize VP-102 in Japan for the treatment of molluscum contagiosum and common warts. The prevalence of molluscum contagiosum alone in Japan was approximately 1.6 million cases in 2017. The option exercise triggers a 60-day period for Torii and us to finalize and execute a license agreement. Further, new analyses of Verrica’s pivotal Phase 3 molluscum trials and Verrica’s Phase 2 study in external genital warts continue to generate positive results, which have been published in medical journals and presented at top dermatology conferences.”

**Business Highlights and Recent Developments**

* The Company recently announced that its resubmitted New Drug Application (NDA) for VP-102 (cantharidin 0.7% Topical Solution), a proprietary topical therapy for the treatment of molluscum, has been accepted for filing by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) goal date assigned by the FDA for this NDA is June 23, 2021.
* On March 2, Torii Pharmaceutical Co., Ltd. (Torii) exercised its option to acquire an exclusive license to develop and commercialize Verrica’s product candidates for the treatment of molluscum contagiosum and common warts in Japan, including VP-102. The parties have 60 days from the option exercise date to finalize and execute a license agreement. Under the terms of the Option Agreement, the license agreement would provide for Torii to make an up-front payment of $11.5 million, up to an additional $58 million in aggregate payments contingent on achievement of specified development, regulatory, and sales milestones, and tiered transfer price payments for supply of product in the percentage range of the mid-30s to the mid-40s of net sales. Torii would be responsible for all development activities and costs in support of obtaining regulatory approval in Japan.

**Clinical Program Results**

* Verrica announced positive topline results from its Phase 2 CARE-1 clinical study of VP-102 in external genital warts (EGW). VP-102 achieved positive results on both the primary endpoint of complete clearance of all treatable EGW at Day 84 and the secondary endpoint of the percentage reduction of EGW at Day 84.
* Positive data from new post-hoc pooled analyses of the pivotal Phase 3 CAMP trials, segmenting molluscum lesions by body region and study visit, were presented in poster format online for the 2021 Winter Clinical Dermatology Conference. The results demonstrated that the percentage of participants with complete clearance of all baseline and new molluscum lesions was statistically significantly higher in the VP-102 group compared to vehicle across all body regions, beginning at earlier timepoints and continuing through the end of study visit (Day 84).
* Positive data from Verrica’s Phase 2 CARE-1 clinical study of VP-102 in EGW were also presented at the 2021 Winter Clinical Dermatology Conference. Results demonstrated that treatment with VP-102 resulted in a statistically significantly higher complete clearance rate of all EGW compared to vehicle at Visit 4 (Day 63) and at the End of Treatment Visit (Day 84) regardless of drug exposure duration (6 or 24 hours).
* Positive results from the Phase 2, open-label study evaluated the safety, efficacy, systemic exposure, and impact on quality of life (QoL) with treatment using VP-102 for the treatment of molluscum were published online in the January 2021 issue of the *Journal of Drugs in* *Dermatology*.
* Positive pooled results from the Company’s two pivotal Phase 3 CAMP studies evaluating VP-102 in children and adults with molluscum were published in the online February 2021 issue of the *American Journal of Clinical Dermatology*.

**Financial Results**

*Fourth Quarter 2020 Financial Results*

* Verrica reported a net loss of $13.0 million for the fourth quarter of 2020, compared to a $7.6 million net loss for the same period in 2019.
* Research and development expenses were $2.3 million in the fourth quarter of 2020, compared to $4.0 million for the same period in 2019. The decrease was primarily attributable to decreased costs related to Verrica’s development of VP-102 for common warts and external genital warts and VP-103 for plantar warts, partially offset by increased costs related to the resubmission of the NDA for VP-102 in December 2020.
* General and administrative expenses were $9.8 million in the fourth quarter of 2020, compared to $4.0 million for the same period in 2019. The increase was primarily a result of higher stock-based compensation costs, which includes $4.8 million of stock-based compensation expense recorded in December 2020 related to the modification of a stock award to a former executive. The increase was also driven by 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.

*Full Year 2020 Financial Results*

* Verrica reported a net loss of $42.7 million for the year ended December 31, 2020, compared to a $28.2 million net loss for the same period in 2019.
* Research and development expenses were $15.7 million for the year ended December 31, 2020, compared to $15.4 million for the same period in 2019. The increase was primarily attributable to increased Chemistry, Manufacturing and Controls (CMC) costs related to Verrica’s development of VP-102 for molluscum contagiosum and increased compensation costs, partially offset by decreased clinical costs related to Verrica’s development of VP-102 for molluscum contagiosum.
* General and administrative expenses were $24.5 million for the year ended December 31, 2020, compared to $14.6 million for the same period in 2019. The increase was primarily a result of higher stock-based compensation costs, which includes $4.8 million of stock-based compensation expense recorded in December 2020 related to the modification of a stock award to a former executive. The increase was also driven by 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.
* As of December 31, 2020, Verrica had aggregate cash, cash equivalents, and marketable securities of $65.5 million, which the Company believes will be sufficient to support planned operations at least into the first quarter of 2022.

**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 June 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)**

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 Company’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, the clinical development of Verrica’s VP-102 for additional indications and Verrica’s other product candidates, the potential entry into a license agreement with Torii and the terms of such license agreement, and Verrica’s cash, cash equivalents and marketable securities being sufficient to support planned operations at least into the first 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, 2019, Verrica’s Quarterly Report on Form 10-Q for the quarter ended September 30, 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.**

**Condensed Statements of Operations**

**(unaudited, in thousands except share and per share data)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | **Three Months Ended** |  |  | **Twelve Months Ended** |  |
|  |  | **December 31,** |  |  | **December 31,** |  |
|  |  | **2020** |  |  |  | **2019** |  |  | **2020** |  |  |  | **2019** |  |  |  |
| Operating expenses: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Research and development | $ | 2,272 | $ | 3,972 | $ | 15,673 | $ | 15,436 |  |  |
| General and administrative |  | 9,761 |  |  | 4,018 |  |  | 24,508 |  |  | 14,644 |  |  |
| Total operating expenses |  | 12,033 |  |  |  | 7,990 |  |  |  | 40,181 |  |  |  | 30,080 |  |  |  |
| Loss from operations |  | (12,033) |  |  | (7,990) |  |  | (40,181) |  |  | (30,080) |  |
| Interest income |  | 48 |  |  | 354 |  |  | 521 |  |  | 1,877 |  |  |
| Interest expense |  | (991) |  |  |  | — |  |  | (3,033) |  |  | — |  |
| Other expense |  | (1) |  |  | (1) |  |  | (1) |  |  | (4) |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Net loss | $ | (12,977) | $ | (7,637) | $ | (42,694) | $ | (28,207) |  |
| Net loss per share, basic and diluted |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| $ | (0.52) |  |  | $ | (0.31) |  |  | $ | (1.71) |  |  | $ | (1.13) |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Weighted average common shares outstanding, basic and diluted |  | 25,062,817 |  |  |  | 24,922,080 |  |  | 24,995,556 |  |  | 24,897,889 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **VERRICA PHARMACEUTICALS INC.** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Selected Balance Sheet Data** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **(unaudited, in thousands)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  | **December 31, 2020** |  |  | **December 31, 2019** |  |
| Cash, cash equivalents and marketable securities |  |  |  |  |  |  | $ |  | 65,470 |  |  | $ |  | 62,017 |  |  |
| Total assets |  |  |  |  |  |  |  |  | 74,154 |  |  |  |  | 68,424 |  |
| Debt, net |  |  |  |  |  |  |  |  | 35,315 |  |  |  |  | — |  |
| Total liabilities |  |  |  |  |  |  |  |  | 41,168 |  |  |  |  | 3,409 |  |
| Total stockholders’ equity |  |  |  |  |  |  |  |  | 32,986 |  |  |  |  | 65,015 |  |

**FOR MORE INFORMATION, PLEASE CONTACT:**

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