Vera Therapeutics Provides Business Update and Reports Third Quarter 2024 Financial Results

Nov 7, 2024

- *Presented positive 96-week long-term eGFR stabilization data from ORIGIN Ph 2b clinical trial of atacicept in IgAN in a late-breaking oral presentation at the American Society of Nephrology (ASN) Kidney Week 2024 with simultaneous peer-reviewed publication in the Journal of the American Society of Nephrology (JASN)*
- *Completed enrollment of the primary endpoint cohort in the pivotal Phase 3 ORIGIN 3 trial of atacicept in IgAN; topline data expected in Q2 2025*
- *Announced expanded atacicept development program in the broad IgAN population and in multiple autoimmune kidney diseases*
- *Completed an equity offering with gross proceeds of approximately $345 million ahead of potential regulatory submission and commercial launch*

BRISBANE, Calif., Nov. 07, 2024 (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 third quarter ended September 30, 2024.

“We have made substantial progress advancing our clinical development program for atacicept in 2024. The positive data announced throughout the year, including the 96-week data from the ORIGIN trial presented in a late-breaking oral presentation at ASN’s Kidney Week 2024 along with simultaneous publication in JASN, have positioned atacicept as a potential best-in-class disease-modifying treatment option for patients with IgAN,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “Our mission is to bring safe and effective therapies to patients with high unmet needs. To this end, we are on track to deliver topline results of our Phase 3 pivotal trial in Q2 2025. In addition, we recently announced plans to expand the development of atacicept into the broad profile of IgAN and in multiple other autoimmune kidney diseases. The PIONEER study will evaluate the use of atacicept in treating IgAN patients that do not meet the inclusion/exclusion criteria of ORIGIN 3, as well as adjacent antibody-mediated autoimmune conditions such as membranous nephropathy (MN) and focal segmental glomerulosclerosis (FSGS). The PIONEER study recognizes that atacicept has true pipeline-in-a-product potential.”

Third Quarter and Recent Business Highlights

- Presented positive data showing eGFR stabilization at 96 weeks in ORIGIN Ph 2b clinical trial of atacicept in IgAN at the American Society of Nephrology Kidney Week 2024 and in manuscript form in JASN
- Completed enrollment of the primary endpoint cohort in the pivotal Phase 3 ORIGIN 3 trial of atacicept in IgAN
- Expanded atacicept development program in multiple autoimmune kidney diseases at its R&D Day in New York, joined by academic leaders Drs. Jonathan Barratt, Richard Lafayette, Brad Rovin
- Appointed industry veteran Matt Skelton as Executive Vice President, Commercial
- Completed a public equity offering of Class A common stock with gross proceeds totaling approximately $345 million, further bolstering balance sheet ahead of potential regulatory submission and commercial launch

Major Upcoming Milestones

- Pivotal ORIGIN 3 trial on track to announce topline results in Q2 2025, with planned BLA submission to the U.S. FDA later in the year
- Plan to initiate the ORIGIN Extend study in Q4 2024, providing ORIGIN participants with extended access to atacicept and capturing longer-term safety and efficacy data
- Plan to initiate the PIONEER trial in 2025, which will evaluate the efficacy and safety of atacicept in expanded IgAN populations and anti-PLA2R and anti-nephrin podocytopathies

Financial Results for the Quarter Ended September 30, 2024
For the quarter ended September 30, 2024, the company reported a net loss of $46.6 million, or a net loss per diluted share of $0.85, compared to a net loss of $20.1 million, or a net loss per diluted share of $0.45, for the same period last year.

During the nine months ended September 30, 2024, net cash used in operating activities was $95.5 million, compared to $67.0 million for the same period last year.

Vera reported $353.3 million in cash, cash equivalents, and marketable securities as of September 30, 2024. Subsequent to

September 30, 2024, the Company strengthened its balance sheet upon completing an underwritten public offering of its Class A common stock with gross proceeds of approximately $345 million, before deducting underwriting discounts and commissions and estimated offering expenses. The Company believes its balance sheet will be sufficient to fund operations through the 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 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 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.

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 BAFF and 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 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

Forward-looking Statements
Statements contained in this press release regarding Vera's expectations regarding the offering are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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, Vera's expectations regarding the completion of the offering. 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:
Madelin Hawtin
LifeSci Communications
MHawtin@lifescicomms.com

VERA THERAPEUTICS, INC.
Condensed Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(unaudited)		*(unaudited)*	
Operating expenses:				
Research and development	$ 40,314	$ 16,100	$ 92,825	$ 57,440
General and administrative	9,487	5,656	25,431	17,544
Total operating expenses	49,801	21,756	118,256	74,984
Loss from operations	(49,801)	(21,756)	(118,256)	(74,984)
Other income, net	3,169	1,652	9,533	4,649
Net loss	$ (46,632)	$ (20,104)	$ (108,723)	$ (70,335)
Change in unrealized gains and losses on marketable securities	$ 1,494	$ 67	$ 793	$ 149
Comprehensive loss	$ (45,138)	$ (20,037)	$ (107,930)	$ (70,186)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.85)	$ (0.45)	$ (2.03)	$ (1.67)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	54,898,297	44,363,419	53,537,910	42,124,779

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

	September 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 353,309	$ 160,716
Prepaid expenses and other current assets	10,822	11,307
Total current assets	364,131	172,023
Operating lease right-of-use assets	3,921	2,949
Other noncurrent assets	508	574
Total assets	$ 368,560	$ 175,546
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,602	$ 11,118
Operating lease liabilities	1,872	2,436
Accrued expenses and other liabilities, current	19,990	8,749
Total current liabilities	26,464	22,303
Long-term debt	50,470	49,877
Operating lease liabilities, noncurrent	2,568	1,395
Accrued expenses and other liabilities, noncurrent	-	286
Total liabilities	79,502	73,861
Stockholders' equity		
Common stock	55	44
Additional paid-in-capital	705,784	410,492
Accumulated other comprehensive income	1,044	251
Accumulated deficit	(417,825)	(309,102)
Total stockholders' equity	289,058	101,685
Total liabilities and stockholders' equity	$ 368,560	$ 175,546