

**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 16, 2022

Vera Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40407
(Commission File Number)

81-2744449
(IRS Employer
Identification No.)

8000 Marina Boulevard, Suite 120
Brisbane, California
(Address of principal executive offices)

94005
(Zip Code)

(650) 770-0077
Registrant's telephone number, including area code

Not Applicable
(Former name or former address, if changed since last report)

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 Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|----------------------|---|
| Class A common stock, \$0.001 par value per share | VERA | 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 May 16, 2022, Vera Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the three months ended March 31, 2022, and providing recent corporate updates. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”), and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press Release of Vera Therapeutics, Inc., dated May 16, 2022. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

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 thereunto duly authorized.

Vera Therapeutics, Inc.

Date: May 16, 2022

By: /s/ Sean Grant
Sean Grant, Chief Financial Officer

FOR IMMEDIATE RELEASE

Vera Therapeutics Provides Business Update and Reports First Quarter 2022 Financial Results

- *Phase 2b ORIGIN clinical trial of atacicept on track, topline data expected Q4 2022*
- *Initiation of Phase 3 pivotal clinical trial of atacicept in lupus nephritis planned for 2H-2022, following positive clinical strategy meeting with FDA earlier this year*
- *Results from a 12-week interim analysis of Phase 2 study of MAU868 in kidney transplant recipients planned in June 2022; Phase 2b or Phase 3 clinical trial of MAU868 expected to initiate in 2023*
- *Strong balance sheet with approximately \$151 million in cash, cash equivalents and marketable securities as of March 31, 2022 and access to a \$45.0 million credit facility expected to fund operations to Q2 2024*

BRISBANE, Calif., May 16, 2022 – Vera Therapeutics, Inc. (Nasdaq: VERA), a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases, today reported its business highlights and financial results for the quarter ended March 31, 2022.

“We continue to successfully execute our development strategy in early 2022 and are on track to achieve several key milestones and announce clinical data across our development pipeline throughout the year. We are positioned to fund our current programs and operations with current cash, cash equivalents, and marketable securities plus available credit, to the second quarter of 2024,” said Marshall Fordyce, MD, founder and CEO of Vera Therapeutics. “Enrollment in the ORIGIN study, which is evaluating the potential for atacicept to treat patients who suffer from the devastating effects of kidney disease, remains on track to be completed in mid-2022. Topline results from the study are expected to be presented in the fourth quarter 2022, which we expect will be used to support the initiation of a pivotal Phase 3 clinical trial of atacicept in 2023. In addition, we are preparing to initiate a Phase 3 pivotal clinical trial for atacicept to treat lupus nephritis in the second half of this year. This is an exciting next step for this program, as we believe that atacicept has the potential to be a best-in-disease treatment for lupus nephritis patients. This is a high unmet medical need, with a high rate of morbidity and mortality, and many patients progressing to end-stage renal disease.”

“During the past quarter, we hosted a KOL event to help educate the market about BK Virus infections and the opportunity for our late-stage clinical asset, MAU868, which included a presentation from world-renowned transplant nephrologist and pioneering kidney transplant researcher, Stanley C. Jordan, M.D., FASN, FAST. We believe this event has helped set the stage for the upcoming presentation of the 12-week interim data from the Phase 2 study of MAU868 at the American Transplant Conference on June 4, 2022. In addition, we continue to make

progress with our planning to initiate a Phase 2b or Phase 3 clinical trial of MAU868 in kidney transplant patients with BK Virus viremia in 2023,” concluded Dr. Fordyce.

First Quarter and Recent Business Highlights

- Enrollment in the Phase 2b ORIGIN clinical trial of atacicept remains on track, topline data expected in the fourth quarter 2022.
- Hosted a KOL webinar featuring a discussion on BK Virus (BKV) by world-renowned transplant nephrologist and pioneering kidney transplant researcher, Stanley C. Jordan, M.D., FASN, FAST, as well as an overview of MAU868, Vera’s lead asset in the treatment of BKV and a potential first-in-class monoclonal antibody to treat BKV infections.
- Effective as of the date of Vera’s 2022 Annual Meeting of Stockholders, appointed Michael M. Morrissey, Ph.D., as chairman of Vera’s board of directors. Dr. Morrissey has served as president and CEO of Exelixis, Inc. since July 2020.
- Strengthened the balance sheet with a completed upsized follow-on public offering in February 2022; reporting total cash, cash equivalents and marketable securities of approximately \$151 million as of March 31, 2022 and access to a \$45.0 million credit facility, which are expected to fund operations to the second quarter of 2024.

Upcoming Milestones

- Two presentations featuring new clinical data from the Phase 2a JANUS clinical trial of atacicept in patients with IgA nephropathy (IgAN) and renal data from a post-hoc analysis of the Phase 2 APRIL-SLE study evaluating atacicept in patients with systemic lupus erythematosus (SLE) are scheduled at the 59th European Renal Association European Dialysis and Transplant Association (ERA-EDTA) Congress being held May 19-22, 2022.
 - The 12-week results from the interim analysis of a Phase 2 study in BKV viremia among kidney transplant recipients are scheduled to be presented at the American Transplant Conference on June 4, 2022. MAU868 has been to be well tolerated and showed a greater proportion of subjects with decrease in BKV plasma viral load versus placebo.
 - Plan to initiate in the second half of 2022 a randomized, double-blinded, placebo-controlled Phase 3 clinical trial of atacicept in lupus nephritis. The trial will evaluate the efficacy and safety of atacicept in subjects with lupus nephritis by assessing 150 mg of once-weekly subcutaneous injections of atacicept versus placebo. The trial consists of a 52-week primary endpoint within a 104-week open-label treatment period and a 52-week safety follow-up period.
 - Plan to announce topline data for the Phase 2b ORIGIN clinical trial – a dose-ranging study evaluating the safety and efficacy of atacicept in patients with IgAN who
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continue to have persistent proteinuria and remain at high risk of disease progression – in the fourth quarter of 2022.

- Expect to initiate in 2023 a Phase 2b or Phase 3 clinical trial of MAU868 in BKV viremia among kidney transplant recipients.

Financial Results for the Quarter Ended March 31, 2022

For the three months ended March 31, 2022, the company reported a net loss of \$17.1 million, or a net loss per diluted share of \$0.71, compared to a net loss of \$4.7 million, or a net loss per diluted share of \$12.23, for the same period last year. Outstanding shares of redeemable convertible preferred stock were excluded from the computation of net loss per diluted share for periods prior to the conversion of those shares to common stock in May 2021.

During the quarter ended March 31, 2022, net cash used in operating activities was \$9.0 million, compared to \$4.1 million for the same period last year.

Vera reported approximately \$151 million in cash, cash equivalents and marketable securities as of March 31, 2022. In addition, the company has secured a credit facility through Oxford with a remaining borrowing capacity of up to \$45.0 million.

About Vera

Vera Therapeutics is a late-stage biotechnology company focused on developing treatments for serious immunological diseases. Vera's mission is to advance treatments that target the source of immunologic diseases in order to change the standard of care for patients. Vera's lead product candidate is atacicept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both B lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases, including IgA nephropathy (IgAN), also known as Berger's disease, and lupus nephritis. In addition, Vera is evaluating additional diseases where the reduction of autoantibodies by atacicept may prove medically useful. Vera is also developing MAU868, a monoclonal antibody designed to neutralize infection with BK Virus, a polyomavirus that can have devastating consequences in certain settings such as kidney transplant. For more information, please visit www.veratx.com.

Forward-Looking Statements

Statements contained in this press release regarding matters, events or results that may occur in the future are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the continued tolerability of Vera's product candidates, research and clinical development plans and timing, the scope, progress, and results of developing Vera's product candidates, strategy, and regulatory matters, including the timing and likelihood of success of obtaining drug approvals. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "plans," "will," "expects," "scheduled," "potential,"

and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Vera's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks related to the regulatory approval process, results of earlier clinical trials may not be obtained in later clinical trials, risks and uncertainties associated with Vera's business in general, the impact of the COVID-19 pandemic, and the other risks described in Vera's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Vera undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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VERA THERAPEUTICS, INC.
Condensed Statement of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

| | Three Months Ended | |
|---|---------------------------|-------------------|
| | March 31, | |
| | 2022 | 2021 |
| | <i>(unaudited)</i> | |
| Operating expenses: | | |
| Research and development | \$ 12,549 | \$ 2,932 |
| General and administrative | 4,472 | 1,784 |
| Total operating expenses | 17,021 | 4,716 |
| Loss from operations | (17,021) | (4,716) |
| Total other (expense) income, net | (64) | 2 |
| Net loss | <u>\$ (17,085)</u> | <u>\$ (4,714)</u> |
| Unrealized loss on available-for-sale securities | (12) | - |
| Total loss and comprehensive loss | <u>\$ (17,097)</u> | <u>\$ (4,714)</u> |
| Net loss per share attributable to common stockholders, basic and diluted | <u>\$ (0.71)</u> | <u>\$ (12.23)</u> |
| Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted | <u>24,227,282</u> | <u>385,401</u> |

VERA THERAPEUTICS, INC.
Condensed Balance Sheets
(in thousands)

| | March 31, 2022 | December 31, 2021 |
|--|---------------------------|------------------------------|
| Assets | <i>(unaudited)</i> | |
| Current assets: | | |
| Cash and cash equivalents | \$ 111,506 | \$ 79,674 |
| Marketable securities | 39,432 | - |
| Prepaid expenses and other current assets | 6,805 | 2,863 |
| Total current assets | 157,743 | 82,537 |
| Restricted cash, noncurrent | 293 | 293 |
| Property and equipment, net | 16 | - |
| Operating lease right-of-use assets | 6,275 | - |
| Prepaid expenses and other noncurrent assets | 67 | 51 |
| Non-marketable equity securities | 580 | 867 |
| Total assets | <u>\$ 164,974</u> | <u>\$ 83,748</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 7,328 | \$ 1,385 |
| Operating lease liabilities | 2,490 | - |
| Restructuring liability | - | 377 |
| Accrued expenses and other current liabilities | 10,151 | 5,928 |
| Total current liabilities | 19,969 | 7,690 |
| Long-term debt | 4,937 | 4,923 |
| Operating lease liabilities, noncurrent | 5,357 | - |
| Restructuring liability, noncurrent | - | 1,257 |
| Accrued and other noncurrent liabilities | 286 | 286 |
| Total liabilities | 30,549 | 14,156 |
| Stockholders' equity | | |
| Common stock | 27 | 21 |
| Additional paid-in capital | 275,551 | 193,627 |
| Accumulated other comprehensive loss | (12) | - |
| Accumulated deficit | (141,141) | (124,056) |
| Total stockholders' equity | 134,425 | 69,592 |
| Total liabilities and stockholders' equity | <u>\$ 164,974</u> | <u>\$ 83,748</u> |

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