

**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 9, 2023

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 November 9, 2023, Vera Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2023, 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 November 9, 2023.
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: November 9, 2023

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

Vera Therapeutics Provides Business Update and Reports Third Quarter Financial Results

- Phase 2b open-label extension eGFR and proteinuria data expected in the first quarter of 2024; actively adding sites and enrolling pivotal Phase 3 ORIGIN 3 study of atacept in IgAN
- Announced analysis of Phase 2b ORIGIN study showing resolution of hematuria in the majority of patients, at the American Society of Nephrology Kidney Week 2023
- Strong balance sheet expected to fund operations to early 2026

BRISBANE, Calif., November 9, 2023 – Vera Therapeutics, Inc. (Nasdaq: VERA), a late clinical-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunologic diseases, today reported its business highlights and financial results for the third quarter ended September 30, 2023.

“Vera presented additional positive data from the Phase 2b ORIGIN trial at Kidney Week 2023, which support the potential of atacept as a disease-modifying treatment for patients with IgAN. We showed that patients on atacept achieved durable and significant Gd-IgA1 reduction over 36 weeks regardless of baseline quartile. We also showed that hematuria – clinical evidence of active nephritis – resolves in the majority of patients receiving atacept, which offers an additional therapeutic benefit of targeting the source of this disease through dual inhibition of BAFF and APRIL,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “These new data from the Phase 2b ORIGIN trial further support the advancement of our clinical development of atacept, including the ongoing pivotal ORIGIN 3 trial.”

Third Quarter and Recent Business Highlights

- Actively adding sites and enrolling pivotal Phase 3 clinical trial (ORIGIN 3) of atacept for the treatment of IgA nephropathy (IgAN)
 - Presented data at ASN Kidney Week 2023 showing patients on atacept 150 mg achieved durable and significant Gd-IgA1 reduction over 36 weeks where regardless of baseline quartile, 82% of patients (n=27/33) achieved reduction to the lowest risk quartile. Gd-IgA1 reduction was also correlated with improvement in hematuria at week 36 (r=0.35, p=0.0003). High serum levels of galactose-deficient IgA1 (Gd-IgA1) are associated with greater risk of end-stage renal disease or death.
 - Presented data at ASN Kidney Week 2023 showing hematuria was resolved in 80% of patients with IgAN (n=12/15) receiving atacept 150 mg compared to 5% (n=1/19) on placebo
 - Strong balance sheet with cash and equivalents and available credit expected to fund operations to early 2026
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Upcoming Milestones

- OLE data from ORIGIN Phase 2b clinical trial to be presented in the first quarter of 2024
- Phase 3 full enrollment estimated in the second half of 2024
- Topline data from the pivotal ORIGIN 3 trial expected to be presented in the first half of 2025

Financial Results for the Quarter Ended September 30, 2023

For the quarter ended September 30, 2023, the company reported a net loss of \$20.1 million, or a net loss per diluted share of \$0.45, compared to a net loss of \$24.7 million, or a net loss per diluted share of \$0.91, for the same period last year.

During the nine months ended September 30, 2023, net cash used in operating activities was \$67.0 million, compared to \$46.4 million for the same period last year.

Vera reported \$159.9 million in cash, cash equivalents, and marketable securities as of September 30, 2023.

About Vera

Vera Therapeutics is a late clinical-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-cell Activating Factor (BAFF or BLYS) and A Proliferation-Inducing Ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases, including 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 (BKV), a polyomavirus that can have devastating consequences in certain settings such as kidney transplant. Vera retains all global developmental and commercial rights to atacicept and MAU868. For more information, please visit www.veratx.com.

About Atacicept

Atacicept is an investigational recombinant fusion protein that contains the soluble transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) receptor that binds to the cytokines B-cell Activating Factor (BAFF) and A Proliferation-Inducing Ligand (APRIL). These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with certain autoimmune diseases, including IgAN and lupus nephritis. The Phase 2b ORIGIN clinical trial of atacicept in IgAN met its primary endpoint and showed a statistically significant placebo-controlled reduction in mean proteinuria versus baseline at 24 and 36 weeks. Vera believes atacicept is positioned for



best-in-class potential, targeting B cells and plasma cells to reduce autoantibodies and having been administered to more than 1,500 patients in clinical studies across different indications.

About MAU868

MAU868, a potential first-in-class monoclonal antibody, has the potential to neutralize infection by blocking BKV virions from binding to host cells. BKV is a polyoma virus that can be reactivated in settings of immunosuppression, such as in kidney transplant. It is a leading cause of kidney transplant loss and transplant-associated morbidity; there are currently no approved treatments for BKV. Vera holds an exclusive worldwide license from Amplyx Pharmaceuticals, Inc., a wholly owned subsidiary of Pfizer Inc., for the development and commercialization of MAU868 in all indications.

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, Vera’s anticipated poster presentations at the American Society of Nephrology Kidney Week 2023, the therapeutic potential of atacicept’s dual inhibitor approach to treating the cause of IgAN, the strength and adequacy of Vera’s balance sheet and its ability to fund operations into early 2026, Vera’s plans to enroll and complete the pivotal Phase 3 ORIGIN 3 trial, the design and management of such trial, Vera’s expectation to report preliminary data from such trial in the first half of 2025, expectations regarding reporting additional data from Vera’s Phase 2b ORIGIN clinical trial in the first half of 2024, and Vera’s product candidates, strategy, and regulatory matters. 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 “potential,” “will,” “plan,” 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, preliminary results may not be predictive of topline results, risks and uncertainties associated with Vera’s business in general, the impact of macroeconomic and geopolitical events, 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.

For more information, please contact:

Investor Contact:



Joyce Allaire
LifeSci Advisors
212-915-2569
jallaire@lifesciadvisors.com

Media Contact:

Minyan Weiss
Uncapped Communications
uncappedverateam@uncappedcommunications.com

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 16,100	\$ 19,656	\$ 57,440	\$ 42,317
General and administrative	5,656	5,588	17,544	15,005
Total operating expenses	<u>21,756</u>	<u>25,244</u>	<u>74,984</u>	<u>57,322</u>
Loss from operations	(21,756)	(25,244)	(74,984)	(57,322)
Total other income, net	1,652	565	4,649	705
Net loss	<u>\$ (20,104)</u>	<u>\$ (24,679)</u>	<u>\$ (70,335)</u>	<u>\$ (56,617)</u>
Other comprehensive gain (loss)	\$ 67	\$ (127)	\$ 149	\$ (279)
Comprehensive loss	<u>\$ (20,037)</u>	<u>\$ (24,806)</u>	<u>\$ (70,186)</u>	<u>\$ (56,896)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.45)</u>	<u>\$ (0.91)</u>	<u>\$ (1.67)</u>	<u>\$ (2.16)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>44,363,419</u>	<u>27,215,874</u>	<u>42,124,779</u>	<u>26,184,816</u>

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

	September 30,	December 31,
	2023	2022
	<i>(unaudited)</i>	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 159,939	\$ 114,653
Prepaid expenses and other current assets	11,681	11,045
Total current assets	<u>171,620</u>	<u>125,698</u>
Operating lease right-of-use assets	3,481	5,173
Other noncurrent assets	517	564
Total assets	<u>\$ 175,618</u>	<u>\$ 131,435</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 12,300	\$ 11,991
Operating lease liabilities	2,518	2,645
Accrued expenses and other current liabilities	9,803	10,964
Total current liabilities	<u>24,621</u>	<u>25,600</u>

Long-term debt

Operating lease liabilities, noncurrent	25,042	24,810
Accrued and other noncurrent liabilities	1,962	3,831
Total liabilities	<u>286</u>	<u>286</u>
	51,911	54,527

Stockholders' equity

Common stock	44	28
Additional paid-in-capital	407,185	290,216
Accumulated other comprehensive loss	(75)	(224)
Accumulated deficit	(283,447)	(213,112)
Total stockholders' equity	<u>123,707</u>	<u>76,908</u>
Total liabilities and stockholders' equity	<u>\$ 175,618</u>	<u>\$ 131,435</u>

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