

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): August 10, 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 August 10, 2023, Vera Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 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 August 10, 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: August 10, 2023

By: /s/ Sean Grant

Sean Grant, Chief Financial Officer

Vera Therapeutics Provides Business Update and Reports Second Quarter Financial Results

- Presented positive 36-week results from the Phase 2b ORIGIN clinical trial of atacicept in IgAN as a late breaking clinical trial at the 60th ERA Congress
- Initiated Phase 3 ORIGIN 3 clinical trial of atacicept in June for the treatment of IgAN
- Strong balance sheet expected to fund operations to early 2026

BRISBANE, Calif., August 10, 2023 – Vera Therapeutics, Inc. (Nasdaq: VERA), a late clinical-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases, today reported its business updates and financial results for the second quarter ended June 30, 2023.

“During the second quarter, we announced positive 36-week data from the Phase 2b ORIGIN trial, which support its potential as a disease-modifying treatment for patients with IgAN,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “We have rapidly advanced atacicept into a pivotal Phase 3 ORIGIN 3 trial in June.”

Second Quarter and Recent Business Highlights

- Released positive 36-week results from the Phase 2b ORIGIN clinical trial of atacicept in IgAN, which showed both statistically significant and clinically meaningful reduction in proteinuria and stabilization of estimated glomerular filtration rate (eGFR) through 36 weeks. These data were presented as a Late Breaking Clinical Trial at the 60th European Renal Association (ERA) Congress 2023
- Initiated the pivotal Phase 3 clinical trial (ORIGIN 3) of atacicept for the treatment of IgA nephropathy (IgAN)
- Strong balance sheet with cash and marketable securities on hand and available credit expected to fund operations to early 2026

Upcoming Milestones

- Additional data from the ongoing Phase 2b ORIGIN clinical trial to be presented in the second half of 2023 and 2024
- Expect to announce preliminary data from the pivotal ORIGIN 3 trial in the first half of 2025

Financial Results for the Period Ended June 30, 2023

For the quarter ended June 30, 2023, the company reported a net loss of \$20.2 million, or \$0.46 per share, compared to a net loss of \$14.9 million, or \$0.55 per share, for the same period last year.

During the six months ended June 30, 2023, net cash used in operating activities was \$44.1 million, compared to \$28.0 million for the same period last year.

Vera reported \$181.0 million in cash, cash equivalents, and marketable securities as of June 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 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 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 BLYS and 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, atacicept’s potential to be a transformational treatment for patients with IgAN and a best-in-class therapy, 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 second half of 2023 and 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 “advance,” “look,” “will,” “potential,” “expect,” “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.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
	<i>(unaudited)</i>		<i>(unaudited)</i>	
Operating expenses:				
Research and development	\$ 16,231	\$ 10,112	\$ 41,340	\$ 22,661
General and administrative	5,739	4,945	11,887	9,417
Total operating expenses	21,970	15,057	53,227	32,078
Loss from operations	(21,970)	(15,057)	(53,227)	(32,078)
Total other income, net	1,808	204	2,996	140
Net loss	\$ (20,162)	\$ (14,853)	\$ (50,231)	\$ (31,938)
Other comprehensive gain (loss)	(138)	(140)	82	(152)
Comprehensive loss	\$ (20,300)	\$ (14,993)	\$ (50,149)	\$ (32,090)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.46)	\$ (0.55)	\$ (1.23)	\$ (1.24)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	44,269,772	27,078,450	40,986,907	25,660,742

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

	June 30,	December 31,
	2023	2022
	<i>(unaudited)</i>	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 181,021	\$ 114,653
Prepaid expenses and other current assets	9,593	11,045
Total current assets	190,614	125,698
Operating lease right-of-use assets	4,030	5,173
Other noncurrent assets	534	564
Total assets	\$ 195,178	\$ 131,435
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 13,280	\$ 11,991
Operating lease liabilities	2,560	2,645
Accrued expenses and other current liabilities	10,995	10,964
Total current liabilities	26,835	25,600
Long-term debt	24,962	24,810
Operating lease liabilities, noncurrent	2,571	3,831
Accrued and other noncurrent liabilities	287	286
Total liabilities	54,655	54,527

Stockholders' equity		
Common stock	44	28
Additional paid-in-capital	403,964	290,216
Accumulated other comprehensive loss	(142)	(224)
Accumulated deficit	(263,343)	(213,112)
Total stockholders' equity	140,523	76,908
Total liabilities and stockholders' equity	\$ 195,178	\$ 131,435

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