



Nkarta Reports Third Quarter 2024 Financial Results and Corporate Highlights

November 7, 2024

- *First patient dosed in each of Ntrust-1 and investigator-sponsored clinical trial (IST) of NKX019; enrollment ongoing in both studies*
- *Enrollment in Ntrust-2 expected to initiate by year-end 2024*
- *Preliminary clinical data from Ntrust-1 and Ntrust-2 clinical trials planned for 2025*
- *No further NKX019 development in lymphoma planned*
- *Platform prioritized to focus on advancement of NKX019 for multiple autoimmune diseases*
- *Cash balance of \$405.3 million on September 30, 2024, including cash, cash equivalents and investments, expected to fund operations into late 2027*

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2024 (GLOBE NEWSWIRE) -- Nkarta, Inc. (Nasdaq: NKTX), a clinical-stage biopharmaceutical company developing engineered natural killer (NK) cell therapies, today reported financial results for the third quarter ended September 30, 2024.

"We're encouraged by the early progress that we've made in the clinical investigation of NKX019 for autoimmune disease," said Paul J. Hastings, CEO of Nkarta. "Having dosed a first patient in both Ntrust-1 and the Columbia University Irving Medical Center IST, our learnings can help us optimize the execution of our current and future clinical trials. This includes our Ntrust-2 trial, which is on track to initiate enrollment later this year. Safety and accessibility are paramount in autoimmune disease, and we believe that an off-the-shelf, engineered NK cell therapy has the greatest potential to help patients."

Hastings continued, "We have decided to forgo future development of NKX019 in non-Hodgkin lymphoma. In reviewing the clinical data from the latest cohort of patients with large B-cell lymphoma and the evolving treatment landscape, Nkarta will focus its efforts on autoimmune diseases, where we believe NKX019 has potential to transform patient care."

Clinical development of NKX019 for autoimmune diseases advances

- Dosing of the first patient in Ntrust-1, a clinical trial of NKX019 for the treatment of lupus nephritis. As previously announced, the first Ntrust-1 patient entered screening in June 2024.
- Dosing of the first patient in the IST of NKX019 in systemic lupus erythematosus at Columbia University Irving Medical Center (CUIMC). As previously announced, the CUIMC IST was initiated in July 2024.
- Both studies continue to enroll participants.

Anticipated autoimmune milestones 2024-2025

- Initiation of patient enrollment expected by year-end 2024 in Ntrust-2, a clinical trial of NKX019 for the treatment of systemic sclerosis, myositis and vasculitis. As previously announced, the Investigational New Drug (IND) Application for Ntrust-2 cleared in June 2024.
- Preliminary clinical data from Ntrust-1 and Ntrust-2 clinical trials planned for 2025.

Update for NKX019 in non-Hodgkin Lymphoma (NHL)

- A cohort of seven patients with heavily pretreated large B-cell lymphoma (LBCL) whose disease progressed following treatment with a CD19 CAR T-cell therapy received NKX019 on Days 0, 3, and 7 following lymphodepletion.
- There were no cases of Grade >2 cytokine release syndrome (CRS) and no cases of immune effector cell-associated neurotoxicity (ICANS).
- Five patients achieved a partial response after a first cycle of treatment. One of these five patients achieved a complete response with >6 months durability after receiving a second cycle of treatment.
- Nkarta aims to report final data from the LBCL cohort at a future medical conference.
- Nkarta will forgo further development in NHL and prioritize development efforts on autoimmune diseases.

Third Quarter 2024 and Recent Financial Highlights

- Nkarta had cash, cash equivalents, restricted cash, and investments in marketable securities of \$405.3 million as of September 30, 2024.
- Research and development (R&D) expenses were \$25.3 million for the third quarter of 2024. Non-cash stock-based compensation expense included in R&D expense was \$1.8 million for the third quarter of 2024.

- General and administrative (G&A) expenses were \$8.5 million for the third quarter of 2024. Non-cash stock-based compensation expense included in G&A expense was \$2.3 million for the third quarter of 2024.
- Net loss was \$28.3 million, or \$0.39 per basic and diluted share, for the third quarter of 2024. This net loss includes non-cash charges of \$5.8 million that consisted primarily of share-based compensation and depreciation expenses.

Financial Guidance

- Nkarta expects its current cash and cash equivalents will be sufficient to fund its current operating plan into late 2027.

About NKX019

NKX019 is an allogeneic, cryopreserved, off-the-shelf immunotherapy candidate that uses natural killer (NK) cells derived from the peripheral blood of healthy adult donors. It is engineered with a humanized CD19-directed chimeric antigen receptor (CAR) for enhanced cell targeting and a proprietary, membrane-bound form of interleukin-15 (IL-15) for greater persistence and activity without exogenous cytokine support. CD19 is a biomarker for normal B cells as well as those implicated in autoimmune disease and B cell-derived malignancies.

About Ntrust™ Clinical Trials in Autoimmune Disease

Ntrust-1 and Ntrust-2 are multi-center, open label, dose escalation clinical trials that build on academic studies of durable, drug-free remissions in patients with autoimmune disease after CD19-targeted cell therapy. Both trials will assess the safety of NKX019 in people living with autoimmune diseases as well as its ability to enable long-term remissions via a “reset” of the immune system through the elimination of pathogenic B cells. Per the trial protocols, patients receive three-dose cycles of NKX019 at 1 billion or 1.5 billion cells per dose following single-agent lymphodepletion with cyclophosphamide, an agent with an established safety profile across autoimmune diseases. Leveraging the engineering of NKX019, no patients in either trial will receive supplemental cytokines or antibody-based therapeutics. This approach is designed to evaluate the single-agent activity of NKX019 and facilitate a more rapid path to regulatory approval.

In the Ntrust-1 study ([NCT06557265](#)), patients with refractory lupus nephritis receive three-dose cycles of NKX019 following lymphodepletion. Patients in Ntrust-1 may also receive additional cycles to restore response.

Once initiated, Ntrust-2 will enroll patients with systemic sclerosis (scleroderma), idiopathic inflammatory myopathy (myositis), and ANCA-associated vasculitis into parallel cohorts, and NKX019 will be dosed on Days 0, 3, and 7, a regimen that may be advantageous across all Nkarta clinical trials. Each trial is designed to initially enroll up to 12 patients.

About the Investigator-Sponsored Clinical Trial of NKX019 for Systemic Lupus Nephritis

The single-center, single-arm, open-label Phase 1 investigator-sponsored clinical trial is designed to enroll up to 6 patients with systemic lupus erythematosus, regardless of renal involvement, and will evaluate safety and clinical outcomes in a potentially different population than Ntrust-1. Translational and biomarker studies, including autoantibodies, cytokine profiles and pharmacokinetics are also planned. Patients receive NKX019 following single-agent lymphodepletion with cyclophosphamide. The clinical trial is being led by Anca D. Askanase, M.D., M.P.H., Director, Lupus Center at Columbia University Irving Medical Center and the Director of Rheumatology Clinical Trials.

About Nkarta

Nkarta is a clinical-stage biotechnology company advancing the development of allogeneic, off-the-shelf natural killer (NK) cell therapies. By combining its cell expansion and cryopreservation platform with proprietary cell engineering technologies and CRISPR-based genome engineering capabilities, Nkarta is building a pipeline of future cell therapies engineered for deep therapeutic activity and intended for broad access in the outpatient treatment setting. For more information, please visit the company’s website at www.nkartatx.com.

Cautionary Note on Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as “anticipates,” “believes,” “expects,” “intends,” “plans,” “potential,” “projects,” “would” and “future” or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include, but are not limited to, statements concerning Nkarta’s expectations regarding any or all of the following: Nkarta’s position, plans, strategies, and timelines for the continued and future clinical development and commercial potential of NKX019 (including initiation of further clinical trials such as Ntrust-2 and the future availability and disclosure of clinical data and other updates from Nkarta’s clinical trials); the therapeutic potential, accessibility, tolerability, advantages, and safety profile of NK cell therapies, including NKX019 for the treatment of autoimmune diseases, lupus, systemic sclerosis, myositis, and vasculitis, and NHL; and Nkarta’s expected cash runway. Interim clinical data for NKX019 included in this press release are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more data on existing patients become available.

Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: Nkarta’s limited operating history and historical losses; Nkarta’s lack of any products approved for sale and its ability to achieve profitability; the risk that the results of preclinical studies and early-stage clinical trials may not be predictive of future results; Nkarta’s ability to raise additional funding to complete the development and any commercialization of its product candidates; Nkarta’s dependence on the clinical success of NKX019; that Nkarta may be delayed in initiating, enrolling or completing its clinical trials; competition from third parties that are developing products for similar uses; Nkarta’s ability to obtain, maintain and protect its intellectual property; Nkarta’s dependence on third parties in connection with manufacturing, clinical trials and pre-clinical studies; and the complexity of the manufacturing process for CAR NK cell therapies.

These and other risks and uncertainties are described more fully in Nkarta’s filings with the Securities and Exchange Commission (“SEC”), including the “Risk Factors” section of Nkarta’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 13, 2024, and Nkarta’s other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Nkarta undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Condensed Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	\$ 25,250	\$ 22,194	\$ 73,617	\$ 73,451
General and administrative	8,544	7,100	23,654	27,014
Total operating expenses	<u>33,794</u>	<u>29,294</u>	<u>97,271</u>	<u>100,465</u>
Loss from operations	(33,794)	(29,294)	(97,271)	(100,465)
Other income, net:				
Interest income	5,453	3,616	14,423	10,651
Other (expense) income, net	(3)	33	(7)	67
Total other income, net	<u>5,450</u>	<u>3,649</u>	<u>14,416</u>	<u>10,718</u>
Net loss	<u>\$ (28,344)</u>	<u>\$ (25,645)</u>	<u>\$ (82,855)</u>	<u>\$ (89,747)</u>
Net loss per share, basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.52)</u>	<u>\$ (1.26)</u>	<u>\$ (1.83)</u>
Weighted average shares used to compute net loss per share, basic and diluted	<u>73,563,316</u>	<u>49,062,799</u>	<u>65,941,355</u>	<u>48,985,373</u>

Nkarta, Inc.
Condensed Balance Sheets
(in thousands)
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents, restricted cash and investments	\$ 405,265	\$ 250,932
Property and equipment, net	76,231	79,326
Operating lease right-of-use assets	38,804	39,949
Other assets	11,734	8,678
Total assets	<u>\$ 532,034</u>	<u>\$ 378,885</u>
Liabilities and stockholders' equity		
Accounts payable, accrued and other liabilities	\$ 15,712	\$ 17,261
Operating lease liabilities	85,449	88,339
Total liabilities	101,161	105,600
Stockholders' equity	430,873	273,285
Total liabilities and stockholders' equity	<u>\$ 532,034</u>	<u>\$ 378,885</u>

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