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): June 27, 2024

Nkarta, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39370**	**47-4515206**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
1150 Veterans Boulevard South San Francisco, CA		**94080**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (925) 407-1049

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
Common Stock, $0.0001 par value per share	NKTX	Nasdaq Global Select Market

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. 7.01 Regulation FD Disclosure.

On June 27, 2024, Nkarta, Inc. (the "Company") issued a press release announcing a pipeline expansion to additional autoimmune indications with the clearance of an Investigational New Drug ("IND") application by the U.S. Food and Drug Administration ("FDA") to evaluate NKX019 for the treatment of systemic sclerosis, idiopathic inflammatory myopathy, and ANCA-associated vasculitis, as well as updates to its clinical trial to evaluate NKX019 for the treatment of lupus nephritis ("LN"), which is discussed in more detail in Item 8.01 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be, or be deemed, incorporated by reference in any filings under the Securities Act of 1933, as amended (the "Securities Act"), unless the Company specifically states that the information is to be considered "filed" under the Exchange Act or incorporates it by reference into a filing under the Securities Act or the Exchange Act.

Item. 8.01 Other Events.

On June 27, 2024, the Company announced the clearance of an IND application by the FDA to evaluate NKX019 for the treatment of systemic sclerosis, idiopathic inflammatory myopathy, and ANCA-associated vasculitis.

In addition to the foregoing, the Company provided an update in relation to the initiation of its clinical trial of NKX019 in patients with refractory LN, announcing the screening of the first patient.

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 plans, strategies and timelines (including initiation of further clinical trials) for the continued and future clinical development and commercial potential of NKX019 for the treatment of autoimmune disease, including lupus, systemic sclerosis, myositis and vasculitis; the therapeutic potential, accessibility, tolerability, advantages, and safety profile of NK cell therapies, including NKX019, for the treatment of autoimmune disease, including lupus, systemic sclerosis, myositis and vasculitis; the advantages of a "Days 0, 3, and 7" dosing regimen; and Nkarta's plans and timelines for the future availability and disclosure of clinical data from Ntrust-1 and Ntrust-2 or other updates regarding the clinical trials.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued on June 27, 2024.
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 hereunto duly authorized.

Nkarta, Inc.

Date: June 27, 2024

By: /s/ Alicia Hager

Alicia J. Hager, J.D., Ph.D.
Chief Legal Officer

Exhibit 99.1

Nkarta Initiates Clinical Trial of NKX019 in Lupus Nephritis with First Patient in Screening and Announces Pipeline Expansion to Additional Autoimmune Indications

Patient screening underway in Ntrust-1, the first U.S.-based clinical trial of an engineered NK cell therapy for the treatment of lupus nephritis

IND cleared for Ntrust-2, a clinical trial for NKX019 for the treatment of systemic sclerosis, myositis and vasculitis

Clinical data from Ntrust-1 and Ntrust-2 planned for 2025

SOUTH SAN FRANCISCO, Calif., June 27, 2024 -- Nkarta, Inc. (Nasdaq: NKTX), a biopharmaceutical company developing engineered natural killer (NK) cell therapies, today announced the initiation of Ntrust-1, a multi-center clinical trial of NKX019 in lupus nephritis, with the first patient in screening. The company also announced the clearance by the U.S. Food and Drug Administration (FDA) of its second Investigational New Drug (IND) application for NKX019 in autoimmune disease. With this new IND, Nkarta plans to initiate Ntrust-2, an open-label, multi-center clinical trial of NKX019 for the treatment of systemic sclerosis (SSc, scleroderma), idiopathic inflammatory myopathy (IIM, myositis) and ANCA-associated vasculitis (AAV).

NKX019 is an allogeneic, off-the-shelf, chimeric antigen receptor (CAR) NK-cell therapy candidate engineered to deplete CD19-positive cells in B-cell mediated disease. The approach leverages the potential advantages of NK cell therapy, including fludarabine-free lymphodepletion to reduce toxicity, deep and rapid B-cell depletion, and the added utility of on-demand dosing, including repeated dosing as needed. NKX019 is engineered to exert its biologic activity without the need for antibodies or exogenous cytokines.

“The initiation of Ntrust-1 in lupus nephritis and the IND clearance for three additional indications are critical milestones in our mission to improve the accessibility and safety of cell therapy. NKX019 is unencumbered by many of the safety, infrastructure and logistical challenges associated with existing cell therapy approaches,” said Paul J. Hastings, President &

CEO of Nkarta. “Many people living with lupus are historically underserved, and our aim is to develop treatments that are broadly accessible and easier to tolerate and administer.”

Hastings continued, “Our vision goes beyond lupus nephritis, as the unmet need in autoimmune disease is substantial. The clearance of our second IND in autoimmune disease broadens the development of NKX019 and enables us to evaluate three additional B-cell mediated diseases in parallel. We have selected a CRO to support Ntrust-2, and trial activation activities are underway. Meanwhile, we are also exploring other opportunities to positively impact the treatment of different populations with autoimmune disease through collaborations with leading investigators.”

“People living with systemic sclerosis have limited treatment options, especially treatments that target the whole patient and not just one organ system,” said Elizabeth Volkmann, M.D., M.S., Director of the UCLA Scleroderma Program and the founder and Co-Director of the UCLA Connective Tissue Disease-Related Interstitial Lung Disease Program. “The early results of studies using cell therapy in autoimmune diseases such as systemic sclerosis are encouraging, and I look forward to seeing how these treatments affect outcomes for people living with this condition.”

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. All patients across both studies will 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.

In the Ntrust-1 study, patients with refractory lupus nephritis receive NKX019 on Days 0, 7 and 14. Patients in Ntrust-1 may also receive additional cycles to restore response. Once initiated, Ntrust-2 will enroll patients with SSc, IIM or AAV 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 SLE
Systemic lupus erythematosus (SLE) is an autoimmune disease characterized by abnormal B-cell function and autoantibody production which results in a range of clinical manifestations, including organ damage and an increased risk of death. Lupus nephritis (LN) is among the most severe manifestations of SLE. Approximately 40 percent of the estimated 200,000 patients in the U.S. diagnosed with SLE will develop LN. Up to 30 percent of patients with LN progress to end stage kidney disease, which can be fatal without dialysis or a kidney transplant.

About Systemic Sclerosis
Systemic sclerosis (SSc, scleroderma) is a progressive autoimmune disease characterized by inflammation and hardening in the skin and other areas of the body including blood vessels and vital organs, especially the lungs. Aberrant immune responses involving autoantibodies induce an inflammatory response in normal tissues that causes the body to produce excess collagen, leading to tight, hard tissue and injury to blood vessels. There are approximately 100,000 people in the U.S. living with SSc. There are no available treatments to halt or reverse the disease process. Approved therapies focus primarily on disease symptoms and can involve significant side effects.

About Myositis
Idiopathic inflammatory myopathy (IIM, myositis) is a group of autoimmune disorders characterized by inflammation, weakness, muscle damage, pain, and compromised quality of life. The disease can affect vital organs and be life-threatening. Across the three major subtypes thought to be driven by B cells, dermatomyositis (DM), immune-mediated necrotizing myopathy (IMNM) and anti-synthetase syndrome (ASyS), there are an estimated 50,000 people in the U.S. living with the disease. Despite approved therapies, many people with myositis have refractory disease.

About ANCA-associated vasculitis
Anti-neutrophilic cytoplasmic autoantibody (ANCA) vasculitis is an autoimmune disease characterized by severe, systemic damage to small blood vessels. ANCAs attach to neutrophils, a type of white blood cell, and cause the neutrophils to attack small blood vessels walls, causing inflammation. Inflamed vessels may rupture or become blocked, leading to clinical symptoms and a systemic inflammatory response. Patients may have disease-related complications, such as life-threatening damage to the kidneys, lungs and other organs, as well as toxicities associated with treatment, such as long-term use of immunosuppressants like glucocorticoids. It is estimated that approximately 140,000 people in the U.S. are living with vasculitis.

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 Nkarta
Nkarta is a clinical-stage biotechnology company advancing the development of allogeneic, off-the-shelf, on-demand 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 plans, strategies and timelines (including initiation of further clinical trials) for the continued and future clinical development and commercial potential of NKX019 for the treatment of autoimmune disease, including lupus, systemic sclerosis, myositis and vasculitis; the therapeutic potential, accessibility, tolerability, advantages, and safety profile of NK cell therapies, including NKX019, for the treatment of autoimmune disease, including lupus, systemic sclerosis, myositis and vasculitis; the advantages of a "Days 0, 3, and 7" dosing regimen; and Nkarta's plans and timelines for the future availability and disclosure of clinical data from Ntrust-1 and Ntrust-2 or other updates regarding the clinical trials.

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 March 31, 2024, filed with the SEC on May 9, 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.

Nkarta Media/Investor Contact:
Greg Mann
Nkarta, Inc.
gmann@nkartatx.com