Vera Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2024 Financial Results

Feb 26, 2025

- *On track to announce the primary endpoint result from the atacicept pivotal Phase 3 ORIGIN trial in IgA Nephropathy (IgAN) in 2Q 2025; BLA submission to the U.S. FDA for accelerated approval planned in 2H 2025*
- *Expanded atacicept clinical development program in multiple autoimmune kidney diseases proceeding in 2025*
- *Strengthened balance sheet to support clinical pipeline development, planned FDA submission, and potential 2026 commercial launch of atacicept for the treatment of IgAN*

BRISBANE, Calif., Feb. 26, 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 fourth quarter and full year ended December 31, 2024.

“Vera is poised to change the standard of care in autoimmune diseases with atacicept, our investigational therapy, beginning with IgA nephropathy. We are on track to announce the primary endpoint result of the ORIGIN Phase 3 study in the second quarter of this year. We look forward to submitting a Biologics License Application (BLA) for this potential best-in-class therapy in the second half of this year. We are grateful to the study investigators and participants for their ongoing and enthusiastic participation in this program,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “In addition, over the past year we have made progress advancing our broader development pipeline, including additional potential indications for atacicept.”

Fiscal 2024 and Recent Business Highlights

- Received FDA Breakthrough Therapy Designation for atacicept in IgAN
- Presented positive data showing eGFR stabilization over 96 weeks in the ORIGIN Phase 2b clinical trial of atacicept in IgAN in a late-breaking oral presentation at the American Society of Nephrology Kidney Week 2024, and in a simultaneous peer-reviewed publication in the *Journal of the American Society of Nephrology*
- Initiated the ORIGIN Extend study, providing ORIGIN 2b/3 participants with extended access to atacicept and capturing longer-term safety and efficacy data
- Announced an expanded development pipeline for atacicept across multiple autoimmune kidney diseases, including primary membranous nephropathy (PMN), focal segmental glomerulosclerosis (FSGS), and minimal change disease (MCD) beginning in 2025
- Acquired exclusive rights 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
- Completed two equity financings in 2024, for a total of approximately $593.2 million in net proceeds, further bolstering the balance sheet ahead of potential regulatory submission and commercial launch
- Appointed multiple industry veterans to the leadership team, including Robert Brenner, M.D., as Chief Medical Officer, William Turner as Chief Regulatory Officer, David Johnson as Chief Operating Officer, and Jason Carter as Chief Legal Officer, throughout 2024

Major Upcoming Milestones

- Planned updates from the ongoing pivotal ORIGIN 3 trial:
  - Anticipate full enrollment in 2Q 2025
  - On track to announce the primary endpoint result in 2Q 2025
- Plan to submit a BLA to the U.S. FDA in 2H 2025 for atacicept in IgAN for accelerated approval assuming supportive data; and would expect a PDUFA date and commercial launch in 2026
- QM dose finding study initiating in 2025 to evaluate extended dosing
- Plan to initiate the PIONEER trial in 2025, which would evaluate atacicept in expanded IgAN populations and anti-PLA2R positive PMN and anti-nephrin positive FSGS and MCD

Financial Results for the Quarter and Year Ended December 31, 2024
For the year ended December 31, 2024, the company reported a net loss of $152.1 million, or a net loss per diluted share of $2.75, compared to a net loss of $96.0 million, or a net loss per diluted share of $2.25, for the year ended December 31, 2023.

During the year ended December 31, 2024, net cash used in operating activities was $134.7 million, compared to $92.2 million for the same period last year.

Vera reported $640.9 million in cash, cash equivalents, and marketable securities as of December 31, 2024, which the company believes to be sufficient to fund operations through potential approval and U.S. commercial launch of atacicept.

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 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 atacicept and placebo. Through 96 weeks, atacicept demonstrated further reductions in Gd-IgA1, hematuria, and proteinuria, as well as stabilization of eGFR reflecting a profile consistent with that of the general population without IgAN.

Atacicept 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 Phase 2b ORIGIN clinical trial, atacicept may demonstrate substantial improvement on a clinically significant endpoint over available therapies for patients with IgAN. Vera believes atacicept 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 studies across different indications.

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 atacicept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both B-cell Activating Factor (BAFF) and A PRoliferation-Inducing Ligand (APRIL), which stimulate B 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. 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. 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 complete enrollment and to receive and report primary endpoint result in the Phase 3 ORIGIN 3 trial, to submit a Biologics License Application to the FDA, and to potentially receive a PDUFA date, receive FDA approval for atacicept in IgAN and launch it commercially, and Vera's ability to fund its operations through potential approval and U.S. commercial launch of atacicept. 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 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)

	For the Year Ended December 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 126,172	$ 78,225
General and administrative	40,998	23,787
Total operating expenses	167,170	102,012
Loss from operations	(167,170)	(102,012)
Other income, net	15,022	6,023
Provision for income taxes	(1)	(1)
Net loss	$ (152,149)	$ (95,990)
Change in unrealized gain/loss on marketable securities	142	251
Comprehensive loss	$ (152,007)	$ (95,739)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.75)	$ (2.25)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	55,326,680	42,707,072

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

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 640,852	$ 160,716
Prepaid expenses and other current assets	10,366	11,307
Total current assets	651,218	172,023
Operating lease right-of-use assets	3,372	2,949
Other noncurrent assets	1,091	574
Total assets	$ 655,681	$ 175,546
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,665	$ 11,118
Operating lease liabilities	1,483	2,436
Accrued expenses and other liabilities, current	16,223	8,749
Total current liabilities	25,371	22,303
Long-term debt	50,687	49,877
Operating lease liabilities, noncurrent	2,468	1,395
Accrued expenses and other liabilities, noncurrent	-	286
Total liabilities	78,526	73,861
Stockholders' equity		
Common stock	64	44

Additional paid-in-capital	1,037,948	410,492
Accumulated other comprehensive income	393	251
Accumulated deficit	(461,250)	(309,102)
Total stockholders' equity	577,155	101,685
Total liabilities and stockholders' equity	$ 655,681	$ 175,546