



Vera Therapeutics Provides Business Update and Reports Second Quarter 2025 Financial Results

Aug 5, 2025

- *On track to submit a Biologics License Application (BLA) for accelerated approval of atacicept to U.S. FDA in Q4 2025; potential commercial launch in 2026*
- *Announced positive primary endpoint results from the ongoing ORIGIN Phase 3 trial*
- *Initiated the PIONEER trial to investigate atacicept in a broader IgAN patient cohort and multiple autoimmune glomerular diseases*
- *Expected to present full primary endpoint results from the ORIGIN 3 trial at a medical congress in Q4 2025*

BRISBANE, Calif., Aug. 05, 2025 (GLOBE NEWSWIRE) -- 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 highlights and financial results for the second quarter ended June 30, 2025.

"Our team delivered exciting new clinical results from our pivotal ORIGIN 3 trial in the second quarter of 2025, which were consistent with or better than our previous trials for atacicept in patients with IgAN. Based on the strength of the overall data accumulated for atacicept over the past few years, we are excited to move ahead with our BLA submission to the U.S. FDA for accelerated approval. We anticipate submitting the BLA in the fourth quarter of 2025, with an expected commercial launch in 2026," said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. "Atacicept has the potential to advance the standard of care in IgAN as the first dual BAFF/APRIL inhibitor. We are thrilled for the potential of atacicept as a possible disease-modifying therapy to address the unmet medical needs of IgAN patients."

Second Quarter 2025 and Recent Business Highlights

- [Announced](#) positive 36-week data from the ongoing pivotal ORIGIN 3 trial of atacicept in patients with IgA Nephropathy (IgAN), including:
 - 46% reduction from baseline in proteinuria for participants treated with atacicept, as measured by 24-hour urine protein-to-creatinine ratio (UPCR); primary endpoint achieved with a statistically significant and clinically meaningful 42% reduction in UPCR compared to placebo ($p < 0.0001$)
 - Atacicept-treated participants demonstrated results across other prespecified endpoints that were consistent with or better than those previously observed in the ORIGIN Phase 2b trial
 - Safety profile of atacicept across ORIGIN program appears favorable, and comparable to placebo
- Completed full enrollment in the ongoing ORIGIN 3 trial
- Enrolling participants in the ORIGIN Extend study, which provides ORIGIN study participants with extended access to atacicept until commercial availability in their region, and captures longer-term safety and efficacy data
- Initiated the PIONEER trial to evaluate atacicept in expanded IgAN populations, anti-PLA2R positive primary membranous nephropathy (PMN), and anti-nephrin positive focal segmental glomerulosclerosis (FSGS) and minimal change disease (MCD) patients
- [Strengthened](#) the Company's financial positioning with a new credit facility of up to \$500 million of term loans with existing partner Oxford Finance LLC, extending the Company's cash runway well beyond potential commercial launch of atacicept

Anticipated Upcoming Milestones

- Submission of a BLA for atacicept in IgAN to the U.S. FDA in Q4 2025 for accelerated approval; potential commercial launch in 2026
- Presentation of the full 36-week results from the pivotal ORIGIN 3 trial expected at a medical congress in Q4 2025
- Initial results from the PIONEER Phase 2 basket trial expected in Q4 2025
- Pivotal ORIGIN 3 study expected to be completed in 2027

Financial Results for the Quarter Ended June 30, 2025

For the quarter ended June 30, 2025, Vera reported a net loss of \$76.5 million, or a net loss per diluted share of \$1.20, compared to a net loss of \$33.7 million, or a net loss per diluted share of \$0.62, for the quarter ended June 30, 2024.

During the six months ended June 30, 2025, net cash used in operating activities was \$109.2 million, compared to \$58.6 million for the same period last year.

Vera reported \$556.8 million in cash, cash equivalents, and marketable securities as of June 30, 2025, which combined with its undrawn debt facility, Vera believes to be sufficient to fund operations through potential approval and U.S. commercial launch of

atacept and beyond.

About Atacept

Atacept 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, other autoimmune kidney diseases and lupus nephritis.

The ORIGIN Phase 2b clinical trial of atacept in IgAN met its primary and key secondary endpoints, with statistically significant and clinically meaningful proteinuria reductions and stabilization of eGFR versus placebo through 36 weeks. The safety profile during the randomized period was comparable between atacept and placebo. Through 96 weeks, atacept demonstrated further improvements in Gd-IgA1, hematuria, and proteinuria, as well as stabilization of eGFR reflecting a profile consistent with that of the general population without IgAN.

Atacept has received FDA Breakthrough Therapy Designation for the treatment of IgAN, which reflects the FDA's determination that, based on an assessment of data from the ORIGIN Phase 2b clinical trial, atacept may demonstrate substantial improvement on a clinically significant endpoint over available therapies for patients with IgAN. Vera believes atacept is positioned for best-in-class potential, targeting B cells to reduce autoantibodies and having been administered to more than 1,500 patients in clinical trials across different disease areas.

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 immunological diseases in order to change the standard of care for patients. Vera's lead product candidate is atacept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both BAFF and APRIL, which stimulate B cells to produce autoantibodies contributing to certain autoimmune diseases, including IgAN and lupus nephritis. In addition, Vera is evaluating additional diseases where the reduction of autoantibodies by atacept may prove medically useful. Vera also holds an exclusive license agreement with Stanford University for a novel, next generation fusion protein targeting BAFF and APRIL, known as VT-109, with wide therapeutic potential across the spectrum of B cell mediated diseases. 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 atacept and MAU868. 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, Vera's plans to submit a Biologics License Application to the U.S. FDA for accelerated approval and to potentially receive FDA approval for atacept in IgAN and launch it commercially, present full primary endpoint results from the ORIGIN 3 trial at a medical congress, obtain initial results from the PIONEER Phase 2 basket trial, and complete the ORIGIN 3 study, as well as statements regarding the timing of each such event; the ability of atacept to advance the standard of care in IgAN and to address the unmet medical needs of IgAN patients; Vera's ability to fund its operations through potential approval and U.S. commercial launch of atacept; and Vera's plans, commitments, aspirations and goals under the caption "About Vera". Because such statements are subject to risk and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believe," "plan," "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, 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 U.S. 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)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 58,195	\$ 29,311	\$ 99,473	\$ 52,511
General and administrative	21,946	8,032	37,862	15,944
Total operating expenses	80,141	37,343	137,335	68,455
Loss from operations	(80,141)	(37,343)	(137,335)	(68,455)
Other income, net	3,610	3,635	9,110	6,364
Net loss	\$ (76,531)	\$ (33,708)	\$ (128,225)	\$ (62,091)
Change in unrealized gain/loss on marketable securities	\$ (127)	\$ (277)	\$ 134	\$ (700)
Comprehensive loss	\$ (76,658)	\$ (33,985)	\$ (128,091)	\$ (62,791)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.20)	\$ (0.62)	\$ (2.01)	\$ (1.17)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	63,789,303	54,728,552	63,730,756	52,850,242

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

	June 30, 2025	December 31, 2024
	(unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 556,827	\$ 640,852
Prepaid expenses and other current assets	14,527	10,366
Total current assets	571,354	651,218
Operating lease right-of-use assets	2,471	3,372
Other noncurrent assets	4,703	1,091
Total assets	\$ 578,528	\$ 655,681
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 13,157	\$ 7,665
Operating lease liabilities	855	1,483
Accrued expenses and other liabilities, current	19,542	16,223
Total current liabilities	33,554	25,371
Long-term debt	74,464	50,687
Operating lease liabilities, noncurrent	2,233	2,468
Total liabilities	110,251	78,526
Stockholders' equity		
Common stock	64	64
Additional paid-in-capital	1,057,161	1,037,948
Accumulated other comprehensive income	527	393

Accumulated deficit	<u>(589,475)</u>	<u>(461,250)</u>
Total stockholders' equity	<u>468,277</u>	<u>577,155</u>
Total liabilities and stockholders' equity	<u><u>\$ 578,528</u></u>	<u><u>\$ 655,681</u></u>