

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-39370

Nkarta, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

1150 Veterans Boulevard
South San Francisco, CA

(Address of principal executive offices)

47-4515206

(I.R.S. Employer
Identification No.)

94080

(Zip Code)

(925) 407-1049

(Registrant's telephone number, including area code)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 4, 2024, the registrant had 70,568,754 shares of common stock, par value \$0.0001 per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, and the information incorporated herein by reference, particularly in the sections captioned “Risk Factors” under Part II, Item 1A, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” under Part I, Item 2, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “predict,” “project,” “potential,” “should,” “will,” or “would,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. Examples of these forward-looking statements include, but are not limited to, statements concerning our financial and business performance, including our future funding requirements, our position, plans, strategies, and timelines (including initiation of further clinical trials and the availability of disclosure of clinical data from our clinical trials) for the continued and future clinical development and commercial potential of our product candidates and the therapeutic potential, accessibility, tolerability, advantages, and safety profile of NK cell therapies, including NKX019 for the treatment of autoimmune diseases. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. In addition, these statements are based on our management’s beliefs and assumptions and on information currently available to our management as of the date of this Quarterly Report on Form 10-Q. While we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. You should read the sections titled “Risk Factor Summary” below and “Risk Factors” set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements, which such factors may be updated or supplemented from time to time by subsequent reports we file with the Securities and Exchange Commission.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

You should read this Quarterly Report on Form 10-Q, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

RISK FACTOR SUMMARY

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q. The below summary is qualified in its entirety by the more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q as part of your evaluation of an investment in our common stock.

- *We have a limited operating history and do not have any products approved for sale.*
- *We have incurred significant losses since our inception and we expect to continue to incur significant losses for the foreseeable future.*
- *We have never generated revenue from product sales and may never achieve or maintain profitability.*
- *We will require additional capital, which, if available, may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.*
- *Our business depends upon the success of our CAR NK-cell technology platform.*
- *Utilizing CAR NK cells represents a novel therapeutic approach, and we must overcome significant challenges in order to develop, commercialize and manufacture our product candidates.*
- *Certain aspects of the function and production of CAR NK cells are currently unknown or poorly understood, and may only become known through further preclinical testing and clinical trials. Any potential re-engineering required may result in delays and additional expense.*
- *Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control.*
- *Our business is highly dependent on the clinical success of our product candidates, and on the clinical success of NKX019, in particular, and we may fail to develop NKX019 and/or our other product candidates successfully or be unable to obtain regulatory approval for them.*
- *Clinical data supporting the effectiveness of CD19-targeted cell therapies against autoimmune disease are limited, and CD19-targeted CAR NK-cell therapies, such as NKX019, may not provide the same, or any, therapeutic benefit against lupus nephritis or other autoimmune diseases, or be competitive with respect to other CD19-targeted therapies for the treatment of autoimmune disease.*
- *Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.*
- *Our preclinical pipeline programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.*
- *The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Interim, “topline” and preliminary data from our clinical trials may differ materially from the final data. Initial success in any clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.*
- *If any of our product candidates, or any competing product candidates, demonstrate relevant, serious adverse events, we may be required to halt or delay further clinical development.*
- *If we fail to compete effectively with academic institutions and other biopharmaceutical companies that develop similar or alternatives to cellular immunotherapy product candidates, our business will be materially adversely affected.*
- *We have entered into a research collaboration with CRISPR Therapeutics regarding certain product candidates, and we may enter into additional collaborations with third parties to develop or commercialize other product candidates. Our prospects with respect to those product candidates will depend in significant part on the success of those collaborations, and we may not realize the benefits of such collaborations.*
- *Our manufacturing process is novel and complex, and we may encounter difficulties in production, or difficulties with internal manufacturing, which would delay or prevent our ability to provide a sufficient supply of our product candidates for clinical trials or our products for patients, if approved.*

- *We rely on third parties to manufacture certain materials for use in the production of our product candidates, or may rely on third parties to manufacture certain of our product candidates in the future, which increases the risk that we will not have sufficient quantities of such materials or product candidates, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.*
- *We are reliant on a sole supplier for certain steps of our manufacturing process.*
- *Delays in commissioning and receiving regulatory approvals for our manufacturing facilities could delay our development plans and thereby limit our ability to develop our product candidates and generate revenues.*
- *If our license agreement with National University of Singapore and St. Jude Children's Research Hospital, Inc. is terminated, we could lose our rights to key components enabling our NK-cell engineering platform.*
- *If any patent protection we obtain is not sufficiently robust, our competitors could develop and commercialize products and technology similar or identical to ours.*
- *If any of our product candidates are approved for marketing and commercialization and we have not developed or secured marketing, sales and distribution capabilities, either internally or from third parties, we will be unable to successfully commercialize such products and may not be able to generate product revenue.*
- *Our product candidates, including NKX019, could be subject to regulatory limitations following approval, if and when such approval is granted.*
- *The market price for our common stock may be volatile, which could contribute to the loss of all or part of your investment.*
- *Concentration of ownership of our shares of common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.*
- *Computer system interruptions or security breaches of our information systems could significantly disrupt our product development programs and our ability to operate our business.*

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

NKARTA, INC.
CONDENSED BALANCE SHEETS
(Unaudited, in thousands)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 56,960	\$ 31,040
Short-term investments	226,095	217,149
Prepaid expenses and other current assets	7,095	4,882
Total current assets	290,150	253,071
Long-term investments	119,467	—
Restricted cash	2,743	2,743
Property and equipment, net	76,231	79,326
Operating lease right-of-use assets	38,804	39,949
Other long-term assets	4,639	3,796
Total assets	<u>\$ 532,034</u>	<u>\$ 378,885</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 1,937	\$ 3,665
Operating lease liabilities, current portion	6,756	6,069
Accrued and other current liabilities	13,775	13,596
Total current liabilities	22,468	23,330
Operating lease liabilities, net of current portion	78,693	82,270
Total liabilities	101,161	105,600
Commitments and contingencies (Note 7)	—	—
Stockholders' equity		
Common stock	7	5
Additional paid-in capital	947,441	708,706
Accumulated other comprehensive income	1,714	8
Accumulated deficit	(518,289)	(435,434)
Total stockholders' equity	<u>430,873</u>	<u>273,285</u>
Total liabilities and stockholders' equity	<u>\$ 532,034</u>	<u>\$ 378,885</u>

The accompanying notes are an integral part of these condensed financial statements.

NKARTA, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited, in thousands, except share and per share data)

	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>
Other comprehensive loss:				
Net unrealized gain on investments	1,977	192	1,706	270
Comprehensive loss	<u>\$ (26,367)</u>	<u>\$ (25,453)</u>	<u>\$ (81,149)</u>	<u>\$ (89,477)</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>

The accompanying notes are an integral part of these condensed financial statements.

NKARTA, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited, in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2023	49,181,295	\$ 5	\$ 708,706	\$ 8	\$ (435,434)	\$ 273,285
Issuance of common stock and pre-funded warrants, net of issuance costs of \$15,027	21,010,000	2	225,071	—	—	225,073
Issuance of common stock upon exercise of stock options	128,671	—	578	—	—	578
Issuance of common stock upon vesting of restricted stock units	133,595	—	—	—	—	—
Share-based compensation expense	—	—	4,368	—	—	4,368
Unrealized loss on investments	—	—	—	(135)	—	(135)
Net loss	—	—	—	—	(29,518)	(29,518)
Balance, March 31, 2024	<u>70,453,561</u>	<u>\$ 7</u>	<u>\$ 938,723</u>	<u>\$ (127)</u>	<u>\$ (464,952)</u>	<u>\$ 473,651</u>
Issuance of common stock upon exercise of stock options	14,382	—	90	—	—	90
Issuance of common stock upon vesting of restricted stock units	22,072	—	—	—	—	—
Common stock issued under employee stock purchase plan	68,531	—	158	—	—	158
Share-based compensation expense	—	—	4,414	—	—	4,414
Unrealized loss on investments	—	—	—	(136)	—	(136)
Net loss	—	—	—	—	(24,993)	(24,993)
Balance, June 30, 2024	<u>70,558,546</u>	<u>\$ 7</u>	<u>\$ 943,385</u>	<u>\$ (263)</u>	<u>\$ (489,945)</u>	<u>\$ 453,184</u>
Issuance of common stock upon exercise of stock options	208	—	1	—	—	1
Issuance of common stock upon vesting of restricted stock units	10,000	—	—	—	—	—
Share-based compensation expense	—	—	4,055	—	—	4,055
Unrealized gain on investments	—	—	—	1,977	—	1,977
Net loss	—	—	—	—	(28,344)	(28,344)
Balance, September 30, 2024	<u>70,568,754</u>	<u>\$ 7</u>	<u>\$ 947,441</u>	<u>\$ 1,714</u>	<u>\$ (518,289)</u>	<u>\$ 430,873</u>

NKARTA, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited, in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2022	48,877,806	\$ 5	\$ 690,814	\$ (679)	\$ (317,933)	\$ 372,207
Vesting of shares of common stock subject to repurchase	395	—	2	—	—	2
Issuance of common stock upon exercise of stock options	253	—	1	—	—	1
Issuance of common stock upon vesting of restricted stock units	50,469	—	—	—	—	—
Share-based compensation expense	—	—	4,746	—	—	4,746
Unrealized gain on investments	—	—	—	505	—	505
Net loss	—	—	—	—	(30,815)	(30,815)
Balance, March 31, 2023	48,928,923	\$ 5	\$ 695,563	\$ (174)	\$ (348,748)	\$ 346,646
Vesting of shares of common stock subject to repurchase	113	—	1	—	—	1
Issuance of common stock upon exercise of stock options	5,892	—	21	—	—	21
Issuance of common stock upon vesting of restricted stock units	28,074	—	—	—	—	—
common stock issued under employee stock purchase plan	95,232	—	374	—	—	374
Share-based compensation expense	—	—	4,650	—	—	4,650
Unrealized loss on investments	—	—	—	(427)	—	(427)
Net loss	—	—	—	—	(33,287)	(33,287)
Balance, June 30, 2023	49,058,234	\$ 5	\$ 700,609	\$ (601)	\$ (382,035)	\$ 317,978
Issuance of common stock upon vesting of restricted stock units	10,000	—	—	—	—	—
Share-based compensation expense	—	—	4,291	—	—	4,291
Unrealized gain on investments	—	—	—	192	—	192
Net loss	—	—	—	—	(25,645)	(25,645)
Balance, September 30, 2023	49,068,234	\$ 5	\$ 704,900	\$ (409)	\$ (407,680)	\$ 296,816

The accompanying notes are an integral part of these condensed financial statements.

NKARTA, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (82,855)	\$ (89,747)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	12,837	13,687
Depreciation and amortization	6,864	3,618
Accretion and amortization of premiums and discounts on investments, net	(4,978)	(6,915)
Realized gain on investments	—	(34)
Impairment of right-of-use assets	—	4,100
Non-cash lease expense	1,725	1,653
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(3,056)	1,093
Operating lease liabilities	(3,469)	6,112
Accounts payable and accrued and other liabilities	(2,013)	3,627
Net cash used in operating activities	(74,945)	(62,806)
Cash flows from investing activities:		
Purchases of property and equipment	(3,306)	(21,340)
Purchases of investments	(320,659)	(196,877)
Maturities of investments	198,930	281,395
Net cash (used in) provided by investing activities	(125,035)	63,178
Cash flows from financing activities:		
Proceeds from stock option exercises	669	22
Proceeds from ESPP purchases	158	374
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	225,073	—
Net cash provided by financing activities	225,900	396
Net increase in cash and cash equivalents	25,920	768
Cash, cash equivalents, and restricted cash beginning of period	33,783	40,237
Cash, cash equivalents, and restricted cash end of period	\$ 59,703	\$ 41,005
Reconciliation of cash, cash equivalents and restricted cash to the balance sheet:		
Cash and cash equivalents	\$ 56,960	\$ 38,262
Restricted cash	2,743	2,743
Total cash, cash equivalents and restricted cash	\$ 59,703	\$ 41,005
Supplemental disclosures of non-cash investing activities:		
Right-of-use assets obtained in exchange for operating lease liabilities resulting from new leases	\$ 579	\$ 431
Acquisitions of property and equipment in accounts payable and accrued and other current liabilities	\$ 463	\$ 1,842

The accompanying notes are an integral part of these condensed financial statements.

NKARTA, INC.
NOTES TO FINANCIAL STATEMENTS
(Unaudited)

1. Organization and Description of Business

Description of the Business

Nkarta, Inc. ("Nkarta" or the "Company") was incorporated in the State of Delaware in July 2015. The Company is a biopharmaceutical company developing engineered natural killer ("NK") cell therapies to treat autoimmune disease and other diseases. The Company is focused on leveraging the natural potent power of NK cells to identify and kill abnormal cells and recruit adaptive immune effectors to generate responses that are specific and durable. Nkarta is combining its NK-cell expansion platform technology with proprietary cell engineering technologies to generate an abundant supply of NK cells, engineer enhanced NK-cell recognition of therapeutic targets, and improve persistence for sustained activity in the body. Nkarta's goal is to develop off-the-shelf NK-cell therapy product candidates to improve outcomes for patients. The Company's operations are based in South San Francisco, California, and it operates in one segment.

Liquidity and Management Plans

The accompanying unaudited condensed financial statements have been prepared assuming that the Company will continue as a going concern. Since inception, the Company has devoted substantially all of its efforts to organizing and staffing, business planning, raising capital, conducting preclinical studies and initiating clinical studies, and has not realized substantial revenues from its planned principal operations. In addition, the Company has incurred operating losses since inception and expects that it will continue to incur net losses into the foreseeable future as it continues its research and development activities. As of September 30, 2024, the Company had an accumulated deficit of \$518.3 million and cash, cash equivalents, restricted cash and investments of \$405.3 million.

Management plans to continue to incur substantial costs in order to conduct research and development activities for which additional capital will be needed. The Company intends to raise such capital through debt or equity financings or other arrangements, as it has primarily done to date to fund its operations. Management believes that the Company's current cash, cash equivalents, restricted cash and investments will provide sufficient funds to enable the Company to meet its obligations for at least twelve months from the filing date of this report.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements as of September 30, 2024 and for the three and nine months ended September 30, 2024 and 2023 have been prepared in accordance with U.S. generally accepted accounting principle ("U.S. GAAP") for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act, as amended. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows for the periods presented.

The results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results expected for the full year or any subsequent interim period. The condensed balance sheet as of December 31, 2023 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed financial statements and the notes accompanying them should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2023, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed by the Company with the SEC on March 21, 2024.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the Company's financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to preclinical studies and clinical trial accruals, fair value of assets and liabilities, impairment of assets, leases, share-based compensation and income taxes. Management bases its estimates on historical experience, knowledge of current events and actions it may undertake in the future that management believes to be reasonable under the circumstances. Actual results may differ from these estimates and assumptions.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares and pre-funded warrants outstanding for the period, without consideration of potential dilutive securities. Pre-funded warrants are considered outstanding for the purposes of computing basic and diluted net loss per share because shares may be issued for little or no additional consideration and are fully vested and exercisable after the original issuance date of the pre-funded warrants. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted average number of common shares and pre-funded warrants plus the potential dilutive effects of potential dilutive securities outstanding during the period. Potential dilutive securities are excluded from diluted earnings or loss per share if the effect of such inclusion is antidilutive. The Company's potentially dilutive securities, which include unvested common stock, outstanding stock options and restricted stock units under the Company's equity incentive plans, have been excluded from the computation of diluted net loss per share as they would be antidilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Long-Lived Asset Impairment

The Company assesses the impairment of long-lived assets whenever events or changes in business circumstances indicate that the carrying amounts of the asset or group of assets may not be fully recoverable. In the case of property and equipment and right-of-use assets for the Company's leases, the Company determines whether there has been an impairment by comparing the carrying value of the group of assets to the anticipated undiscounted net future cash flows associated with the group of assets. If such cash flows are less than the carrying value, the Company writes down the group of assets to its fair value, which may be measured as anticipated net cash flows associated with the group of assets, discounted at a rate that the Company believes a market participant would utilize to reflect the risks associated with the cash flows, such as credit risk. See Note 6 for additional information regarding the prior year impairment charge the Company recorded in connection with its leased facilities.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standard Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires disclosure of incremental segment information on an interim and annual basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal periods beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. The Company is currently evaluating the impact of the guidance on the financial statements and disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"). ASU 2023-09 is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. ASU 2023-09 will be effective for us in the annual period beginning January 1, 2025, though early adoption is permitted. The Company is currently evaluating the presentational effect that ASU 2023-09 will have on its financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 740-20) and Derivative and Hedging – Contracts in Entity's Own Equity* (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. ASU 2020-06 also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it simplifies the diluted earnings per share calculation in certain areas. ASU 2020-06 is effective for the Company beginning on January 1, 2024. The adoption of ASU 2020-06 does not have a material impact on the financial position, results of operations or cash flows of the Company.

There were no other significant updates to the recently issued accounting standards other than as disclosed herewith. Although there are several other new accounting pronouncements issued or proposed by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

3. Net Loss Per Share

The following tables summarize the computation of the basic and diluted net loss per share (in thousands except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (28,344)	\$ (25,645)	\$ (82,855)	\$ (89,747)
Denominator:				
Weighted average common shares outstanding	70,563,285	49,062,799	63,882,940	48,985,448
Less: weighted average unvested common stock issued upon early exercise of common stock options	—	—	—	(75)
Add: weighted average of common stock to be issued upon exercise of pre-funded warrants	3,000,031	—	2,058,415	—
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>
Net loss per share, basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.52)</u>	<u>\$ (1.26)</u>	<u>\$ (1.83)</u>

The following table summarizes the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be antidilutive:

	As of September 30,	
	2024	2023
Common stock options	9,101,686	7,127,449
Restricted stock units	1,183,129	695,110
	<u>10,284,815</u>	<u>7,822,559</u>

4. Fair Value of Financial Instruments

The following tables summarize the Company's financial instruments measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

		September 30, 2024			
	Valuation Hierarchy	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	\$ 34,938	\$ —	\$ —	\$ 34,938
Commercial paper	Level 2	16,443	—	—	16,443
U.S. Government securities	Level 2	5,361	—	—	5,361
Total Cash equivalents		<u>56,742</u>	<u>—</u>	<u>—</u>	<u>56,742</u>
Short-term investments:					
Corporate debt securities	Level 2	\$ 102,410	\$ —	\$ 450	\$ 102,860
Commercial paper	Level 2	16,401	—	—	16,401
U.S. Government securities	Level 2	106,662	(2)	174	106,834
Total short-term investments		<u>225,473</u>	<u>(2)</u>	<u>624</u>	<u>226,095</u>
Long-term investments:					
Corporate debt securities	Level 2	\$ 89,110	\$ (10)	\$ 923	\$ 90,023
U.S. Government securities	Level 2	29,265	(6)	185	29,444
Total long-term investments		<u>118,375</u>	<u>(16)</u>	<u>1,108</u>	<u>119,467</u>
Total		<u>\$ 400,590</u>	<u>\$ (18)</u>	<u>\$ 1,732</u>	<u>\$ 402,304</u>

		December 31, 2023			
	Valuation Hierarchy	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	\$ 30,751	\$ —	\$ —	\$ 30,751
Short-term investments:					
Corporate debt securities	Level 2	\$ 40,602	\$ (11)	\$ 18	\$ 40,609
Commercial paper	Level 2	38,198	(2)	1	38,197
U.S. Government securities	Level 2	138,341	(56)	58	138,343
Total short-term investments		<u>217,141</u>	<u>(69)</u>	<u>77</u>	<u>217,149</u>
Total		<u>\$ 247,892</u>	<u>\$ (69)</u>	<u>\$ 77</u>	<u>\$ 247,900</u>

Investments are classified as Level 1 within the fair value hierarchy if their quoted prices are available in active markets for identical securities. Investments in money market funds of \$34.9 million and \$30.8 million as of September 30, 2024 and December 31, 2023, respectively, were classified as Level 1 instruments and were included in cash equivalents.

Investments in corporate debt securities, commercial paper and U.S. Government securities are valued using Level 2 inputs. Level 2 securities are initially valued at the transaction price and subsequently valued and reported upon utilizing inputs other than quoted prices that are observable either directly or indirectly, such as quotes from third-party pricing vendors. Fair values determined by Level 2 inputs, which utilize data points that are observable such as quoted prices, interest rates and yield curves, require the exercise of judgment and use of estimates, that if changed, could significantly affect the Company's financial position and results of operations. The marketable securities of \$367.4 million and \$217.1 million as of September 30, 2024 and December 31, 2023, respectively, were classified as Level 2 instruments. Accrued interest receivable related to investments was \$2.5 million and \$1.2 million as of September 30, 2024 and December 31, 2023, respectively, and included as part of prepaid expenses and other current assets in the condensed balance sheets.

The Company has classified its investment securities as current and non-current assets on the condensed balance sheets based on each security's contractual maturity date, and all investment securities are accounted for as available-for-sale because these investment securities are considered available for use in operations.

The Company considers whether unrealized losses have resulted from a credit loss or other factors. The unrealized losses on the Company's available-for-sale securities as of September 30, 2024 and December 31, 2023 were caused by fluctuations in market value

and interest rates as a result of the economic environment and not credit risk. The Company concluded that an allowance for credit losses was unnecessary as of September 30, 2024 and December 31, 2023. It is neither management's intention to sell nor is it more likely than not that the Company will be required to sell these investments prior to recovery of their cost basis or recovery of fair value. Unrealized gains and losses are included in accumulated other comprehensive loss.

There was no realized gain or loss on available-for-sale securities for the nine months ended September 30, 2024. During the nine months ended September 30, 2023, there were immaterial realized gains recognized on available-for-sale securities sold in the period. The Company uses the specific identification method to determine the cost basis of investments sold.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net is comprised of the following (in thousands):

	September 30, 2024	December 31, 2023
Leasehold improvements	\$ 66,618	\$ 66,618
Furniture and fixtures	746	745
Research equipment	16,729	14,298
Computers and software	404	404
Construction in progress	10,291	8,954
Total property and equipment, gross	94,788	91,019
Less accumulated depreciation and amortization	(18,557)	(11,693)
Total property and equipment, net	\$ 76,231	\$ 79,326

Depreciation and amortization expense was \$2.4 million and \$6.9 million for the three and nine months ended September 30, 2024, and \$2.0 million and \$3.6 million for the three and nine months ended September 30, 2023.

Accrued and Other Current Liabilities

Accrued other current liabilities are comprised of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued compensation	\$ 7,007	\$ 6,722
Accrued research and development costs	5,539	5,845
Accrued property and equipment	250	174
Other accrued and current liabilities	979	855
Total accrued and other liabilities	\$ 13,775	\$ 13,596

6. Leases

The Company has operating leases for its current corporate offices, laboratories, manufacturing facilities, and dedicated space in a vivarium in South San Francisco, California. Rent expense was \$2.6 million and \$7.9 million for the three and nine months ended September 30, 2024, respectively, and \$2.7 million and \$8.2 million for the three and nine months ended September 30, 2023, respectively. The total cash paid for the nine months ended September 30, 2024 for operating leases included in the operating cash flows was \$9.7 million, inclusive of \$9.2 million of rent payments and \$0.5 million of tenant improvement allowance repayment, as compared to net cash paid of \$0.5 million for the nine months ended September 30, 2023, comprised of \$8.3 million of rent payments less \$7.8 million cash received for the tenant improvement allowance reimbursement. The weighted average remaining lease term was 9.1 years for the corporate office, laboratory space leases, and additional facility as of September 30, 2024. The weighted average discount rate was 9.8% as of September 30, 2024.

Initial Lease Agreement

In May 2018, the Company entered into a lease agreement for corporate office and laboratory space located in South San Francisco, California with an expiration date in May 2025 (the "Initial Lease Agreement"). In April 2019, the Company executed the first amendment to the Initial Lease Agreement for additional corporate space, laboratory space and manufacturing capabilities. In May 2020, the Company executed the second amendment to the Initial Lease Agreement for additional corporate space and laboratory space in the same building. The lease for this additional space commenced in January 2021. In January 2021, the Company signed a

third amendment to the Initial Lease Agreement for additional space in the same building. The lease amendment for this additional space commenced in April 2021 and expired in March 2024. In October 2021, the Company signed a fourth amendment to the Initial Lease Agreement for additional space in the same building, that commenced in April 2022. All space leased under the Initial Lease Agreement, together with the first amendment, second amendment, and fourth amendment to the Initial Lease Agreement, has a lease term through July 31, 2030, with an option to extend the lease for an additional seven-year term. This lease extension option was not considered in the right-of-use assets or the lease liability as the Company did not consider it reasonably certain the option would be exercised.

Additional Lease Agreement

In July 2021, the Company entered into an additional lease agreement for corporate office, manufacturing and laboratory space located in South San Francisco, California with an expiration date approximately twelve years after the lease commencement date (as amended from time to time, the "Additional Lease Agreement"). The lease for this additional space and the Company's obligation to pay rent commenced in January 2022. In addition to base rent, the Company is responsible for payment of direct expenses, which include operating, insurance and tax expenses. The Additional Lease Agreement provided for certain tenant improvement allowances that were fully utilized and reimbursed to the Company, and an additional tenant improvement allowance to be utilized at the option of the Company. In June 2023, the Company entered into an amendment to utilize the additional tenant improvement allowance of \$4.4 million and under this amendment the Company is required to repay the tenant improvement costs in equal monthly payments at an annual rate of 8.5% over the remainder of the lease term starting in July 2023.

Maturities of operating lease liabilities under existing operating leases as of September 30, 2024 were as follows (in thousands):

<u>Year ending December 31,</u>	<u>Amount</u>
2024 (remaining three months)	\$ 3,314
2025	13,403
2026	13,462
2027	13,912
2028	14,378
2029 and thereafter	72,876
Total undiscounted future minimum lease payments	131,345
Less imputed interest	(45,896)
Total operating lease liabilities	<u>\$ 85,449</u>
Operating lease liabilities:	
Current	6,756
Non-current	78,693
Total lease liability	<u>\$ 85,449</u>

Lease Impairment

The Company tests long-lived assets for recoverability whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets may not be recoverable. Beginning in the second quarter of 2023, the Company started to market for sublease portions of the Company's leased corporate office space in South San Francisco. As a result of these plans, the Company reviewed these spaces for impairment. As part of the impairment evaluation of the spaces being marketed for sublease, the Company compared the estimated undiscounted income for the marketed sublease spaces to the net book value of the related long-term assets, which include right-of-use assets and certain property and equipment, primarily for leasehold improvements (collectively, "Sublease Asset Group"). The Company estimated potential sublease income using market participant assumptions, which the Company evaluated based on current real estate trends and market conditions. For the Sublease Asset Group, the Company determined that the respective right-of-use assets had net carrying values that exceeded their estimated undiscounted future cash flows. Accordingly, the Company then estimated the fair value of the Sublease Asset Group based on its discounted cash flows. The carrying value of the Sublease Asset Group exceeded its fair values and, as a result, the Company recorded a right-of-use asset impairment of \$4.1 million for the nine months ended September 30, 2023. The impairment is recorded within general and administrative expenses in the condensed statements of operations and comprehensive loss. There was no additional impairment recorded for the three and nine months ended September 30, 2024.

Sublease Agreement

In September 2024, the Company entered into an agreement to sublease a portion of the Company's leased corporate office space. The sublease will commence during the fourth quarter of 2024 and rent payments will commence in the first quarter of 2025. The Company accounts for this sublease in accordance with ASC 842, Leases.

7. Commitments & Contingencies

Guarantee Agreement

The Company has agreements whereby it indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and enables the Company to recover a portion of any future amounts under certain circumstances and subject to deductibles and exclusions. The Company had no liabilities recorded for these agreements as of September 30, 2024, and December 31, 2023.

Letters of Credit

The Company has \$2.7 million in letter of credit agreements with a financial institution that are used as collateral for the Company's corporate headquarters' operating leases. The letters of credit automatically renew annually without amendment unless cancelled by the financial institutions within 30 to 60 days of the annual expiration date. The letters of credit are presented as restricted cash in the condensed balance sheet.

Contingencies

The Company, from time to time, may be involved in litigation arising in the ordinary course of business. The Company assesses its potential liability in such situations by analyzing potential outcomes, assuming various litigation, regulatory and settlement strategies. If the Company determines a loss is probable and its amount can be reasonably estimated, the Company accrues an amount equal to the estimated loss. No losses and no provision for a loss contingency have been recorded to date.

Purchase Commitments

The Company enters into contracts in the normal course of business for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore the Company believes that non-cancelable obligations under these agreements are not material.

8. CRISPR Collaboration Agreement

On May 5, 2021, the Company entered into a research collaboration agreement (as amended, the "CRISPR Agreement") with CRISPR Therapeutics AG ("CRISPR") to co-develop and co-commercialize an allogeneic, off-the-shelf chimeric antigen receptor-natural killer ("CAR NK") product candidate targeting the CD70 tumor antigen ("NKX070") and an allogeneic, off-the-shelf product candidate that comprises both engineered NK cells and engineered T cells ("NK+T"). In May 2022, the CRISPR Agreement was amended to revise the transfer of materials and nomination provisions, and in March 2023, the CRISPR Agreement was further amended to permit Nkarta's advancement of CRISPR-licensed product candidates targeting a specified tumor antigen (the "Specified TA") and incorporate associated development and regulatory approval milestones and sales based royalties. In addition, the Company has received licenses from CRISPR for four CRISPR-Cas9 gene editing targets and will receive a license from CRISPR for up to one more CRISPR-Cas9 gene editing target that can be engineered into an unlimited number of its own NK-cell products. CRISPR also has an option to co-develop and co-commercialize a future CAR NK program. On April 3, 2024, the CRISPR Agreement was amended to further revise the nomination provision, and on May 2, 2024, it was amended to align the designation term and additional-gene-editing target provisions with the revised nomination provision from April 3, 2024.

Under the terms of the CRISPR Agreement, the Company and CRISPR share equally in all research and development costs and potential profits worldwide related to the NKX070 product candidate, NK+T product candidate, and the potential future CAR NK program. For the NK+T program, CRISPR is responsible for gene-editing activities and T-cell related activities, and Nkarta is responsible for NK-cell related activities. The impact of the cost sharing associated with the research and development activities is included in research and development expense on the condensed statements of operations and comprehensive loss. Expenses related to services performed by the Company are classified as research and development expense. Payments received from CRISPR for partial reimbursement of expenses are recorded as a reduction of research and development expense. Reduction of research and development expense resulting from partial reimbursement from CRISPR was zero and \$0.1 million for the three and nine months ended September 30, 2024, respectively, and \$0.3 million and \$1.4 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024, there was no receivable under the research cost sharing provision.

For each non-collaboration product candidate incorporating a genome editing target licensed from CRISPR (a "CRISPR-Licensed Product Candidate"), other than those targeting the Specified TA, the Company would retain worldwide rights and may be required to make potential future payments based on the achievement of development and regulatory approval milestones totaling less than mid-twenty million dollars, as well as tiered royalties up to the mid-single digits on net product sales of such product candidate. For each CRISPR-Licensed Product Candidate targeting the Specified TA, the Company would retain worldwide rights and may be required to make potential future payments based on the achievement of development and regulatory approval milestones totaling less than high-forty million dollars, as well as tiered royalties up to the mid-single digits on net product sales of such product candidate. As of September 30, 2024, the Company has not paid any amounts nor are any amounts owed by the Company under the CRISPR Agreement, and no milestones have been achieved.

9. Stockholders' Equity

Equity Incentive Plan

The Company's 2020 Performance Incentive Plan (the "2020 Plan"), which was adopted by the Company's board of directors in June 2020 and approved by the Company's stockholders in July 2020, became effective upon the consummation of the Company's initial public offering in July 2020 ("IPO"). Upon the effectiveness of the 2020 Plan, no further grants may be made under the Company's 2015 Equity Incentive Plan (the "2015 Plan"). The 2020 Plan allows for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, stock bonuses, restricted stock, stock units and other forms of awards including cash awards to its officers, directors, employees, consultants and advisors.

As of September 30, 2024, a total of 10,847,981 shares of the Company's common stock were authorized for issuance with respect to awards granted under the 2020 Plan (this number of shares gives effect to the annual increases in the 2020 Plan share limit, as described in the next sentence, through that date). The share limit will automatically increase on the first trading day in January of each year by an amount equal to the lesser of (1) 5% of the total number of outstanding shares of the Company's common stock on the last trading day in December in the prior year, or (2) such lesser number as determined by the Company's board of directors. Any shares subject to awards granted under the 2020 Plan or the 2015 Plan that are not paid, delivered or exercised before they expire or are canceled or terminated, or otherwise fail to vest, as well as shares used to pay the purchase or exercise price of such awards or related tax withholding obligations, will become available for new award grants under the 2020 Plan. A total of 1,821,927 shares were available for issuance under the 2020 Plan as of September 30, 2024.

The following table summarizes the option activity under the 2020 Plan and 2015 Plan during the nine months ended September 30, 2024:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2023	6,716,526	\$ 12.99	7.5	8,279
Granted	2,987,850	6.17		
Exercised	(143,261)	4.66		
Forfeited	(459,429)	18.67		
Outstanding at September 30, 2024	9,101,686	\$ 10.60	7.8	2,535
Exercisable at September 30, 2024	4,560,175	\$ 14.29	6.7	1,198
Vested and expected to vest at September 30, 2024	9,101,686	\$ 10.60	7.8	2,535

The weighted average grant date fair value of stock option grants was \$5.05 and \$3.35 per share for the nine months ended September 30, 2024 and 2023, respectively.

The following table summarizes the restricted stock unit activity under the 2020 Plan during the nine months ended September 30, 2024:

	Number of shares	Weighted average grant date fair value per share	Weighted average remaining contractual term (in years)
Outstanding at December 31, 2023	594,768	\$ 8.16	1.4
Granted	798,574	6.04	
Vested	(165,667)	8.63	
Forfeited	(44,546)	6.65	
Outstanding at September 30, 2024	<u>1,183,129</u>	<u>\$ 6.72</u>	<u>1.6</u>

The weighted average grant date fair value of restricted stock units was \$6.04 and \$5.57 per share for the nine months ended September 30, 2024 and 2023, respectively.

Employee Stock Purchase Plan

The Company's 2020 Employee Stock Purchase Plan (the "ESPP"), which was adopted by the Company's board of directors in June 2020 and approved by the Company's stockholders in July 2020, became effective upon the consummation of the IPO. The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP provides for six-month offering periods, and at the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last trading day of the offering period. The six-month offering periods extend from June to November and December to May. As of September 30, 2024, 1,638,267 shares of the Company's common stock remained available for issuance under the ESPP (after giving effect to share purchases under the ESPP, and annual increases in the ESPP share limit as described in the next sentence through that date). The number of shares of the Company's common stock available for issuance under the ESPP automatically increases on the first trading day in January of each year by an amount equal to the lesser of (i) 1% of the total number of outstanding shares of the Company's common stock issued and outstanding on December 31 of the immediately preceding calendar year, (ii) 1,000,000 shares, or (iii) such lesser number as determined by the Company's board of directors. As of September 30, 2024, employee contributions to the ESPP were \$0.3 million and included as part of accrued and other current liabilities in the condensed balance sheets.

Share-Based Compensation Expense

Share-based compensation expense for the three and nine months ended September 30, 2024 and 2023 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 1,793	\$ 2,077	\$ 6,198	\$ 6,283
General and administrative	2,262	2,214	6,639	7,404
Total share-based compensation	<u>\$ 4,055</u>	<u>\$ 4,291</u>	<u>\$ 12,837</u>	<u>\$ 13,687</u>

The total unrecognized compensation cost related to unvested stock options was \$22.8 million, which is expected to be recognized over a weighted average remaining service period of 2.8 years as of September 30, 2024.

The total unrecognized compensation cost related to unvested restricted stock units was \$6.4 million, which is expected to be recognized over a weighted average remaining service period of 2.9 years as of September 30, 2024.

Sale of Common Stock and Pre-funded Warrants

In March 2024, the Company completed an underwritten public offering utilizing the Shelf Registration Statement, pursuant to which it sold an aggregate of (i) 21,010,000 shares of its common stock at a price of \$10.00 per share, and (ii) pre-funded warrants to purchase 3,000,031 shares of its common stock at a price of \$9.9999 per pre-funded warrant. The pre-funded warrants can be exercised at any time after issuance for an exercise price of \$0.0001 per share, subject to certain ownership limitations. As of September 30, 2024, none of the pre-funded warrants have been exercised. The Company raised \$240.1 million in gross proceeds before underwriting discounts and commissions of \$14.4 million and other offering expenses of \$0.6 million.

In accordance with ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ("ASC 480"), and ASC 815-40 ("ASC 815"), Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock, the Company determined that the pre-funded warrants should be equity classified because they are freestanding financial instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of shares of common stock upon exercise, are indexed to the Company's common stock and meet the equity classification criteria.

10. Income Taxes

There was no provision for income taxes recorded during the three and nine months ended September 30, 2024, and 2023. The Company's deferred tax assets continue to be fully offset by a valuation allowance.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited financial statements and the related notes included in our Annual Report on Form 10-K filed with the SEC on March 21, 2024 for the fiscal year ended December 31, 2023, including information with respect to our plans and strategy for our business and related financing. The discussion and analysis below includes forward-looking statements that involve risks and uncertainties, including those risks and uncertainties set forth in the sections titled "Risk Factors" of this Quarterly Report on Form 10-Q, which may cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See "Cautionary Note Regarding Forward-Looking Statements" above. Unless the context otherwise requires, the terms "Company," "Nkarta, Inc.," "we," "us," or "our" refer to Nkarta, Inc. We do not have any subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company pioneering the development of allogeneic, off-the-shelf engineered NK-cell therapies. We are currently developing NKX019, a CAR NK product candidate targeting the CD19 antigen, as our lead product candidate for the treatment of patients with autoimmune disease. NKX019 and our other CAR NK product candidates incorporate proprietary technologies that enable us to generate an abundant supply of NK cells, increase NK-cell recognition of target antigens, enhance NK-cell fitness and freeze, store, and thaw our engineered NK cells for off-the-shelf administration. Our product candidates are allogeneic, which means they are produced using cells from a different person than the patient(s) being treated, and they are produced in quantity, then frozen and therefore available for treating patients without delay, unlike autologous cell therapies, which are derived from a patient's own cells and must be manufactured as needed for each patient. We believe that engineered NK cells have the potential to be effective and accessible therapies for autoimmune diseases and other diseases, be well tolerated, and avoid some of the toxicities observed with other cell therapies.

Our modular engineering platform builds on the distinctive biology of NK cells and their role in eradicating aberrant and pathologically transformed cells. Our process starts with differentiated, mature NK cells derived from healthy donors. We build on the intrinsic ability of these immune cells to identify and kill transformed cells with cell engineering to further enhance their activity. This engineering involves inducing the expression of a chimeric antigen receptor ("CAR") on the surface of an NK-cell to enable the cell to recognize specific proteins or antigens that are present on the surface of target cells. Our engineered CAR NK cells generally consist of an NK-cell engineered with a targeting receptor, OX40 costimulatory domain, CD3ζ(zeta) signaling moiety, and a membrane-bound form of the cytokine IL(interleukin)-15 ("mbIL-15").

In June 2024, we announced the initiation of Ntrust-1, a multi-center, open-label, dose-escalation Phase 1 clinical trial of NKX019 for lupus nephritis ("LN"). At that time, we also announced that we had received clearance of an Investigational New Drug ("IND") application by the United States Food and Drug Administration ("FDA") to evaluate NKX019 for the treatment of additional autoimmune diseases. Ntrust-2 is a planned multi-center, open-label, dose-escalation Phase 1 clinical trial that will evaluate the safety and clinical activity of NKX019 in humans with systemic sclerosis ("scleroderma"), idiopathic inflammatory myopathy ("myositis") and antineutrophil cytoplasmic antibody ("ANCA")-associated vasculitis ("AAV"). In July 2024, we announced that researchers at Columbia University Irving Medical Center ("CUIMC") initiated an investigator-sponsored trial ("IST") of NKX019 in patients with systemic lupus erythematosus ("SLE"). In November 2024, we announced that the first patient was dosed in both Ntrust-1 and the IST at CUIMC.

NKX019 is also being studied in a multi-center Phase 1 clinical trial for the treatment of a variety of B-cell malignancies, which evaluates the safety, pharmacology, and preliminary anti-tumor activity of NKX019. In November 2024, we announced new clinical data from a cohort of heavily pretreated patients with large B-cell lymphoma ("LBCL") whose disease had already progressed following treatment with a CD19 CAR T cell therapy. Based on these data and the highly competitive landscape for treatments of B-cell malignancies, we will refocus our research and development activities on autoimmune disease and plan for no further investment in the clinical development of NKX019 for the treatment of B-cell malignancies.

NKX101, our CAR NK-cell product candidate targeting cells that display NKG2D ligands, has been evaluated in a multi-center Phase 1 clinical trial in the U.S. for the treatment of relapsed or refractory acute myeloid leukemia ("r/r AML") and higher risk myelodysplastic syndromes ("MDS"). This first-in-human study evaluated the safety, pharmacology, and preliminary anti-tumor activity of NKX101. We have deprioritized further development of NKX101 to direct primary resources to development of our lead product candidate, NKX019, for the treatment of autoimmune diseases.

Under the CRISPR Agreement entered into in May 2021, we agreed with CRISPR to collaboratively design and advance (a) up to two allogeneic, gene-edited NK-cell therapies, one of which is the engineered CAR NK product candidate targeting the CD70 tumor antigen, and (b) one allogeneic, gene-edited NK+T cell therapy.

Since the commencement of our operations in 2015, we have devoted substantially all our resources in support of our product development efforts, hiring personnel, raising capital to support and expand such activities and providing general and administrative

support for these operations. We have incurred net operating losses since inception and have not generated any revenue from product sales. In the future, we expect that our operating expenses will significantly increase as we continue to develop and seek regulatory approvals for our product candidates, continue to engage in other research and development activities to expand our pipeline of product candidates, maintain and expand our intellectual property portfolio, maintain and expand our product manufacturing capabilities, and ultimately establish a commercial organization. We have funded our operations primarily through the issuance of Company stock and intend to raise additional capital to fund operations until such time that we are able to generate sufficient revenues to cover our operating expenses. We may seek additional funding through the issuance of common stock, including through equity or debt financing or collaborations or partnerships with other companies. The amount and timing of our future funding requirements will depend on many factors, including, among other things, the pace and results of our clinical development efforts for our product candidates. We may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise capital as and when needed would compromise our ability to execute our business plan and may cause us to undertake cost containment measures and/or significantly delay, scale back or discontinue the development of some of our programs. We have also incurred increased operating expenses since becoming a public company, which we expect will further increase when we are no longer able to rely on certain “emerging growth company” exemptions we are afforded under the Jumpstart Our Business Startups Act (the “JOBS Act”) as further described under “—JOBS Act” below. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

On March 27, 2024, we sold an aggregate of (i) 21,010,000 shares of its common stock at a price of \$10.00 per share, and (ii) pre-funded warrants to purchase 3,000,031 shares of common stock at a price of \$9.9999 per pre-funded warrant in an underwritten public offering. The pre-funded warrants can be exercised at any time after issuance for an exercise price of \$0.0001 per share, subject to certain ownership limitations. The total net proceeds from the offering were approximately \$225.1 million, after deducting underwriting discounts and commissions and offering expenses.

Financial Operations Overview

Operating Expenses

Research and Development

Research and development costs consist primarily of costs incurred for the discovery and clinical development of our drug candidates, which include:

- employee-related expenses, including salaries, related benefits, travel and share-based compensation expenses for employees engaged in research and development functions;
- expenses incurred in connection with research, laboratory consumables, sponsored research, and preclinical studies;
- expenses incurred in connection with conducting clinical trials including investigator grants and site payments for time and pass-through expenses and expenses incurred under agreements with CROs, other vendors or central laboratories and service providers engaged to conduct our trials;
- the cost of consultants engaged in research and development related services;
- the cost to manufacture drug product candidates for use in our preclinical studies and clinical trials;
- facilities, depreciation and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies;
- costs related to regulatory compliance; and
- the cost of annual license fees under our third-party licensing agreements.

We typically have various early-stage research and drug discovery projects as well as various product candidates undergoing clinical trials. Our internal resources, employees and infrastructure are generally not directly tied to any one research or drug discovery project and are typically deployed across multiple projects. As such, we do not maintain information regarding the costs incurred for these early-stage research and drug discovery programs on a project-specific basis. As part of our October 2023 announcement of cost containment measures, early discovery and preclinical programs have been deprioritized with less personnel and funding allocated to advancing these programs.

We expense research and development costs as they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

The following table summarizes our research and development expenses for the three and nine months ended September 30, 2024 and 2023. The direct external development program expenses reflect external costs attributable to our clinical development candidates and preclinical candidates selected for further development. Such expenses include third-party contract costs relating to manufacturing, clinical trial activities, translational medicine and toxicology activities. The unallocated internal research and development costs include personnel, facility costs, laboratory consumables and discovery and research related activities associated with our pipeline. The partner cost sharing represents reimbursable research and development expenses from the CRISPR Agreement.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands)		(in thousands)	
Direct external development program expenses:				
NKX019	\$ 5,103	\$ 1,303	\$ 12,727	\$ 9,658
NKX101	704	3,952	4,149	13,476
CD70	12	142	37	792
NK+T	—	—	—	108
Unallocated internal research and development costs:				
Personnel related (including share-based compensation)	10,030	10,392	30,409	31,134
Others	9,401	6,666	26,377	19,695
Partner cost sharing	—	(261)	(82)	(1,412)
Total research and development costs	\$ 25,250	\$ 22,194	\$ 73,617	\$ 73,451

Research and development activities are central to our business model. There are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our drug candidates. However, we expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the future, including as a result of Ntrust-1, our clinical trial of NKX019 for the treatment of LN, and Ntrust-2, our planned clinical trial of NKX019 for the treatment of scleroderma, myositis, and AAV.

The successful development of our drug candidates is highly uncertain. A change in the outcome of any of a number of variables with respect to the development of our drug candidates may significantly impact the costs and timing associated with the development of our drug candidates. A discussion of the risks and uncertainties that we face in the development and commercialization of our drug candidates can be found under Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q. We may never succeed in obtaining regulatory approval for any of our drug candidates.

General and Administrative

General and administrative expenses consist primarily of salaries and employee-related costs, including share-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and facility-related costs.

While we continue to closely manage our expenditures, we still expect our general and administrative expenses will increase in the future in support of increased research and development activities and to reflect increased costs associated with operating as a public company. These anticipated increased costs will include increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, insurance premiums and investor relations costs.

Other Income (Expense), net

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and investments and adjustments related to amortization of purchase premiums and accretion of discounts of investments.

Results of Operations

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Operating expenses:						
Research and development	\$ 25,250	\$ 22,194	\$ 3,056	\$ 73,617	\$ 73,451	\$ 166
General and administrative	8,544	7,100	1,444	23,654	27,014	(3,360)
Total operating expenses	33,794	29,294	4,500	97,271	100,465	(3,194)
Loss from operations	(33,794)	(29,294)	(4,500)	(97,271)	(100,465)	3,194
Other income (expense), net:						
Interest income	5,453	3,616	1,837	14,423	10,651	3,772
Other income (expense), net	(3)	33	(36)	(7)	67	(74)
Total other income, net	5,450	3,649	1,801	14,416	10,718	3,698
Net loss	\$ (28,344)	\$ (25,645)	\$ (2,699)	\$ (82,855)	\$ (89,747)	\$ 6,892

Research and development expenses. Research and development expenses were \$25.3 million and \$22.2 million for the three months ended September 30, 2024 and 2023, respectively. Research and development expenses were \$73.6 million and \$73.5 million for the nine months ended September 30, 2024 and 2023, respectively.

The increase of \$3.1 million for the three months ended September 30, 2024 was primarily due to the following:

- a \$0.4 million increase in program costs primarily from higher manufacturing, materials, and clinical spending related to NKX019 to support Phase I clinical trials in autoimmune diseases, which was partially offset by lower manufacturing, materials, and clinical expenses related to NKX101 as the program was deprioritized;
- a \$0.9 million increase in research supplies purchased due to fewer purchases in 2023 from lab facility relocation;
- a \$0.3 million increase in depreciation expense due to the timing of when assets were placed in-service during the year in 2023; and
- a \$1.5 million net increase in other research costs, primarily consisting of facility allocation expenses, which was partially offset by partner cost sharing reimbursable expenses and a decrease in payroll expenses.

The increase of \$0.2 million for the nine months ended September 30, 2024 was primarily due to the following:

- a \$2.8 million increase in depreciation expense due to the timing of when assets were placed in-service during the year in 2023;
- a \$1.9 million increase in research supplies purchased due to fewer purchases in 2023 from lab facility relocation;
- a \$1.3 million decrease in partner cost sharing reimbursable expenses related to a decrease in activities performed under our collaboration with CRISPR;
- a \$1.3 million net increase in other research costs, primarily consisting of consulting expenses, which was partially offset by a decrease in payroll and facility expenses due to the reallocation of the Sublease Asset Group to general and administrative expenses; and
- a \$7.1 million decrease in program costs primarily from lower manufacturing, materials, and clinical expenses related to NKX101 as the program was deprioritized and reduced manufacturing and materials expenses related to programs under the CRISPR partnership, which were partially offset by higher manufacturing, materials, and clinical spending related to NKX019 to support Phase I clinical trials in autoimmune diseases.

General and administrative expenses. General and administrative expenses were \$8.5 million and \$23.7 million for the three and nine months ended September 30, 2024, respectively, and \$7.1 million and \$27.0 million for the three and nine months ended September 30, 2023, respectively.

The increase of \$1.4 million for the three months ended September 30, 2024 was primarily due to an increase in depreciation, personnel-related expenses, and consulting expenses. The decrease of \$3.4 million for the nine months ended September 30, 2024 was primarily due to the \$4.1 million impairment of the right-of-use assets during the nine months ended September 30, 2023 and a

decrease in personnel-related expenses for the nine months ended September 30, 2024 resulting from the reduction in force completed in October 2023, partially offset by an increase in depreciation.

Interest income. Interest income was \$5.5 million and \$14.4 million for the three and nine months ended September 30, 2024, respectively, and \$3.6 million and \$10.7 million for the three and nine months ended September 30, 2023, respectively. The increase of \$1.8 million and \$3.8 million for the three and nine months ended September 30, 2024, respectively, were primarily due to higher average investment balances and higher yields in the current period. Interest income includes interest earned from investments, partially offset by amortization of purchase premiums and accretion of discounts of investments.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2024, we had cash, cash equivalents, restricted cash and investments of \$405.3 million. We estimate that all \$265.1 million in net proceeds from our July 2020 initial public offering have been spent. On April 28, 2022, we received \$215.3 million in net proceeds, after deducting underwriting discounts, commissions and other offering expenses, in connection with our secondary offering of our common stock. On March 27, 2024, we received \$225.1 million in net proceeds from an underwritten public offering, after deducting underwriting discounts, commissions and expenses, described further below.

On March 17, 2023, the Company filed a Registration Statement on Form S-3, as amended by the Form S-3/A filed on April 24, 2023 (the "Shelf Registration Statement"), covering the offer and sale from time to time, pursuant to Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"), of up to \$350.0 million in aggregate offering price of shares of the Company's common stock, shares of the Company's preferred stock, debt securities, warrants, rights and/or units, including up to \$120.0 million in aggregate offering price of shares of the Company's common stock, shares of the Company's preferred stock, debt securities, warrants, rights and/or units registered on the Company's Registration Statement on Form S-3 declared effective by the Securities and Exchange Commission (the "SEC") on September 2, 2021 (the "Prior Registration Statement") that had not yet been sold. The Shelf Registration Statement was declared effective by the SEC on May 5, 2023.

On March 27, 2024, we completed an underwritten public offering utilizing the Shelf Registration Statement, pursuant to which we sold an aggregate of (i) 21,010,000 shares of common stock at a price of \$10.00 per share, and (ii) pre-funded warrants to purchase 3,000,031 shares of common stock at a price of \$9.9999 per pre-funded warrant. The pre-funded warrants can be exercised at any time after issuance for an exercise price of \$0.0001 per share, subject to certain ownership limitations. As of September 30, 2024, none of the pre-funded warrants have been exercised. We raised \$240.1 million in gross proceeds before underwriting discounts, commissions and other expenses of \$15.0 million.

Effective August 27, 2024, the Company and Cowen and Company, LLC mutually terminated the sales agreement entered into on August 12, 2021 related to the Company's \$150.0 million "at-the-market" equity offering program, pursuant to the terms of the sales agreement. Prior to the termination of the sales agreement, \$1.8 million of shares of common stock had been sold.

We have incurred net losses and negative cash flows from operations since our inception. As of September 30, 2024, we had an accumulated deficit of \$518.3 million and anticipate that we will continue to incur net losses for the foreseeable future. We expect to incur substantial expenditures as we develop our product pipeline and advance our drug candidates through clinical development, undergo the regulatory approval process and, if approved, launch commercial activities. Specifically, in the near term we expect to incur substantial expenses relating to initiating and completing our clinical trials, the development and validation of our manufacturing processes, and other development activities.

We will need substantial additional funding to support our continuing operations and pursue our long-term development strategy, including the potential initiation of a pivotal stage clinical trial for any or all of our current development programs. Until such time as we can generate significant revenue from sales of our drug candidates, if ever, we may seek additional funding through the issuance of our common stock, including through equity or debt financing or collaborations or partnerships with other companies. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts for our product candidates and other research, development and manufacturing activities, market conditions, and the success of our planned cost-containment measures. We may not be able to raise additional capital on terms acceptable to us, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of our drug candidates or delay our efforts to expand our product pipeline. We may also be required to sell or license to other parties' rights to develop or commercialize our drug candidates that we would prefer to retain.

We believe that our current cash, cash equivalents and investments as of September 30, 2024 will be sufficient to meet our cash needs for at least 12 months following the date of this Quarterly Report on Form 10-Q.

Cash Flows

The following table sets forth a summary of our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	\$ (74,945)	\$ (62,806)
Net cash (used in) provided by investing activities	(125,035)	63,178
Net cash provided by financing activities	225,900	396
Net increase in cash and cash equivalents	\$ 25,920	\$ 768

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2024 was \$74.9 million primarily due to a net loss of \$82.9 million adjusted for a decrease in net change in operating assets and liabilities of \$8.5 million, which was offset by an increase in net of non-cash charges of \$16.4 million. The change in net operating assets and liabilities was primarily due to an increase in prepaid expenses for the maintenance of laboratory equipment, interest receivable, and accruals, and a decrease in accounts payable and operating lease liability. The non-cash charges primarily consisted of stock-based compensation of \$12.8 million, depreciation and amortization of \$6.9 million, which was offset by investment accretion and amortization of \$5.0 million.

Net cash used in operating activities for the nine months ended September 30, 2023 was \$62.8 million, primarily due to a net loss of \$89.7 million, adjusted for \$26.9 million of net non-cash charges consisting primarily of share-based compensation of \$13.7 million, depreciation and amortization of \$3.6 million, investment accretion and amortization of \$6.9 million, non-cash lease expense of \$1.7 million, impairment of right-of-use assets of \$4.1 million, and a \$10.8 million net change in operating assets and liabilities.

Investing Activities

Net cash used by investing activities for the nine months ended September 30, 2024 was \$125.0 million, which consisted primarily of the purchase of marketable securities of \$320.7 million and the purchase of property and equipment of \$3.3 million, partially offset by proceeds from the maturities of marketable securities of \$198.9 million.

Net cash provided by investing activities for the nine months ended September 30, 2023, was \$63.2 million, which consisted primarily of proceeds from the sales and maturities of marketable securities of \$281.4 million, partially offset by the purchase of marketable securities of \$196.9 million and the purchase of property and equipment of \$21.3 million related to the construction of our manufacturing facility.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024, was \$225.9 million, which primarily consisted of net proceeds from our underwritten public offering of \$225.1 million that closed in March 2024.

Net cash provided by financing activities for the nine months ended September 30, 2023, was \$0.4 million, which consisted of proceeds from stock options and the employee stock plan purchase.

Funding Requirements

Based upon our current operating plans, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations for at least the next 12 months from the date of this Quarterly Report on Form 10-Q. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing therapeutic product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, enrollment rate, expansions, results, costs and timing of our clinical trials and preclinical studies for our product candidates or other potential product candidates or indications which we are pursuing or may choose to pursue in the future;
- the outcome, timing and costs of regulatory review of our product candidates;

- the costs and timing of manufacturing for our product candidates, including commercial manufacturing;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness or ability to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements, including payments required for meeting regulatory and commercial milestones or sales based royalties;
- the costs of obtaining, maintaining and enforcing our patent and other intellectual property rights;
- costs associated with any product candidates, products or technologies that we may in-license or acquire; and
- our ability to closely monitor our expenditures, including subleasing portions of our leased corporate office space in South San Francisco.

Until such time as we can generate significant revenue from sales of our therapeutic product candidates, if ever, we expect to finance our cash needs through public or private equity, including debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. We may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. There may also be instances where our ability to access a portion of our existing cash, cash equivalents and investments may be threatened due to financial conditions affecting the banking system and financial markets. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or may have to grant licenses on terms that may not be favorable to us and may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to undertake additional cost-containment measures and/or delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Material Cash Requirements

As of September 30, 2024, there have been no material changes from the contractual obligations and commitments previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023.

See Note 6 to our financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information regarding our lease liability.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of assets and liabilities in our financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments, including those related to preclinical studies and clinical trial accruals, share-based compensation, pre-funded warrants and impairment of long-lived assets. We base our estimates and assumptions on historical experience, known trends and events, and various other factors that are believed to be reasonable and appropriate under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2024, as compared to the critical accounting policies and estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K.

Indemnification

As permitted under Delaware law and in accordance with our bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. We are also party to indemnification agreements with our officers and directors. We believe the fair value of the indemnification rights and agreements is minimal. Accordingly, we have not recorded any liabilities for these indemnification rights and agreements as of September 30, 2024 and December 31, 2023.

Segment Information

We have one business activity and operate in one reportable segment.

JOBS Act

We are an “emerging growth company” as described under the JOBS Act, and we could have taken advantage of an extended transition period for complying with new or revised accounting standards. This would have allowed us to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have chosen irrevocably to “opt out” of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act").

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company or a non-accelerated filer, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our prospectuses and in our periodic reports and proxy statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We hold certain financial instruments for which a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash and investments. We invest our excess cash primarily in money market funds, commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. For marketable investment securities with short-term maturities, we do not believe that an increase or decrease in market rates would have a significant impact on the realized values or the statements of operations and comprehensive loss. As such, we believe that if a 10.0% change in interest rates were to have occurred on September 30, 2024, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

We are exposed to market risk related to changes in foreign currency exchange rates. We contract with vendors that are located outside the United States and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with such arrangements. We do not currently hedge our foreign currency exchange risk.

Inflation generally affects us by increasing labor, commercial support, construction, and research and development contract costs (including manufacturing and clinical supply costs). We do not believe inflation has had a material effect on our results of operations during the periods presented.

We do not believe that inflation, interest rate changes, or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.**Disclosure Controls and Procedures**

Our management, with the participation of our chief executive officer and chief financial and business officer, evaluated the effectiveness of our disclosures controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2024. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our chief executive officer and chief financial and business officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

Management determined that, as of September 30, 2024, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. There are currently no claims or actions pending against us that, in the opinion of our management, are likely to have a material adverse effect on our business, results of operations, financial condition or growth prospects.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as all of the other information contained in this Quarterly Report on Form 10-Q, before making an investment decision. The risks described below are not the only ones facing us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could significantly harm our business, financial condition, results of operations and growth prospects. In such case, the trading price of shares of our common stock could decline, and you may lose part or all of your investment. This Quarterly Report on Form 10-Q also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below. The risks relating to our business set forth in our Annual Report on Form 10-K for the year ended December 31, 2023 and filed with the Securities and Exchange Commission ("SEC") on March 21, 2024, in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 and filed with the SEC on May 9, 2024, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 and filed with the SEC on August 13, 2024, are set forth below and are unchanged substantively as of the date of this Quarterly Report on Form 10-Q, except for those risks designated by an asterisk (*).

We may disclose further changes to the factors below or disclose additional factors from time to time in our future filings with the SEC.

Risks Related to our Financial Position

We have a limited operating history and do not have any products approved for sale.

We are a clinical-stage biopharmaceutical company without any products approved for commercial sale and have not generated any revenue from product sales. We are focused on developing genetically-engineered human cells as therapeutics and our technologies are new and largely unproven. Since our inception in 2015, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain and in-house manufacturing capability, conducting business planning, raising capital and providing general and administrative support for these operations. Consequently, we have limited operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in the rapidly evolving biotechnology industry. If we do not address these risks, our business, financial condition, results of operations and growth prospects will be materially adversely affected.

We have incurred significant losses since our inception, and we expect to continue to incur significant losses for the foreseeable future.*

Since our inception in 2015, we have incurred significant operating losses. Our net losses were \$82.9 million, \$117.5 million and \$113.8 million for the nine months ended September 30, 2024 and the years ended December 31, 2023 and 2022, respectively. Our accumulated deficit was \$518.3 million as of September 30, 2024. We expect to continue to incur increasing operating losses for the foreseeable future as we continue to develop our product candidates. In addition, we anticipate that our expenses will increase substantially if, and as, we:

- continue the clinical development of NKX019 and our other product candidates, including in new indications;
- continue scale up and optimization of manufacturing process and prepare for commercial manufacturing;
- advance additional product candidates to clinical trials, including product candidates under the collaboration with CRISPR Therapeutics AG ("CRISPR");
- develop our current product candidates for additional disease indications;
- seek to discover and develop additional product candidates;

- establish and qualify our own clinical- and commercial-scale current good manufacturing practice ("cGMP") facilities;
- submit a biologics license application ("BLA") or marketing authorization application ("MAA") for NKX019 and/or our other product candidates and/or seek marketing approvals for any of our other product candidates that successfully complete clinical trials;
- seek regulatory approval of our product candidates in various jurisdictions for commercial sale;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;
- incur additional costs associated with operating as a public company;
- develop or secure marketing, sales and distribution capabilities, either internally or with third parties, to support commercialization; and
- increase our employee headcount and related expenses to support the foregoing activities.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability.

We have never generated revenue from product sales and may never achieve or maintain profitability.

We continue to incur significant research and development and other expenses related to ongoing operations and the development of our product candidates, including NKX019. All of our product candidates will require substantial additional development time and resources before we are able to apply for or receive regulatory approvals and begin generating revenue from product sales. Neither the United States Food and Drug Administration ("FDA") nor any other regulatory authority has approved NKX019, NKX101 or any of our other product candidates, and we do not anticipate generating revenues from product sales unless and until such time as NKX019, NKX101 or another of our product candidates has been approved by the FDA or another regulatory authority, if ever, and we are able to successfully market and sell a product candidate. Our ability to generate revenues from product sales depends on our, or potential future collaborators', success in:

- completing clinical development of our product candidates;
- seeking and obtaining regulatory approvals for product candidates for which we successfully complete positive clinical trials, if any;
- launching and commercializing product candidates, by establishing a commercial infrastructure or, alternatively, collaborating with a commercialization partner;
- qualifying for adequate coverage and reimbursement by government and third-party payors for our product candidates;
- establishing, maintaining and enhancing a sustainable, scalable, reproducible and transferable manufacturing process for each of our cell therapy product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate products and services, in both amount and quality, to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates as a viable clinical option;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, know-how, and trademarks;
- avoiding and defending against third-party interference or infringement claims; and
- attracting, hiring and retaining qualified personnel.

We anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our current expectations if we are required by the FDA or other global regulatory authorities to perform clinical trials and/or other preclinical studies in addition to, or beyond the scope of, those that we currently anticipate being required to perform.

Even if we are able to generate revenues from the sale of any approved products, we may not become profitable or be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could decrease the value of our company and impair our ability to raise capital, thereby limiting our research and development programs and efforts to expand our business or continue our operations.

We will require additional capital, which, if available, may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.*

We have financed our operations primarily through private placements of our preferred stock, proceeds from our previous collaboration with GlaxoSmithKline, proceeds from our initial public offering ("IPO") completed in July 2020, proceeds from our "at the market" equity offering program (the "ATM Offering Program"), and proceeds from both our underwritten public offering of our common stock completed in April 2022 and our underwritten public offering of our common stock and pre-funded warrants completed in March 2024 (collectively, the "Secondary Offerings"). We estimate that we used the proceeds of our IPO primarily to advance our product candidates through preclinical studies and clinical trial programs, the construction of our manufacturing facility, and for working capital and general corporate purposes, and that we have and will continue to use the proceeds from our Secondary Offerings and ATM Offering Program to, among other uses, advance NKX019 further in clinical development. However, developing pharmaceutical products and conducting preclinical studies and clinical trials is expensive. Advancing NKX019 or any product candidate into pivotal trials will require us to raise additional capital. As of September 30, 2024, we had cash, cash equivalents, restricted cash, and investments of \$405.3 million. Our research and development expenses increased from \$90.9 million for the year ended December 31, 2022 to \$96.8 million for the year ended December 31, 2023 and increased from \$73.5 million for the nine months ended September 30, 2023 to \$73.6 million for the nine months ended September 30, 2024. We expect to continue to incur operating losses for the foreseeable future as we continue to develop our product candidates, which may increase, among other things, as we advance NKX019 in clinical development.

Until and unless we can generate substantial product revenue, we expect to finance our cash needs through the proceeds from our Secondary Offerings, a combination of equity offerings and debt financings, and potentially through additional license and development agreements or strategic partnerships with third parties. Financing may not be available in sufficient amounts or on reasonable terms. In addition, market volatility resulting from international conflict, global economic developments, political unrest, high inflation or other factors could adversely impact our ability to access capital as and when needed. We have no commitments for any additional financing and will likely be required to raise such financing through the sale of additional securities. If we sell equity or equity-linked securities, our current stockholders may be diluted, and the terms may include liquidation or other preferences that are senior to or otherwise adversely affect the rights of our stockholders. Moreover, if we issue debt, we may need to dedicate a substantial portion of our operating cash flow to paying principal and interest on such debt and we may need to comply with operating restrictions, such as limitations on incurring additional debt, which could impair our ability to acquire, sell or license intellectual property rights which could impede our ability to conduct our business. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline.

If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Attempting to secure additional financing may also divert our management from our day-to-day activities, which may impair or delay our ability to develop our product candidates. In addition, demands on our cash resources may change as a result of many factors currently unknown to us including, but not limited to, delays or undesired outcomes from our cost-containment efforts, such as those related to our cap on future headcount growth, centralizing our operations to a single location, or subleasing portions of our leased corporate office space in South San Francisco, and any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to health epidemics or other causes, and we may need to seek additional funds sooner than planned as a result. Furthermore, if, in the future, one or more banks or financial institutions enter receivership or become insolvent in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material impact on our business and financial condition. If we are unable to obtain funding on a timely basis or at all, we may be required to undertake additional cost-containment measures and/or significantly curtail or stop one or more of our research or development programs.

Risks Related to Our Business and Industry

*Our business depends upon the success of our CAR NK-cell technology platform.**

Our success depends on our ability to utilize our chimeric antigen receptor natural killer ("CAR NK") cell technology platform to generate product candidates, to obtain regulatory approval for product candidates derived from it, and to then commercialize our product candidates addressing one or more indications. We are enrolling patients in Ntrust-1, a multi-center, open-label, dose-escalation Phase 1 clinical trial to evaluate NKX019, our lead CAR NK-cell product candidate, in humans with lupus nephritis ("LN"). We also plan to initiate Ntrust-2, a multi-center, open-label, dose-escalation Phase 1 clinical trial that will evaluate the safety and clinical activity of NKX019 in humans with systemic sclerosis ("scleroderma"), idiopathic inflammatory myopathy ("myositis"), and ANCA-associated vasculitis ("AAV"). Although both NKX019 and NKX101 have been in Phase 1 clinical trials for certain hematologic malignancies, we have stopped enrolling new patients in those clinical trials. Although we may explore our options for implementing certain changes in those programs, we cannot guarantee that we will pursue any further development of our product candidates for the treatment of hematologic malignancies in the near future or at all. All of our product candidates developed from our technology platform will require significant additional clinical and non-clinical development, review and approval by the FDA or other regulatory authorities in one or more jurisdictions, substantial investment, access to sufficient manufacturing capacity and significant marketing efforts before they can be successfully commercialized. If any of our product candidates encounter safety or efficacy problems, developmental delays or regulatory issues or other problems, such problems could impact the development plans for our other product candidates because all of our product candidates are based on the same core CAR NK-cell engineering technology.

Utilizing CAR NK cells represents a novel therapeutic approach, and we must overcome significant challenges in order to develop, commercialize and manufacture our product candidates.

We have concentrated our research and development efforts on utilizing CAR NK cells as an immunotherapy for the treatment of certain diseases, specifically cancers and, most recently, autoimmune diseases. To date, the FDA has approved only a limited number of cell-based therapies for commercialization as treatments for cancer, no cell-based therapies have been approved for commercial use for the treatment of an autoimmune disease, and no natural killer ("NK")-based cell therapy has been approved for commercial use by any regulatory authority. The processes and requirements imposed by the FDA or other applicable regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for our product candidates. Because our CAR NK-cell platform product candidates are novel, and cell-based therapies are relatively new, especially as potential treatments for autoimmune diseases, regulatory agencies may lack precedents for evaluating product candidates like our CAR NK-cell product candidates. As the cell therapy field develops further, the processes and requirements imposed by the regulatory agencies may evolve in a manner that adversely impacts us. The novelty of our product candidates may lengthen the regulatory review process, including the time it takes for the FDA to review our IND applications if and when submitted, increase our development costs and delay or prevent approval and commercialization of our CAR NK-cell platform product candidates.

Use of CAR NK-cell therapies may not gain the acceptance of the public or the medical community, especially for the treatment of autoimmune diseases. The patients with autoimmune disease that we will target with NKX019 are typically not at risk of near-term death, even if they may suffer life-threatening symptoms, so the patients will need to deem the benefits of cell therapy to be worth the risk of unknown potential adverse side effects.

Additionally, advancing novel immunotherapies creates significant challenges for us, including:

- enrolling sufficient numbers of patients in clinical trials;
- training a sufficient number of medical personnel on how to properly thaw and administer our cells, especially in any solid tumor trial wherein the cells are given through a procedure by trained medical doctors;
- training a sufficient number of medical and clinical laboratory personnel in the proper collection and handling of clinical samples in our clinical trials to enable a sufficient understanding of CAR NK-cell pharmacokinetics and pharmacodynamics for the design of an optimal dosing regimen;
- educating medical personnel regarding the potential side-effect profile of our cells and, as the clinical program progresses, on observed side effects with the therapy;
- developing a reliable and safe and an effective means of genetically modifying our cells;
- manufacturing and cryopreservation our cells on a large scale and in a cost-effective manner;
- sourcing starting material suitable for clinical and commercial manufacturing; and

- establishing sales and marketing capabilities, as well as developing a manufacturing process and distribution network to support the commercialization of any approved products.

We must be able to overcome these challenges in order for us to develop, commercialize and manufacture our product candidates utilizing CAR NK cells.

Certain aspects of the function and production of CAR NK cells are currently unknown or poorly understood, and may only become known through further preclinical testing and clinical trials. Any potential re-engineering required may result in delays and additional expenses.*

CAR NK-cell therapy is a relatively new field. To date, no CAR NK-cell therapies have been licensed in the United States or elsewhere to treat cancer, and no cell therapies of any type have been licensed for the treatment of autoimmune diseases. The history of manufacturing CAR NK cells for clinical use is limited. Our understanding of NK-cell biology is continuously expanding and this is particularly true in relation to autoimmune diseases where there is limited clinical data available and where we have no prior experience. If we find that our current manufacturing processes are inadequate, or should we identify opportunities for material improvement, adaptation of process improvements may require significant additional time and resources to complete. As studies utilizing NK-cell biology develop, new information may become available requiring us to change our product candidate. Process improvements or new clinical data might also necessitate new pre-clinical studies and clinical protocols to establish product comparability. If we are unable to show comparability after a process change, further changes to our manufacturing process and/or clinical trials will be required. For example, if sufficient comparability is not shown, we may be required to repeat one or more clinical trials. A requirement to run a new clinical trial or repeat a clinical trial would delay clinical development and commercialization of the relevant product candidate.

Prior clinical experience with NK-cell therapy has been predominantly based on cells from haplomatched donors, i.e., at least half of the major Human Leukocyte Antigen ("HLA") types matched between donor and recipient. Our Phase 1 clinical trials, however, are currently evaluating product candidates manufactured from completely unrelated donors (i.e. used "off-the-shelf"). There is a risk that our early clinical results from our Phase 1 clinical trials using off-the-shelf NKX019 and NKX101 may not be reflective of future clinical trial results which may require us to re-evaluate HLA matching. If it becomes apparent through future preclinical testing or clinical trials that such matching is required, the production of NKX019 or our other product candidates as standardized, off-the-shelf products for all patients will not be achievable. Instead, we would need to establish an alternative approach for each of our product candidates to achieve coverage of the addressable patient population.

Furthermore, the killer immunoglobulin-like receptor ("KIR") is found on the surface of NK cells and recognizes certain HLA types. If there is a match between certain KIR molecules and the HLA type, KIR acts as a natural inhibitor of NK activity, thereby serving to prevent immune reactions against an individual's own cells. In our Phase 1 clinical trials, the product candidate is administered regardless of specific KIR phenotype. As we continue our clinical trials, we may discover that retaining a KIR mismatch is required to achieve clinically meaningful activity, and we may need to factor KIR mismatch into the donor and product selection process for patients enrolled in our clinical trials. We also continue to analyze for donor characteristics that correlate with clinical activity and we may decide to select for donors to enhance activity of our product candidates in the clinic.

In addition, with respect to the development of the deprioritized NKX101 program for the treatment of malignancies, tumors are sometimes able to evade detection by naturally occurring NK cells by shedding the NKG2D ligands found on malignant cells. While NKX101 has been engineered to resist this shedding mechanism, there can be no guarantee that tumor cells will not retain or regain the ability to shed NKG2D ligand completely despite the presence of NKX101, which would give such tumors a degree of resistance against NKX101. If, upon continued development of NKX101, we were to discover that tumors develop a resistance to NKX101 as a result of such NKG2D ligand shedding, we would need to reengineer NKX101 to counteract this effect, or we might decide to change, pause or abandon any future development efforts for NKX101.

Any reengineering of our product candidates or change to the processes we use to manufacture our product candidates could require the redesign of our clinical protocols and clinical trials for our product candidates, significant additional time and resources to complete, and the participation of a significant number of additional clinical trial participants and donors, any of which would delay the clinical development of our product candidates and their eventual commercialization.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control.*

Clinical trials are expensive, time consuming and subject to substantial uncertainty. Failure can occur at any time during the clinical trial process, due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA, or other applicable regulatory authorities may suspend or terminate clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that patients participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. The FDA, or other applicable regulatory authorities may also require us to conduct additional preclinical studies or clinical trials due to negative or inconclusive results or other reasons, fail to approve the raw materials, manufacturing processes or facilities of third-party manufacturers upon which we rely, find deficiencies in the manufacturing processes or facilities upon which we rely, and change their approval policies or regulations or their prior guidance to us during clinical development in a manner rendering our clinical data insufficient for approval. In addition, data collected from clinical trials may not be sufficient to support the submission of a BLA, MAA or other applicable regulatory filings. We cannot guarantee that any clinical trials that we may plan or initiate will be conducted as planned or completed on schedule, if at all.

A failure of one or more of our clinical trials could occur at any stage, and any failure could prevent us from obtaining the FDA and other regulatory approvals necessary to commercialize our product candidates. Events that may prevent successful initiation, timely completion, or positive outcomes of our clinical development include, but are not limited to:

- delays in obtaining regulatory approval to commence a clinical trial;
- delays in reaching agreement on acceptable terms with prospective clinical trial sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites and CROs, including delays due to administrative hurdles, lack of significant prior experience with cell therapy for autoimmune disease, or competition between cell therapy companies for prospective clinical trial sites and investigators;
- our inability to recruit sufficient patients for our clinical trials in a timely manner or at all;
- delays in achieving a sufficient number of clinical trial sites or obtaining the required institutional review board ("IRB"), approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by us or by the FDA or other regulatory agencies based on emerging data;
- clinical sites deviating from trial protocol or dropping out of a trial;
- our inability to obtain long-term follow-up data due to patient drop out or in cases where patients elect to receive post-protocol treatment for their disease before it progresses;
- suspension or termination of a clinical trial by the IRB of the institutions in which such trials are being conducted or by the Data Safety Monitoring Board ("DSMB") (where applicable);
- delays in sufficiently developing, characterizing, scaling up, optimizing or controlling a manufacturing process suitable for clinical trials, or production delays, shutdowns or setbacks at any of our contract manufacturers;
- delays due to additional regulatory, site and clinical trial participant approvals required if a product candidate, especially a product candidate custom manufactured for a specific patient, does not meet the required specifications;
- delays in reaching a consensus with regulatory agencies on the design or implementation of our clinical trials;
- changes in regulatory requirements or guidance that may require us to amend or submit new clinical protocols, or such requirements may not be as we anticipate;
- changes in the standard of care or treatment landscape on which a clinical development plan was based, which may require new or additional trials;
- insufficient quantities or inadequate quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates, including potential limitations to the availability of agents such as fludarabine ("Flu"), cyclophosphamide ("Cy"), or other agents administered to patients prior to treatment or in combination with our product candidates or delays in the manufacturing of product candidates due to scale up or improvements to our manufacturing process;

- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, or additional administrative burdens associated with foreign regulatory schemes; or
- failure of ourselves or any third-party manufacturers, contractors or suppliers to comply with regulatory requirements, maintain adequate quality controls, or be able to provide sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates.

For example, after initially studying NKX019 and NKX101 in Phase 1 clinical trials for hematologic malignancies, we deprioritized development of the product candidates for the treatment of hematologic malignancies to focus our research and development activities on NKX019 for the treatment autoimmune disease. Following an interim evaluation of response data in our NKX101 clinical trial for the treatment of relapsed or refractory acute myeloid leukemia ("r/r AML") or higher risk myelodysplastic syndromes ("MDS"), we decided to deprioritize our NKX101 program. In November 2024, we announced new clinical data from our NKX019 clinical trial in B-cell malignancies. The data came from a cohort of heavily pretreated patients with large B-cell lymphoma ("LBCL") whose disease had already progressed following treatment with a CD19 CAR T cell therapy. Based on these data and the highly competitive landscape for the treatment of B-cell malignancies, we have deprioritized the clinical development of NKX019 for the treatment of B-cell malignancies. We do not plan to enroll further patients in our clinical trials for hematologic malignancies, and we cannot guarantee that we will pursue any further development of NKX101 or NKX019 for the treatment of hematologic malignancies in the near future or at all.

Disruptions caused by or related to pandemics, epidemics, or outbreaks of infectious disease, including future outbreaks of COVID-19 variants, may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical studies and clinical trials, as applicable. For example, we periodically interact with health authorities such as the FDA to obtain advice, or reach consensus, on our ongoing clinical trials, product development, and manufacturing activities. If these health authorities need to prioritize efforts related to a pandemic, epidemic, or outbreak of infectious disease, including future outbreaks of COVID-19 variants, then we may experience delays in obtaining periodic advice which may affect our ability to move our clinical programs forward into the next phase of development.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, refusal to accept or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of our product candidates.

We may, from time to time, such as for our NKX019 clinical trial for the treatment of LN (Ntrust-1), establish partnerships in relation to our clinical trials, receiving advisory services and other support from third parties. For example, we have partnered with Lupus Therapeutics, the clinical research affiliate of the Lupus Research Alliance, to accelerate development of NKX019 through select sites of the Lupus Clinical Investigators Network ("LuCIN"). Although we believe that these partnerships will enable us to accelerate the development of our product candidates and clinical trials, we cannot guarantee that such collaborations will be successful and, in the event they are not, we may lose our competitive advantage and/or incur additional costs.

As regulatory expectations regarding the genome editing of cellular therapies continue to evolve with data emerging on chromosomal abnormalities from CAR T therapies or other sources, our pipeline programs that involve gene-edited cells, including an allogeneic, off-the-shelf CAR NK-cell product candidate targeting the CD70 tumor antigen ("NKX070") and an allogeneic, off-the-shelf product candidate that comprises both engineered NK cells and engineered T cells ("NK+T"), on which we are collaborating with CRISPR, could be impacted. For example, the FDA may require additional or new release assays for manufactured lots of any product candidates that have been gene edited, which, as a result, could slow development of our gene-edited product candidates and increase expenses.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For example, passed in December 2022, the Food and Drug Omnibus Reform Act ("FDORA") requires sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, actions plans must include the sponsor's goals for enrollment, the underlying rationale for those goals and an explanation of how the sponsor intends to meet them. In addition to these requirements, the

legislation directs the FDA to issue new guidance on diversity action plans. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

If we experience delays in the initiation, enrollment, or completion of any preclinical study or clinical trial of our product candidates, or if any preclinical studies or clinical trials of our product candidates are canceled, the commercial prospects of our product candidates may be materially adversely affected, and our ability to generate product revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs and slow down our product candidate development and approval process.

Our business is highly dependent on the clinical success of our product candidates, and on the clinical success of NKX019, in particular, and we may fail to develop NKX019 and/or our other product candidates successfully or be unable to obtain regulatory approval for them.*

We cannot guarantee that NKX019 or any of our other product candidates, will be safe and effective, or will be approved for commercialization, on a timely basis or at all. Although certain of our employees have prior experience with clinical trials, regulatory approvals, and cGMP manufacturing, we have not previously completed any clinical trials or submitted a BLA to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that NKX019 or any of our other product candidates will be successful in clinical trials or receive regulatory approval. In particular, we have limited prior experience in developing treatments for autoimmune diseases and our resources and processes have historically been focused on the development of NK-cell therapies for cancer. The FDA, and other comparable global regulatory authorities can delay, limit or deny approval of a product candidate for many reasons. For further details about such reasons, see “—*Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control.*” Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully commercialize NKX019 or any of our other product candidates, especially and could materially adversely affect our business, financial condition, results of operations and growth prospects.

NKX019 is in Phase I clinical development and subject to the risks inherent in drug development. In October 2023, we announced that we had received clearance of an Investigational New Drug (“IND”) application by the FDA to evaluate NKX019 for the treatment of LN, and in June 2024, we announced we had received clearance of an IND by the FDA to evaluate NKX019 for the treatment of scleroderma, myositis, and AAV. Ntrust-1 is our multi-center, open-label, dose-escalation Phase 1 clinical trial that evaluates the safety and clinical activity of NKX019 in humans with refractory LN, and Ntrust-2 is our planned multi-center, open-label, dose-escalation Phase 1 clinical trial that will evaluate the safety and clinical activity of NKX019 in humans with scleroderma, myositis, and AAV. In both Ntrust-1 and Ntrust-2, Cy will be used as the lymphodepleting conditioning (“LD”) prior to administration of NKX019. There are no cell therapies licensed to date in the United States or elsewhere to treat autoimmune diseases and we have no prior experience in developing treatments for autoimmune diseases. We cannot guarantee that our development of NKX019 for the treatment of LN, scleroderma, myositis, or AAV will be successful. We may also choose to develop NKX019 for additional autoimmune or other indications, but we may not be able to advance NKX019 through the development process for any of these additional indications. Even if we receive regulatory approval to market NKX019 for the treatment of LN, scleroderma, myositis, AAV, or any additional indications, NKX019 for any of these indications may not be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize NKX019 for LN, scleroderma, myositis, AAV, or these additional autoimmune indications, our commercial opportunity will be limited, and our business, financial condition and growth prospects will be materially adversely affected.

NKX019 is also being studied in a multi-center Phase 1 clinical trial for the treatment of a variety of B-cell malignancies, which evaluates the safety, pharmacology, and preliminary anti-tumor activity of NKX019. In November 2024, we announced new clinical data from a cohort of heavily pretreated patients with LBCL whose disease had already progressed following treatment with a CD19 CAR T cell therapy. Based on these data and the highly competitive landscape for treatments of B-cell malignancies, We have decided to focus our research and development activities on autoimmune disease and plan for no further investment in the clinical development of NKX019 for the treatment of B-cell malignancies.

Due to the commercial availability of multiple therapeutic agents that target CD19, as well as others that are in various stages of development, we have previously had significant difficulty, and may continue to have significant difficulty, enrolling patients. If our ongoing Phase 1 or later clinical trials of NKX019 encounter safety, efficacy, manufacturing problems, enrollment issues, development delays, regulatory issues, or other problems, our development plans for NKX019 could be significantly impaired, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

NKX101, our deprioritized clinical-stage product candidate, is also subject to the risks inherent in drug development. NKX101 has been studied in a Phase 1 clinical trial for the treatment of blood cancers including r/r AML or MDS. Following an interim evaluation of the clinical response data, we decided to deprioritize the clinical development of NKX101. Further enrollment in the trial has been closed. We do not plan to pursue any further development of NKX101 without first evaluating our options for the trial design, dosing regimen, and manufacturing process for the program. We cannot guarantee that we will pursue any further development of NKX101 in the near future or at all. Even if we do decide in the future to further develop NKX101 for the treatment of r/r AML or MDS, we may not be successful in doing so. If clinical development of NKX101 is restarted in the future and the Phase 1 or clinical trials of NKX101 for the treatment of AML or MDS encounter concerning safety signals, efficacy concerns, manufacturing problems, enrollment issues, development delays, regulatory issues, or other problems, our development plans for NKX101 could be significantly impaired, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

If we restart development of NKX101 at a later point and are able to obtain clinical proof-of-concept from our NKX101 Phase 1 trial for blood cancers including r/r AML and MDS, we may also develop NKX101 for additional indications. We may not be able to advance any of these indications through the development process. The potential development of NKX101 for treating solid tumors, for example, would be subject to a number of risks including a hostile tumor microenvironment and trafficking to tumor site. The development of treatments to treat solid tumors often requires larger and more expensive clinical trials than for treating blood cancers. Even if we receive regulatory approval to market NKX101 for the treatment of any of these additional indications, any such additional indications may not be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize NKX101 for these additional indications, our commercial opportunity may be limited.

Furthermore, because NKX019 and NKX101 are our most advanced product candidates, and because our other product candidates are based on similar technology, if our current clinical trials of NKX019 or any future clinical trials of NKX019 or NKX101 experience any of the foregoing issues, our development plans for our other product candidates in our pipeline could also be significantly impaired, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

We may develop our product candidates as monotherapy or potentially as combination therapy with one or more currently approved therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the combination therapy used with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market our product candidates.

Clinical data supporting the effectiveness of CD19-targeted cell therapies against autoimmune disease are limited, and CD19-targeted CAR NK-cell therapies, such as NKX019, may not provide the same, or any, therapeutic benefit against LN or other autoimmune diseases, or be competitive with respect to other CD19-targeted therapies for the treatment of autoimmune disease.*

Although we believe that our allogeneic CD19-targeting CAR NK-cell product candidate NKX019 may have disease-modifying potential in autoimmune disease, such as LN, the use of CD19-targeted CAR cell therapies, and, in particular, allogeneic CD19 CAR NK-cell therapies, represents a novel approach for the treatment of autoimmune disease, and is supported by limited clinical data. To date, no cell therapies have been approved by the FDA for the treatment of autoimmune disease. We cannot guarantee that Ntrust-1, our clinical trial for NKX019 in LN, Ntrust-2, our planned clinical trial for NKX019 in scleroderma, myositis, and AAV, or any other future clinical development of NKX019 for the treatment of autoimmune diseases will be successful. Our belief that NKX019 may be effective as a treatment for autoimmune disease is based largely on our understanding of the mechanism behind the positive clinical data reported by certain academic groups for the use of a CD19 CAR T-cell therapy in a limited number of patients with autoimmune disease, as well as on our own in vitro studies showing that NKX019 can kill B-cells in peripheral blood mononuclear cells ("PBMCs") obtained from patients with autoimmune diseases and observations regarding the effect of NKX019 on B cells from our ongoing NKX019 Phase 1 clinical trial in patients with non-Hodgkin lymphoma ("NHL"). We have made certain assumptions regarding the mechanism of action responsible for the preliminary efficacy shown in the reported studies and how that mechanism of action and our own in vitro data and data from our NKX019 trial in NHL will translate to the response of patients with autoimmune diseases, such as LN, to NKX019, which may or may not be correct. We plan to use Cy alone as the LD in our current, planned and future NKX019 clinical trials for the treatment of autoimmune disease, but there is a risk that Cy alone will not be effective as LD prior to NKX019 in patients with autoimmune disease. We cannot know with any certainty whether NKX019 will be effective against LN, other forms of systemic lupus erythematosus ("SLE") or any other autoimmune disease, or whether NKX019 will be competitive as a treatment for such indications against CD19 CAR T-cell therapies. We also face competition from a large number of cell therapy companies who are also advancing development programs in autoimmune diseases, which may impact our ability to successfully develop and commercialize NKX019. For instance, competition among cell therapy companies for clinical trial sites, investigators, and/or patients for autoimmune clinical trials, may cause delays in the initiation of clinical trials sites and enrollment of patients in our clinical trials. For further details about such reasons, see "*—Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control*" and "*—If we fail to compete effectively with academic institutions and other biopharmaceutical companies that develop similar or alternatives to cellular immunotherapy product candidates, our business will be materially adversely affected.*" The competition for clinical trial sites, investigators or patients may also lead to increased development costs. If NKX019 is shown to not be sufficiently effective against LN, scleroderma, myositis, AAV, or other autoimmune diseases in clinical trials, we experience delays in our ability to advance NKX019 through clinical development for LN, scleroderma, myositis, AAV, or other autoimmune diseases, or we are unable to successfully compete against other companies in the development and commercialization of NKX019, the commercial prospects of NKX019, as well as our business, financial condition and growth prospects, would be materially adversely affected.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.*

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease that the product candidate is intended to treat and who meet other eligibility criteria. The rates of patient enrollment, a significant component in the timing of clinical trials, are affected by many factors, including:

- our ability to open clinical trial sites;
- the size and nature of the patient population;
- the design and eligibility criteria of the clinical trial;
- the proximity of patients to clinical sites;
- the patient referral practices of physicians, including as a result of their assessment of the clinical trial parameters;
- changing medical practice patterns or guidelines related to the indications we are investigating;
- competing clinical trials or approved therapies which present an attractive alternative to patients and their physicians;
- perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies;
- our ability to obtain and maintain patient consents due to various reasons;
- the risk that enrolled patients will drop out or die before completion of the trial;

- patients failing to complete a clinical trial or returning for post-treatment follow-up;
- our ability to manufacture the requisite supply of our product candidates for our clinical trials; and
- any failure or any delay by us or by our clinical sites to obtain sufficient quantities of components and supplies necessary for the conduct of our clinical trials, including any inability to obtain agents such as Cy, Flu, or other agents administered to patients prior to treatment or in combination with our product candidates.

We need to compete with many ongoing clinical trials and approved therapies to recruit patients into our clinical trials. Our clinical trials may also compete with other clinical trials of product candidates that are in a similar cellular immunotherapy area as our product candidates, and this competition could reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. For example, due to the commercial availability of multiple therapeutic agents that target CD19 for the treatment of cancer, as well as others that are in various stages of development, we have had significant difficulty in our Phase 1 NKX019 clinical trial for the treatment of B-cell malignancies and may continue to have significant difficulty in our current or future NKX019 clinical trials for certain indications, enrolling patients who have not previously been exposed to a CD19-directed cellular therapy. Additionally, for our ongoing NKX019 clinical trial for the treatment of LN, our planned NKX019 clinical trial for the treatment of additional autoimmune indications, and any future NKX019 clinical trials of ours for the treatment of other autoimmune diseases, the number of qualified clinical investigators is limited, so we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. A number of cell therapy companies have announced initiation of plans for clinical trials for the treatment of LN and/or other autoimmune diseases, which has resulted in and/or may increase competition in the future for investigators and/or patients for our NKX019 clinical trial for the treatment of LN, our planned NKX019 clinical trial for the treatment of additional autoimmune indications, and any other NKX019 clinical trials that we may initiate in the future for the treatment of other autoimmune diseases. Furthermore, we intend to use Cy as the LD prior to treatment with NKX019 in our NKX019 clinical trial for the treatment of LN and our planned NKX019 clinical trial for the treatment of additional autoimmune indications. If this is ineffective or we decide to change the protocol to use a combination of Flu and Cy, as the LD, physicians may choose to refer patients to other clinical trials conducted by one of our competitors. If we are unable to enroll a sufficient number of patients in our clinical trials in a timely manner, our completion of clinical trials may be delayed or may not be achieved, which would prevent us from further developing or commercializing our product candidates in certain patient subpopulations or at all.

The clinical development of our product candidates depends on our ability to manufacture and provide the requisite supply of our product candidates for our clinical trials. Any failure or delays by us to manufacture and provide our product candidates in sufficient quantity and quality for the conduct of our clinical trials, may delay our ability to enroll and treat patients in, or complete, our current or future clinical trials of our product candidates on time, if at all. For further details regarding risks related to the manufacture of our product candidates, see “Risks Related to Manufacturing” below, including “— *Our manufacturing process is novel and complex, and we may encounter difficulties in production, or difficulties with internal manufacturing, which would delay or prevent our ability to provide a sufficient supply of our product candidates for clinical trials or our products for patients, if approved.*” The clinical development of our product candidates also depends on the availability of a sufficient supply of certain other materials and agents used in our clinical trials. For example, certain of our clinical trial protocols require the use of Flu and/or Cy, agents which are routinely used in oncology studies, and which we use in certain of our clinical trial protocols to condition patients for treatment with our product candidates. Further, we may develop certain of our product candidates as a combination therapy with other therapies, which would require the availability and use of those therapeutic agents in certain of our clinical trial protocols. Any failure or delays by us or by our clinical sites to obtain sufficient quantities of our product candidates and other agents necessary for the conduct of our clinical trials, may delay our ability to enroll and treat patients in, or complete, our current or future clinical trials of our product candidates on time, if at all.

If we are unable to enroll a sufficient number of patients in our clinical trials in a timely manner, our completion of clinical trials may be delayed or may not be achieved, which would prevent us from further developing or commercializing our product candidates.

Our preclinical pipeline programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

In order to obtain FDA or other regulatory authority approval to market a new biological product we must demonstrate safety, purity, potency and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. Other than NKX019 and NKX101, all of our programs, including NKX070, are in preclinical development. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Any delays in preclinical testing and studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on acceptable clinical trial design or manufacturing process; and
- the FDA not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, because standards for pre-clinical assessment are evolving and may change rapidly, even if we reach an agreement with the FDA on a pre-IND proposal, the FDA may not accept the IND submission as presented, in which case patient enrollment would be placed on partial or complete hold and treatment of enrolled patients could be discontinued while the product candidate is re-evaluated. Even if clinical trials do begin for our preclinical programs, our clinical trials or development efforts may not be successful.

The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Interim, “topline” and preliminary data from our clinical trials may differ materially from the final data. Initial success in any clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.*

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. For example, preclinical models as applied to cell therapy in oncology do not adequately represent the clinical setting, and thus cannot predict clinical activity nor all potential risks, and may not provide adequate guidance as to appropriate dose or administration regimen of a given therapy.

From time to time, we may publicly disclose preliminary or “topline” data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial, including as patient enrollment continues and more data on existing patients becomes available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from, and may not be indicative of, future results of the same clinical trials, or different conclusions or considerations may qualify such topline results once additional data have been received and fully evaluated. For example, the preliminary results from the three dose expansion cohorts we announced opening in December 2022 as part of our Phase 1 NKX019 clinical trial for the treatment of B-cell malignancies did not meet expectations. In November 2024, we announced new clinical data from a cohort with a new, condensed dosing schedule. Based on these data and the highly competitive landscape for treatments of B-cell malignancies, we have decided to refocus our research and development activities on autoimmune disease and deprioritized further development of NKX019 for the treatment of B-cell malignancies. Also, an interim evaluation of the data from the most recent dose-expansion cohort of our NKX101 Phase 1 clinical trial indicated that the aggregate clinical response rate for the 20 patients in the cohort was meaningfully lower than it had been for the first six patients in the cohort. As a result, we have now deprioritized further development of NKX101.

Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available and negative differences between preliminary or interim data and final data could materially adversely affect the prospects of any product candidate that is impacted by such data updates.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically a summary of extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed.

If any of our product candidates, or any competing product candidates, demonstrate relevant, serious adverse events, we may be required to halt or delay further clinical development.*

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label than anticipated or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

Updated data from the dose-escalation portion of our NKX019 Phase 1 clinical trial in B-cell malignancies were reported in December 2022, and updated interim data from our NKX101 Phase 1 clinical trial were reported in June 2023. The most common higher-grade (Grade ≥ 3) adverse events in the interim data reported for patients in the NKX019 Phase 1 clinical trial for B-cell malignancies were myelosuppression, which is common in the treated patient population after LD. In the dose-escalation phase of the NKX019 Phase 1 clinical trial, certain patients experienced adverse events including transient fevers and infusion-related reactions. Three patients in the NKX019 dose-escalation study were assessed to have cytokine release syndrome ("CRS"), despite the rapid onset and rapid resolution, not consistent with previously described presentations of CRS with CAR T-cell therapies. The most common higher-grade (Grade ≥ 3) adverse events in the interim data reported in June 2023 for patients with r/r AML in the NKX101 Phase 1 clinical trial were myelosuppression – a condition resulting in fewer red blood cells, white blood cells and platelets, as well as infections such as sepsis and pneumonia, occasionally requiring supplementary oxygen, which are common in the treated patient population after LD. The interim data from the NKX101 clinical trial indicated that adverse events experienced by certain patients with r/r AML included infusion reactions, CRS, and one case of immune effector cell-associated neurotoxicity (in each case, \leq grade 2). A more recent review of the data from additional patients enrolled in a dose-expansion cohort in our NKX101 clinical trial has indicated that the safety profile of NKX101 is consistent with the data reported in June 2023.

While the interim data reported to date from our NKX019 and NKX101 Phase 1 clinical trials indicate that NK cell-based therapies may be better-tolerated as compared to T-cell-based therapies due to biologic differences between these cell types, there can be no assurance that patients will not experience CRS, neurotoxicity, Graft-versus-host disease ("GvHD"), or other serious adverse events associated with our specific product candidates NKX019 and NKX101. For instance, NKX101 targets NKG2D ligands, which is not yet a well-characterized modality. NKG2D targets multiple ligands, and the extent and impact of ligand expression is currently not fully characterized. For example, there are risks that ligands may be expressed on either known or an as-yet-underappreciated population of healthy cells. Therefore, such cells may also be targeted by NKX101 and lead to adverse events of unknown frequency and severity as well as potentially decreased efficacy. Such adverse events may cause delays in completion of our clinical programs.

Furthermore, in some instances, the diseases we may be seeking to treat may be less serious than the later stage cancers traditionally being treated with cell therapies or other immunotherapy products. Therefore, we believe the FDA and other regulatory authorities likely will apply a different benefit-risk threshold such that any potential harmful side effects may outweigh the benefits of our product candidates and require us to cease clinical trials or deny approval of our product candidates. We believe tolerance for adverse events in the autoimmune patient populations being pursued with cell-based therapies, such as in the LN patients in our NKX019 clinical trial, will be lower than it is in oncology, and the risks of negative impact from these toxicities may therefore be higher for our autoimmune programs than for our oncology programs or the oncology programs of others.

If unacceptable side effects arise in the development of our product candidates such that there is no longer a positive benefit-risk profile, we, the FDA, the IRBs at the institutions in which our trials are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death.

If we fail to compete effectively with academic institutions and other biopharmaceutical companies that develop similar or alternatives to cellular immunotherapy product candidates, our business will be materially adversely affected.*

The development and commercialization of new cellular immunotherapy products is highly competitive. We face competition from existing and future competitors with respect to each of our product candidates currently in development and will face competition with respect to other product candidates that we may seek to develop or commercialize in the future. For example, the autologous cell therapies tisagenlecleucel, axicabtagene ciloleucel, brexucabtagene autoleucel, and lisocabtagene maraleucel, which have been commercially approved, are direct competitors to our product candidate NKX019. A large number of cell therapy companies with capabilities and expertise in oncology are advancing development programs in autoimmune diseases. In addition, other competitors, including biopharmaceutical companies, have clinical-stage or earlier stage cell therapy product candidates for autoimmune diseases and/or hematologic malignancies. Other biopharmaceutical companies are developing bispecific T-cell engagers, NK-cell engagers and monoclonal antibodies, which are also direct competitors to NKX019 for autoimmune diseases and hematologic malignancies. Numerous academic institutions are also conducting preclinical and clinical research in these areas, as well as with other white blood cell types including NKT cells, regulatory T cells and gamma-delta T cells. It is also possible that new competitors, including those developing similar product candidates or alternatives to cellular immunotherapy product candidates, may emerge and acquire significant market share. Such competitors may have an advantage over us due to their greater size, resources or institutional experience, or may develop product candidates that are safer, more effective, more widely accepted, more cost-effective or enable higher patient quality of life than ours. More established biopharmaceutical companies may also develop and commercialize their product candidates at a faster rate, which could render our product candidates obsolete or non-competitive before they are fully developed or commercialized. If we are not able to compete effectively against our existing and potential competitors, our business, financial condition, results of operations and growth prospects may be materially adversely affected.

We have entered into a research collaboration with CRISPR Therapeutics regarding certain product candidates, and we may enter into additional collaborations with third parties to develop or commercialize other product candidates. Our prospects with respect to those product candidates will depend in significant part on the success of those collaborations, and we may not realize the benefits of such collaborations.

We may form strategic alliances or create joint ventures or collaborations with respect to our product candidates that we believe will complement or augment our existing business. We routinely engage, and are engaged, in partnering discussions with a range of pharmaceutical and biotechnology companies and could enter into new collaborations at any time. If we enter into a collaboration, strategic alliance or license arrangement, there is no guarantee that the collaboration will be successful, or that any future partner will commit sufficient resources to the development, regulatory approval, and commercialization effort for such products, or that such alliances will result in us achieving revenues that justify such transactions.

In May 2021, we entered into a Research Collaboration Agreement with CRISPR (as amended, the "CRISPR Agreement") to establish research plans for the purpose of collaboratively designing and advancing up to two allogeneic, gene-edited NK-cell therapies and one allogeneic, gene-edited NK+T-cell therapy for use in the treatment of autoimmune disease, oncology, or infectious disease up to the filing of an application to a regulatory authority to request the ability to start a clinical trial. The first product candidate being developed in partnership with CRISPR is NKX070, and together with CRISPR, we may advance NKX070 for the treatment of solid tumors and blood cancers. The second product candidate being developed in partnership with CRISPR is NK+T. In May 2022, we amended the CRISPR Agreement to revise the transfer of materials and nomination provisions. On March 8, 2023, the CRISPR Agreement was further amended to permit Nkarta's advancement of CRISPR-licensed product candidates targeting a specified tumor antigen and incorporate associated development and regulatory approval milestones and sales based royalties. In addition, under the CRISPR Agreement, we have received licenses from CRISPR for four CRISPR-Cas9 gene editing targets and will receive a license from CRISPR for up to one more CRISPR-Cas9 gene editing target that can be engineered into an unlimited number of its own NK-cell products. CRISPR also has an option to co-develop and co-commercialize a future CAR NK-cell program.

If CRISPR, or any potential future collaboration partner, does not perform in the manner that we expect or fulfill their responsibilities in a timely manner or at all, the research, clinical development, regulatory approval and commercialization efforts related to the product candidates that are the subject of the collaboration with CRISPR, or that potential future collaboration partner, could be delayed or terminated. If we terminate the CRISPR Agreement in its entirety or with respect to a particular product candidate under the research collaboration with CRISPR, due to a material breach by CRISPR or CRISPR's insolvency, then we have the right to negotiate a license from CRISPR to continue research, development, and commercialization of the terminated product candidate(s) on our own at our sole expense. We would need to pay CRISPR milestones and royalties for the terminated product candidate(s), and we may not be able to negotiate terms to the license that are favorable to us. Furthermore, assumption of sole responsibility for further development would greatly increase our expenditures and may mean we would need to limit the size and scope of one or more of our programs, seek additional funding and/or choose to stop work altogether on one or more of the affected product candidates. This could result in a limited potential to generate future revenue from such product candidates, and our business could be materially and adversely affected.

Whenever we enter into collaborations with third parties, we could face the following risks:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products and processes that compete directly or indirectly with our products or product candidates;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

If conflicts arise between our collaborators and us, including CRISPR, our collaborators may act in a manner adverse to us and could limit our ability to implement our strategies. CRISPR or future collaborators may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates. Our collaborators may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

As a result, we may not be able to realize the benefit of new or existing collaboration agreements and strategic partnerships if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction.

Results of any patient who receives NKX019 or any of our other product candidates in an investigator-sponsored trial ("IST") should not be viewed as representative of how the product candidate will perform in our clinical trials, may not be able to be used to establish safety or efficacy for regulatory approval, and may negatively impact our ability to develop and commercialize the product candidate depending on the results.*

In some instances, our product candidates may be evaluated in ISTs conducted by certain clinical investigators who are our collaborators. In addition to supplying product candidate for such trials, we may also provide financial support. In July 2024, we announced that researchers at Columbia University Irving Medical Center (“CUIMC”) initiated an IST of NKX019 in patients with SLE, and in November 2024, we announced that the first patient had been dosed in the IST. Although ISTs may provide valuable insights, they also pose regulatory and operational challenges that could impact our ability to bring our product candidates to market. We have limited or no control over the design, administration, and timing of the ISTs and will have no control over the submission or approval of any IND or foreign equivalent required to conduct these trials. We rely on the investigators and physicians to ensure their compliance with clinical and regulatory requirements when using our product candidates for these trials. Their failure to comply could expose us to liability. The ISTs could, depending on the actions of the investigators and other third parties involved in the ISTs, jeopardize the validity of the clinical data generated, identify significant concerns with respect to our product candidates that could impact our findings or clinical trials, and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities. To the extent the results of any of these ISTs are inconsistent with, or different from, the results of our current or future company-sponsored trials or raise concerns regarding our product candidates, the FDA or a foreign regulatory authority may question the results of our company-sponsored trials or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing approval of our product candidates. In addition, while ISTs could be useful to inform our own clinical development efforts or provide other valuable insights, there is no guarantee that we will be able to use the data from these trials to form the basis for regulatory approval of our product candidates. Moreover, the patient population in such trials is at risk for serious adverse events. If these events are attributed to our product candidates, it could negatively impact their safety profile, leading to delays or failure in obtaining regulatory approval or successfully commercializing our drug candidates. Additionally, our supply capabilities may limit patient enrollment in these trials. We may need to restructure or pause supply to enroll sufficient patients in our company sponsored trials, potentially leading to adverse publicity or other disruptions.

We may seek special designations by the regulatory authorities to expedite regulatory approvals, but may not be successful in receiving such designations, and even if received, they may not benefit the development and regulatory approval process.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our product candidates from the FDA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA’s implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of the accelerated approval program, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor’s agreement to conduct, in a diligent manner, additional post-approval confirmatory clinical trials to verify and describe the drug’s clinical benefit. If such post-approval clinical trials fail to confirm the drug’s clinical benefit, the FDA may withdraw its approval of the drug.

We may seek approval from the FDA or comparable regulatory authorities through the use of other expedited approval program, such as Regenerative Medicine Advanced Therapy (“RMAT”) designation, Breakthrough Therapy designation, Fast Track designation, or PRiority Medicine (“PRIME”), from regulatory authorities, for certain product candidates that we develop. A product candidate may receive RMAT designation from the FDA if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening condition, and preliminary clinical evidence on a clinically meaningful endpoint, indicates that the product candidate has the potential to address an unmet medical need for such condition. A breakthrough therapy is defined by the FDA as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation by the FDA. PRIME is a voluntary scheme launched by the European Medicines Agency (“EMA”), to strengthen support for the development of medicines that target an unmet medical need through enhanced interaction and early dialogue with developers of promising medicines in order to optimize development plans and speed up evaluation to help such medicines reach patients earlier.

Seeking and obtaining these designations is dependent upon results of our clinical program, and we cannot guarantee whether and when we may have the data from our clinical programs to support an application to obtain any such designation. Prior to submitting a BLA, we may seek feedback from the FDA or comparable foreign regulatory authorities and will otherwise evaluate our ability to receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for an expedited regulatory designation (e.g., Fast Track designation or Breakthrough Therapy designation), there can be no assurance that such submission or application will be granted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA and the EMA, as applicable, have broad discretion whether or not to grant any of these designations, so even if we believe a particular product candidate is eligible for one or more of these designations, we cannot assure you that the applicable regulatory authority would decide to grant it. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further clinical trials prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. Furthermore, even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or EMA procedures, as applicable. The FDA or EMA, as applicable, may rescind any granted designations if it believes that the designation is no longer supported by data from our clinical development program.

In addition, changes in regulatory frameworks may impact our clinical development programs. For instance, the recent enactment of FDORA introduces reforms intending to expand the FDA's ability to regulate products receiving accelerated approval. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval in addition to being completed within a specified time period following approval. FDORA also requires the FDA to specify the conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports. Additionally, FDORA increased the FDA's oversight of confirmatory trials and created a formal procedure to withdraw products approved through accelerated approval on an expedited basis for non-compliance with post-approval requirements. In March 2023, the FDA issued draft guidance on clinical trial considerations for supporting accelerated approval of oncology therapeutics, noting that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach for more robust efficacy and safety assessment. It is unclear how these proposals, future policy changes, and changes in FDA regulation will impact our clinical development programs. To the extent the FDA requires us to amend the design of our clinical trials or requires additional trials to meet changes in the data requirements for approval, our clinical timelines and approval will be delayed, which can have an adverse effect on our business and operations.

We may seek and obtain orphan drug designation for our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively low prevalence populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. On December 16, 2021, we announced that the FDA granted orphan drug designation to NKX101 for the treatment of AML.

Similarly, in Europe, the European Commission grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances (“sameness”). The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for our product candidates, that exclusivity may not effectively protect those product candidates from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

Public opinion and scrutiny of cell-based immunotherapies may impact public perception of our company and product candidates, or impair our ability to conduct our business.

Our platform utilizes a relatively novel technology involving the genetic modification of human NK cells derived from adult healthy donors, and utilization of those modified cells in other individuals, and no NK cell-based immunotherapy has been approved to date. Further, many other cell therapies are in development, including NK cells derived from induced pluripotent stem cells (“iPSCs”), and negative results from those therapies may affect perception of NK-cell therapy derived from adult healthy donors. Public perception may be influenced by claims, such as claims that NK cell-based immunotherapy is ineffective, unsafe, unethical, or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general could result in greater government regulation and stricter labeling requirements of cell-based immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Adverse public attitudes may adversely impact our ability to enroll clinical trials. More restrictive government regulations or negative public opinion could have an adverse effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

We may not identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our NK-cell engineering platform. We are seeking to do so through our internal research programs and may also explore strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, different therapeutic targets may require changes to our NK manufacturing platform, which may slow down development or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology platform used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- we may choose to cease development if we determine that clinical results do not show promise;
- product candidates we develop may nevertheless be covered by third parties’ patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of autoimmune disease, and we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

If third parties that we rely on to conduct clinical trials do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates.*

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs to advise on, conduct, or otherwise support clinical trials for our product candidates, including conducting our NKX019 clinical trial for the treatment of LN, a disease area in which we have no prior experience. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs and other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled letters, warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and the third parties on which we rely for clinical trials are required to comply with regulations and requirements, including good clinical practices ("GCP") for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the competent authorities of the European Union member states, and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or these third parties fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials do not deviate from GCP. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. For example, government measures taken in response to the COVID-19 pandemic had a significant impact on our CROs, and similar measures in response to future pandemics, epidemics, or outbreaks of infectious disease may result in further disruptions, which would affect our ability to initiate and complete our preclinical studies and clinical trials. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we typically design the clinical trials for our product candidates, we rely on third parties to conduct our clinical trials. As a result, many important aspects of our clinical development, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct our current and future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

If third parties do not perform our clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, we would be unable to rely on clinical data collected by these third parties and may be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Our business and the business or operations of our research partners and other third parties with whom we conduct business have been and could in the future be adversely affected by the effects of pandemics, epidemics, and outbreaks of infectious diseases in regions where we or third parties on which we rely have business operations.*

The COVID-19 pandemic and measures taken to mitigate the impact of the pandemic disrupted economic activity and business operations worldwide, including the San Francisco Bay Area, where our primary operations are located. The emergence of one or more pandemics, epidemics, or outbreaks of infectious diseases, including future outbreaks of COVID-19 variants, Respiratory Syncytial Virus ("RSV"), or the flu, could result in similar disruptions.

Our operations, as well as the operations of some of our contract research organizations ("CROs"), contract development and manufacturing organizations ("CDMOs"), and clinical trial sites, were impacted by the COVID-19 pandemic and may in the future be similarly impacted by future pandemics, epidemics, or outbreaks of infectious disease. For example, as a result of the COVID-19 pandemic, we experienced some delays in completing the construction of our cGMP manufacturing facilities, global supply shortages of certain materials that we and our CDMOs use for research and cGMP manufacturing, employee turnover/attrition, delays and/or disruptions at our CROs, and delays in setting up certain clinical sites and enrollment in our clinical trials.

The emergence of a future pandemic, epidemic, or outbreak of infectious disease may impact the regulatory authorities to which we are subject in our industry, which may, in turn, hamper or delay our clinical development efforts. For instance, the COVID-19 pandemic resulted in a significant increase in the FDA workload, as well as the need to reprioritize the projects under review, and a future pandemic, epidemic, or outbreak of infectious disease may do so again in the future.

We cannot predict the potential future impacts of the emergence of another pandemic, epidemic, or outbreak of infectious disease on us, our research partners, including CRISPR, and other third parties with whom we conduct business. We may experience disruptions as a result of a pandemic, epidemic, or outbreak of infectious disease that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials, including our ongoing NKX019 clinical trial for LN and planned NKX019 clinical trial for scleroderma, myositis, and AAV;
- delays or difficulties in clinical site initiation, including difficulties in recruiting and training clinical site investigators and clinical site staff;
- delays or difficulties in recruitment of key personnel;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines, including the review of IND or other regulatory submissions for our product candidates;
- interruption of, or delays in receiving, supplies of our product candidates, or materials necessary for production of our product candidates, from our vendors or contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery or supply systems;

- interruption of or delays in manufacturing of our product candidates at our in-house manufacturing facility due to staffing shortages, production slowdowns and disruptions, or inability to procure critical raw materials or other supplies in a timely fashion;
- delays or disruptions in the qualification of our cGMP facility for commercial-scale manufacture of our product candidates;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- interruptions, or delays in receiving supplies and materials necessary for our business operations, and research and development activities;
- increases in the cost of services or supplies necessary for our research and development activities; and
- interruption or delays to our discovery and clinical activities.

The extent of any delays or impacts due to pandemics, epidemics, or outbreaks of infectious disease, or government regulations in response to the foregoing, will depend on future developments that are highly uncertain and cannot be predicted with confidence, but these delays could have a material impact on our business, financial condition, and/or results of operations.

If we are not able to establish pharmaceutical or biotechnology collaborations on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may seek to collaborate with pharmaceutical and biotechnology companies to develop and commercialize such product candidates, such as our collaboration with CRISPR. Any of these relationships, including our relationship with CRISPR, may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, relinquish valuable rights to our product candidates, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for new collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view them as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition, and results of operations.

We may need to increase the size of our organization, and we may experience difficulties in managing growth.*

As of September 30, 2024, we had 159 full-time employees. Our operation may require us to expand our managerial, operational, clinical, quality, human resources, legal, manufacturing, supply chain, finance, commercial and/or other resources in order to manage our clinical trials, continue our development activities and eventually commercialize our product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. In addition, competition for qualified personnel needed to support this future growth is intense and it may be difficult for us to attract and retain quality personnel generally, and as a result of any impact the reduction in force may have on potential employees' perception of our company and culture. Our need to effectively execute our growth strategy requires that we:

- discover new product candidates, develop the process and analytical methods for IND-enabling studies and FDA submissions, complete the required IND-enabling studies for each, and receive approval from the FDA and other regulatory authorities to initiate clinical trials for such product candidates;
- manage our clinical trials effectively;

- identify, recruit, retain, incentivize and integrate additional employees;
- expand into additional office and laboratory space if we grow our employee base;
- manage our in-house clinical cGMP manufacturing facility and establish and validate our commercial cGMP manufacturing facility; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

If we are unable to attract skilled employees or manage our future growth effectively, it will impair our ability to execute our business strategy and our business, financial condition, results of operations and growth prospects will be materially adversely affected.

If we fail to attract and retain senior management, clinical, and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our chief executive officer, as well as other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our future product candidates. We do not have employment agreements with our senior management team.

Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. In October 2023, we announced implementation of certain cost containment measures and a reduction in force of approximately 10%. This reduction in force, as well as any others we may need to implement in the future, may have a detrimental impact on company culture and employee morale, which may hurt our ability to retain employees. We will need to hire additional personnel if we expand our clinical development and manufacturing activities, or if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. If we are unable to hire and retain the qualified personnel we need to operate our business, our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Any such outcomes could materially adversely affect our business, financial condition, results of operations and growth prospects.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our product candidates are being developed to treat. We intend to utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.

We do not carry insurance for all categories of risk that our business may encounter. Although we maintain product liability insurance coverage that also covers our clinical trials, such insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

In addition, although we are dependent on certain key personnel, we do not have any key man life insurance policies on any such individuals. Therefore, if any of our chief executive officer or other executive officers die or become disabled, we will not receive any compensation to assist with such individual's absence. The loss of such person could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development and manufacturing activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal.

We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, including drug supply and inventory, and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Any contamination by such hazardous materials could therefore materially adversely affect our business, financial condition, results of operations and growth prospects.

Our business could be negatively impacted by the failure to address emerging environmental, social, and corporate governance matters.

There is an increasing focus from investors, employees, business partners, and other stakeholders concerning environmental, social, and corporate governance ("ESG") matters. The expectations related to ESG matters are rapidly evolving and, while we have internal efforts directed at ESG matters and preparations for any increased required future disclosures, we may be perceived to not be adequately addressing these matters, which could negatively impact our reputation and our business. In addition, we currently do not report our environmental emissions, and our lack of reporting could result in certain investors declining to invest in our common stock. We may also be required to increase our disclosure of ESG-related matters in the coming years as a result of regulatory changes that have been adopted or may be adopted in the future. For example, the SEC has recently adopted certain mandated ESG reporting requirements designed to enhance and standardize climate-related disclosures and the State of California has also enacted its own climate-disclosure requirements. Compliance with these disclosure requirements may require us to significantly increase our compliance and reporting costs and may also result in disclosures that could have a negative impact on investor perception.

Risks Related to Manufacturing

Our manufacturing process is novel and complex, and we may encounter difficulties in production, or difficulties with internal manufacturing, which would delay or prevent our ability to provide a sufficient supply of our product candidates for clinical trials or our products for patients, if approved.

Our product candidates are genetically engineered human cells, and the process of manufacturing such product candidates, as well as engineered K562 cells and viral vectors, is complex, highly regulated and subject to numerous risks. Manufacturing our product candidates involves harvesting white blood cells from a donor, isolating the NK cells, activating and expanding the NK cells, genome editing the NK cells (for certain product candidates with such edits), introducing a gamma-retrovirus with genes encoding the proteins we wish to express, cryopreservation, storage and eventually shipment. As a result of these complexities, the cost to manufacture our cellular product candidates, our proprietary, engineered K562 stimulatory cells ("NKSTIM"), and viral vector is generally higher than traditional small-molecule chemical compounds or biologics, and the manufacturing process is presently less reliable and more difficult to reproduce.

Our manufacturing process will be susceptible to product loss or failure, or product variation that may negatively impact patient outcomes, due to logistical issues associated with the collection of starting material from the donor, shipping such material to the manufacturing site, shipping the final product to the clinical trial recipient, preparing the product for administration, manufacturing issues or different product characteristics resulting from the differences in donor starting materials, variations between reagent lots, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth and variability in product characteristics.

Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any failure in the manufacturing processes could render a batch of product unusable, could impact supply and delay the progress of our clinical trials, could affect the regulatory approval of such product candidate, could cause us to incur fines or penalties or could harm our reputation and that of our product candidates.

Our manufactured product candidates may fail to meet the required specifications for any of a variety of reasons, including variability in starting material, deviations from normal manufacturing process, or insufficient optimization of specific process steps. This failure to meet specifications could result in supply shortages, or delays related to obtaining additional regulatory, site and patient approvals to continue dosing patients in the clinical trial. If the required additional approvals cannot be obtained, additional delays may occur as manufacturing would need to be restarted, enrollment may be delayed, and/or patients may be unable to remain in the study. Any delay in the clinical development or commercialization of NKX019 or our other product candidates could materially adversely affect our business, financial condition, results of operations and growth prospects.

We may make changes to our manufacturing process at various points during development, and even after commercialization, for various reasons, such as to control costs, achieve scale, decrease processing time, increase manufacturing success rate or for other reasons. Efforts to scale up and improve our manufacturing processes across our platform are ongoing. Changes to our manufacturing process carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials, or the performance of the product once commercialized. We previously filed a manufacturing process change amendment with the FDA for our NKX101 Phase 1 clinical trial for the treatment of AML as part of ongoing scale up and optimization of manufacturing across our platform. In October 2023, we announced that, in the dose-expansion cohort in the NKX101 clinical trial in which fludarabine and cytarabine (“flu/ara-C”) was being used as LD, we had begun dosing patients with NKX101 product that had been generated with the amended manufacturing process. However, a subsequent interim review of the clinical response data from the cohort indicated that the aggregate response rate for the 20 patients in total in the cohort was meaningfully lower than what had been observed and previously reported for the first 6 patients in the cohort. We have closed enrollment in the clinical trial and deprioritized the NKX101 program.

Changes to our process made during the course of clinical development could also require us to show the comparability of the product candidate used in earlier clinical phases or at earlier portions of a trial to the product candidate used in later clinical phases or later portions of the trial. It is difficult to establish comparability of cell therapy products, and this may complicate efforts to verify process changes during scale up. Other changes to our manufacturing process made before or after commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes. Such showings could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, or if regulatory authorities do not agree that comparability has been established, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

We are manufacturing in our own internal manufacturing facility to supply drug product for our NKX019 Phase 1 clinical trials. We have in the past, and may again in the future, encounter problems or delays with the internal production of our product candidates. We believe our current clinical cGMP manufacturing facility together with our new commercial-scale manufacturing facility, once qualified, will supply our anticipated non-pivotal clinical trial needs, but if the dose and number of cycles needed increases, our current manufacturing process may not be able to support the enrollment of trials which could lead to delays until we scale up the manufacturing. Although we have an internal cGMP manufacturing facility for the production of certain of our product candidates for our clinical trials, we do not yet operate a cGMP facility for the commercial-scale manufacture of our product candidates. Although we built a commercial-scale manufacturing facility, maintaining our commercial-scale facility and manufacturing product candidates in our own facilities will require an increase in staff and significant internal resources. Our manufacturing facilities will be subject to compliance with regulatory requirements, which we may struggle to meet. We may encounter problems with properly staffing our internal manufacturing facilities due to hiring challenges or other issues. For example, factors such as potential future pandemics, epidemics, or outbreaks of infectious disease or government-imposed restrictions in response to the foregoing could impact our ability to properly staff production of our product candidates. We may also encounter problems with training the staff we have to effectively manage and control the complex manufacturing process required to produce our product candidates and comply with all necessary regulations. We may also find it difficult to properly manage supply chain issues critical to the manufacturing process. If we are unable to build, maintain, and properly staff our manufacturing facilities, manage and control the manufacturing process, and comply with regulations, the clinical development or commercialization of our product candidates could be significantly delayed, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

We rely on third parties to manufacture certain materials for use in the production of our product candidates, or may rely on third parties to manufacture certain of our product candidates in the future, which increases the risk that we will not have sufficient quantities of such materials or product candidates, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

Although we have built a commercial-scale manufacturing facility, we do not yet operate our own cGMP facility for the production of commercial supplies of the product candidates that we are developing or evaluating in our development programs or supplies of such product candidates for pivotal clinical trials. We have limited personnel with experience in drug manufacturing and currently lack the resources and the capabilities to manufacture any of our product candidates on a commercial scale. If we are unable to successfully maintain and staff our own commercial-scale cGMP facility, we will need to rely on third parties for commercial-scale manufacture of our product candidates.

Also, although we currently manufacture our clinical supply at our own cGMP facility, we currently outsource manufacturing of certain critical materials necessary for production of our product candidates, including NKSTIM and viral vectors. Even though we have established our own internal cGMP facility for clinical supply of certain product candidates, and even if we successfully establish our own cGMP manufacturing facility for manufacture of our product candidates on a commercial scale, we will continue to outsource manufacturing of certain materials necessary for production of our product candidates. If we are unable to outsource the manufacturing of these materials or our established third-party manufacturers delay delivery of or fail to provide certain materials as needed for the production of our product candidates, then the production of our clinical or commercial supply may be impacted. We compete with other companies for access to third party cGMP facilities and cannot assure continued access.

In order to conduct clinical trials of product candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers may be unable to increase the manufacturing capacity for any of our product candidates or other necessary materials in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. If these third-party manufacturers are unable to, or do not, scale up the manufacture of our product candidates or other necessary materials in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

We do not currently have any agreements with third-party manufacturers for long-term commercial supply. We may be unable to enter into agreements with third-party manufacturers for commercial supplies of any product candidate or any material necessary for production of a product candidate that we develop, or may be unable to do so on acceptable terms. Even if we establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers for either clinical or commercial supply entails risks, including:

- reliance on the third-party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third-party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. The failure of our third-party manufacturers to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

If the third parties that we engage to supply any materials or to manufacture any product candidates for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the effects of a pandemic, epidemic, or outbreak of infectious disease, such as a future outbreak of a COVID-19 variant, and the actions undertaken by governments and private enterprises to contain such health event, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. For example, at some of our contract manufacturing sites, we have experienced delays in the past as a result of COVID-19-related restrictions, including temporary shutdowns, and instances of COVID-19 cases impacting personnel.

Our current and anticipated dependence upon others for the manufacture of our product candidates and/or materials necessary for production of our product candidates may adversely affect our profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

We are reliant on a sole supplier for certain steps of our manufacturing process.

Our manufacturing process for NKX019 and for NKX101 depends on the use of the Miltenyi CliniMACS® Plus system, and related reagents, all of which are only available from Miltenyi as the sole supplier. In addition, some of these reagents, at the time of procurement, typically expire after approximately four to six months. This short expiration period means that stocking the reagents in large quantities for future needs would not be an effective strategy to mitigate against the risk of shortage due to disruption of the supply chain.

Furthermore, while many of the reagents and consumables used in our manufacturing process are available from more than one commercial supplier, we have not confirmed the suitability of the use of all such reagents and consumables in our manufacturing process. Even if we are able to replace any raw materials or consumables with an alternative, such alternatives may cost more, result in lower yields or not be as suitable for our purposes. In addition, some of the raw materials that we use are complex materials, which may be more difficult to substitute. Therefore, supply disruptions could result in delays and additional regulatory submissions and prevent us from being able to manufacture our product candidates due to the unsuitability of the substituted reagent or consumable that we are able to procure. Substitution of some or all of these reagents and materials may require substantial changes to our manufacturing process, which may require us to establish product comparability. If we are unable to show comparability after a process change, further changes to our manufacturing process and/or clinical trials will be required. For example, if sufficient comparability is not shown, we may be required to repeat one or more clinical trials.

Any disruption in supply of these instruments and reagents could also result in delays in our clinical trials, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

Delays in commissioning and receiving regulatory approvals for our manufacturing facilities could delay our development plans and thereby limit our ability to develop our product candidates and generate revenues.*

We believe that internal cGMP manufacturing is important to facilitate clinical product supply, lower the risk of manufacturing disruptions and enable more cost-effective manufacturing. We have a cGMP facility in South San Francisco, California that allows us to supply the product candidates needed for our early-stage clinical trials. We have also built, and are working to fully qualify, a facility for the commercial-scale manufacture of our product candidates. The design, construction, qualification, regulatory approvals and maintenance for such facilities require substantial capital and technical expertise and any delay would limit our development activities and our opportunities for growth.

Furthermore, our manufacturing facilities will be subject to ongoing, periodic inspection by the FDA and other comparable regulatory agencies to ensure compliance with cGMP. Our failure to follow and document our adherence to these regulations or other regulatory requirements may lead to significant delays in the availability of product candidates for clinical use or may result in the termination of or a hold on a clinical study. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates, operating restrictions and criminal prosecutions, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

We also may encounter problems with the following:

- complying with regulations regarding evolving donor infectious disease testing, traceability, manufacturing, release of product candidates and other requirements from regulatory authorities at the state or federal level or outside the United States;
- achieving adequate or clinical-grade materials that meet regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- bacterial, fungal or viral contamination in our manufacturing facilities;
- disruptions due to natural disasters or supply chain interruptions; and
- shortages of qualified personnel, raw materials or key contractors.

Our product candidates, if approved by applicable regulatory authorities, may require significant commercial supply to meet market demand. In these cases, we may need to increase, or “scale up,” the production process by a significant factor over the initial level of production. If we fail to develop sufficient manufacturing capacity and experience, whether internally or with a third party, are delayed in doing so, or fail to manufacture our product candidates economically or on reasonable scale or volumes, or in accordance with cGMP, or if the cost of this scale-up is not economically feasible, our development programs and commercialization of any approved products will be materially adversely affected and we may not be able to produce our product candidates in a sufficient quantity to meet future demand and our business, financial condition, results of operations and growth prospects may be materially adversely affected.

The optimal donor and manufacturing parameters for our product candidates have not been definitively established, which may hinder our ability to optimize our product candidates or to address any safety or efficacy issues that may arise.

If any of our clinical trials reveal issues with the safety or efficacy of any of our product candidates, modification of the donor selection criteria or the manufacturing process may be necessary to address such issues. Alternatively, we may choose to modify the manufacturing process in an effort to improve the efficiency of the process or efficacy of the product candidates. However, although research to establish the optimal donor and manufacturing parameters is ongoing, we have not, at present, fully characterized or identified how donor characteristics and manufacturing process parameters affect the optimal cell killing ability for our engineered NK-cell product candidates for in vitro and animal efficacy studies or how such potency differences may translate into efficacy to be seen in human clinical trials, including both the proportion of patients who achieve a meaningful clinical response, and the duration of any such clinical responses. As a result, our ability to improve our manufacturing process or product potency, safety, or efficacy according to such parameters is limited and may require significant trial and error, which may cause us to incur significant costs or could result in significant delays to the clinical development and eventual commercialization of our product candidates. We continue to work to better establish the optimal donor and manufacturing parameters for our product candidates. Efforts to scale up and optimize our manufacturing processes across our platform are ongoing. If we are unable to manufacture sufficient supply of our product candidates for our current, planned, or future clinical trials, the clinical development and potential eventual commercialization of may be delayed, and we may be materially harmed as a result.

We are dependent on third parties to store our CAR NK cells, viral vector, master and working cell banks of NKSTIM, and any damage or loss would cause delays in replacement, and our business could suffer.

The CAR NK cells, the viral vector, and the master and working cell banks of NKSTIM are stored in freezers at third-party biorepositories and will also be stored in our freezers at our production facilities. If these materials are damaged at these facilities, including by the loss or malfunction of these freezers or our back-up power systems, as well as by damage from fire, power loss or other natural disasters, we would need to establish replacement CAR NK cells, viral vector, and master and working cell banks of NKSTIM, which would impact clinical supply and delay our patients' treatments. If we are unable to establish replacement materials, we could incur significant additional expenses and liability to patients whose treatment is delayed, and our business could suffer.

We have not yet developed a validated methodology for freezing and thawing commercial-scale quantities of CAR NK cells, which we believe will be required for the storage and distribution of our CAR NK-cell product candidates.

We have not yet demonstrated that CAR NK cells, which can be frozen and thawed in smaller quantities, can also be frozen and thawed in commercial scale quantities without damage, in a cost-efficient manner and without degradation over time. We may encounter difficulties not only in developing freezing and thawing methodologies for large scale use, but also in obtaining the necessary regulatory approvals for using such methodologies in treatment. If we are unable to freeze CAR NK cells for shipping purposes, our ability to promote adoption and standardization of our product candidates, as well as achieve economies of scale by centralizing our production facility, will be limited. Even if we are able to successfully freeze and thaw CAR NK cells in large quantities, we will still need to develop a cost-effective and reliable distribution and logistics network, which we may be unable to accomplish. For these and other reasons, we may not be able to commercialize CAR NK cells on a large scale or in a cost-effective manner. If such product candidate is found to be unstable, we would be required to conduct more frequent manufacturing runs, which could cause us to incur significant additional expenses.

Risks Related to Our Intellectual Property

If our license agreement with National University of Singapore and St. Jude Children's Research Hospital, Inc. is terminated, we could lose our rights to key components enabling our NK cell engineering platform.

In August 2016, we entered into a license agreement with the National University of Singapore and St. Jude Children's Research Hospital, Inc. (the "Licensors"). Pursuant to this license, the Licensors granted to us an exclusive, worldwide, royalty-bearing, sublicensable license to specified patents and patent applications related to NK-cell technology in the field of therapeutics. We are reliant upon certain rights and proprietary technology provided to us under this license for the production and development of certain of our product candidates, such as NKX019, NKX101 and NKX070. We make single-digit royalty payments, patent expenses, license maintenance fees and milestone payments to the Licensors. The term of the license agreement extends until expiration of the last of the patent rights licensed to us by the Licensors, which is currently expected to occur in approximately 2039. The Licensors may terminate the license agreement upon the occurrence of certain events, such as an uncured material breach by us, the cessation of our business or our insolvency, liquidation or receivership. If the Licensors terminate or narrow the license agreement, we could lose the use of intellectual property rights that may be material or necessary to the development or production of our product candidates, including NKX019, NKX101 and NKX070, which could impede or prevent our successful commercialization of such product candidates and materially adversely affect our business, financial condition, results of operations and growth prospects.

Furthermore, our license agreement with the Licensors is field-specific and has been granted to us in the field of therapeutics. This license agreement permits the Licensors to practice the licensed rights, and to allow non-profit academic third parties to practice the licensed rights for certain academic purposes. Further, one of the Licensors' patent families from which we license certain patents and patent applications contains other certain patents and patent applications that the Licensors have licensed to at least one third party. Although the patents and patent applications licensed to the at least one third party should not overlap with our licensed patents and patent applications, there is a risk that inadvertent overlap may occur, and thus, resources may have to be expended to resolve any such overlap and to prevent other licensees from practicing under our licensed patents rights. If any of the foregoing were to occur, it could delay our development and commercialization of our product candidates, which in turn could materially adversely affect our business, financial condition, results of operations and growth prospects.

If any patent protection we obtain is not sufficiently robust, our competitors could develop and commercialize products and technology similar or identical to ours.

The market for cell therapy is highly competitive and subject to rapid technological change. Our success depends, in large part, on our ability to maintain a competitive position in the development and protection of technologies and products for use in these fields and to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business. If we are unable to protect our intellectual property, our competitive position could be materially adversely affected, as third parties may be able to make, use or sell products and technologies that are substantially the same as ours without incurring the sizeable development and licensing costs that we have incurred. This, in turn, would materially adversely affect our ability to compete in the market.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, term, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates or effectively prevent others from commercializing competitive technologies and product candidates.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We also may fail to identify patentable aspects of our research and development output, or may identify patentable aspects of our research and development output once it is too late to obtain patent protection.

Claim scope in a patent application can be significantly reduced before the patent is issued, and claim scope in a patent can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

Claims brought against us for infringing, misappropriating or otherwise violating intellectual property rights of third parties or engaging in unfair competition, would be costly and time-consuming and could prevent or delay us from successfully developing or commercializing our product candidates.

Our success depends in part on our ability to develop, manufacture and market our technology and use our technology without infringing the proprietary rights of third parties. We, our licensors, or our collaborators may be subject to third-party claims that could cause us to incur substantial expenses to defend, and these claims, if successful, could require us to pay substantial damages and/or limit our ability to commercialize our product candidates if we, our licensors, or our collaborators are found to be infringing a third party's intellectual property rights.

We are aware of third-party patents and patent applications that may relate to the areas in which we are developing product candidates. For example, under the CRISPR Agreement, we are collaboratively designing and advancing certain gene-edited NK-cell therapies and have received licenses from CRISPR for certain CRISPR-Cas9 gene editing targets that can be engineered into our own NK-cell therapies. Third parties could assert that CRISPR does not have rights to certain CRISPR-Cas9 technologies, or could assert and have asserted in the past, that the CVC Group does not have rights to certain CRISPR-Cas9 technologies, including inventorship and ownership rights to some of the CVC Group's patents, or that such rights are limited. Third parties could seek to assert their issued patents relating to CRISPR-Cas9 technologies against us or our collaborators based on our CRISPR-Cas9-based activities, or those of our collaborators, including commercialization of gene-edited NK-cell therapies.

Additionally, as our industry expands and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our product candidates and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated. As a result, our technology and any future products that we commercialize could be alleged to infringe patent rights or other proprietary rights of third parties, which may require costly litigation and, if we are not successful in defending against such litigation, could cause us to pay substantial damages and/or limit our ability to commercialize our product candidates. Issued patents are entitled to a presumption of validity in many countries, including the United States and many European countries, and issued patents held by others that claim our technology or any of our product candidates may limit our freedom to operate, including our ability to commercialize our product candidates, unless and until these patents expire or are declared invalid or unenforceable in a court of applicable jurisdiction, if we do not obtain a license or other right to practice the claimed inventions. We may decide to file reexaminations, inter partes reviews, and other post-grant proceedings before the USPTO and other comparable proceedings (e.g., oppositions) in foreign jurisdictions, including to challenge the validity of third-party patents that may relate to the areas in which we are developing product candidates and technology. Such proceedings can be unpredictable and time-consuming and can divert management attention and financial resources.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Accordingly, we may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers.

Third parties could threaten or initiate litigation or other legal proceedings alleging that we have infringed their patents, trade secrets, trademarks or other intellectual property rights. Litigation may make it necessary to defend ourselves by determining the scope, enforceability and validity of third-party proprietary rights, or to establish our proprietary rights. Regardless of whether any such claims that we are infringing patents or other intellectual property rights have merit, such claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend.

Results of any such litigation are difficult to predict and may require us to stop treating certain conditions, obtain licenses or modify our product candidates or technology while we develop non-infringing substitutes, or may result in significant settlement costs. Litigation can involve substantial damages for infringement (and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees), and the court could prohibit us from selling our product candidates or require us to take a license from a third party, which the third party is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties, upfront fees, or milestone fees, or grant cross-licenses to intellectual property rights for our product candidates or technology. We may also have to redesign our product candidates or technology so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time, during which our product candidates may not be available for manufacture, use, or sale.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which could materially adversely affect our ability to develop, manufacture and market our product candidates.

There are many patents issued and applied for in the biotechnology industry, and we may not be aware of patents or patent applications held by others that relate to our business. We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and elsewhere that is relevant to or necessary for the development and commercialization of our product candidates in any jurisdiction.

For example, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Thus, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications directed to our product candidates or technology similar to ours or that of our licensors. Any such patent application may have an earlier priority date than our patent applications or patents, or those of our licensors, which could further require us to obtain rights to patents directed to such technologies. Under certain circumstances, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by any such third party, or by the USPTO itself, to determine who was the first to invent any of the subject matter recited by the patent claims of our applications or issued patents.

Furthermore, after issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, and we may incorrectly determine that our product candidates or technology are not covered by a third party's patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or elsewhere that we consider relevant may also be incorrect. Changes in patent laws and regulations may also affect the expiration date of any patent in the United States or elsewhere that we consider relevant. If we fail to correctly identify or interpret relevant patents or the expiration dates thereof, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We may also be forced to attempt to redesign our product candidates or technology in a manner that no longer infringes third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to the development and commercialization of our product candidates.

Our development and commercialization rights to our current and future product candidates and technology are subject, in part, to the terms and conditions of licenses granted to us by others.

We are a party to a variety of intellectual property license agreements with third parties and expect to enter into additional license agreements in the future. These license agreements provide us with access to certain rights and proprietary technology from third parties for the production and development of our current and future product candidates, including NKX019, NKX101 and NKX070. However, these licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we choose to develop or commercialize our technology and product candidates in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

We also engage in collaborations with scientists at academic and non-profit institutions to access technologies and materials that are not otherwise available to us. Although the agreements that govern these collaborations may include an option to negotiate an exclusive license to the institution's rights in any inventions that are created in the course of these collaborations, we may not be able to come to a final agreement for an exclusive license with the institution.

We also have entered, and may in the future enter, into collaboration or license agreements with commercial entities to access technologies and materials that are not otherwise available to us. Our agreements with such entities may provide licenses to technology useful for the discovery, development, or commercialization of our product candidates. These licenses may, in some instances, be non-exclusive. For example, we have entered into an agreement with CRISPR, which grants us a non-exclusive license on up to five gene-editing targets to enable us to independently research, develop and commercialize NK-cell therapies that have been gene-edited using CRISPR's gene-editing technology.

Such licenses and other contracts may be the subject of disagreements with the grantors and/or various third parties regarding the interpretation of such licenses and contracts. The resolution of any such disagreements that may arise could affect the scope of our rights to the relevant technology, or affect financial or other obligations under the relevant agreement, either of which could inhibit our ability to utilize the underlying technology in a cost-effective manner to develop and commercialize our product candidates, which in turn could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance, indemnification and other obligations on us. Under certain circumstances such as a material breach of terms, our licensors could terminate our license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors could have the freedom to seek regulatory approval of, and to market, products substantially the same as or identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications directed to the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with our best interests. For example, if we do not have the right to control patent prosecution and maintenance of patents and patent applications directed to the technology that we license from licensors, such licensors could file terminal disclaimers and/or take other actions that could shorten the term of the patents or patent applications. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be impaired. Additionally, we may be required to reimburse our licensors for all of their expenses related to the prosecution, maintenance, enforcement and defense of patents and patent applications that we in-license from them.

Furthermore, our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. For example, CRISPR has licensed certain rights to a worldwide patent portfolio that covers various aspects of the CRISPR-Cas9 editing platform technology including, compositions of matter and methods of use, including their use in targeting or cutting DNA, from Dr. Emmanuelle Charpentier. In addition to Dr. Charpentier, this patent portfolio has named inventors who assigned their rights to the Regents of the University of California or the University of Vienna, to whom we refer together with Dr. Charpentier, as the CVC Group. Accordingly, CRISPR has non-exclusive or co-exclusive rights to the patent rights that protect the core CRISPR-Cas9 gene-editing technology. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could harm our competitive position, and our business.

Duration of patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time, and the expiration of our patents may subject us to increased competition.*

As of September 30, 2024, the patent portfolio that is assigned to us, jointly owned with others or licensed to us includes issued patents in the United States, Europe, Japan, and other jurisdictions outside the United States, and pending patent applications in the United States, Europe, Japan, and other jurisdictions outside the United States across our platform, NKX019, NKX101 and NKX070 patent families. Our portfolio of issued patents, excluding pending patent applications, has estimated expiration dates between 2024 and 2041. Our portfolio, including issued patents, and including pending applications, to the extent they issue as patents or are used to establish nonprovisional patent applications that issue as patents, is expected to have estimated expiration dates between 2024 and 2045. For instance, composition-of-matter claims in our licensed patent portfolio that relate to our NKSTIM are estimated to expire in Q4 2024. We plan to file additional patent applications that could potentially allow for further increase of the exclusive market protection for certain uses of NKX019, NKX101 and NKX070 product candidates. However, we can provide no assurance that we will be able to file or receive additional patent protection for these or other product candidates.

Patent expiration dates may be shortened or lengthened by a number of factors, including terminal disclaimers, patent term adjustments, supplemental protection certificates and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Our patent protection could also be reduced or eliminated for noncompliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, or by changes in regulations or laws. In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights.

Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent; provided that the patent is not enforceable for more than 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, only one patent per approved product can be extended and only those claims directed to the approved product, a method for using it or a method for manufacturing it may be extended. However, the applicable authorities, including the FDA and the United States Patent and Trademark Office (the "USPTO") in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, we could be exposed to liability to the applicable patent owner. If we or our licensors fail to maintain the patents and patent applications covering our product candidates and technologies, we may not be able to prevent a competitor from marketing products that are the same as or similar to our product candidates. Further, others commercializing products similar or identical to ours, and our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, which could increase competition for our product candidates and materially adversely affect our business, financial condition, results of operations and growth prospects.

Even after issuance, our owned and in-licensed patents may be subject to challenge, which if successful could result in a partial or complete loss of patent rights, which could materially adversely affect our ability to protect our competitive position.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, even after issuance, may be challenged in the courts or patent offices in the United States and abroad. Third-party challenges may result in a loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to prevent others from using or commercializing similar or identical technology and products, or could limit the duration of the patent protection of our technology and product candidates.

Even if our patents are determined to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents.

Post-grant proceedings such as inter partes review, post-grant review, and ex parte reexaminations in the United States, or comparable proceedings (e.g., oppositions) in foreign jurisdictions, could be filed in the future and although we plan to vigorously protect our intellectual property rights, as with all legal proceedings, there can be no guarantee as to the outcome, and, regardless of the merits of third-party challenges, such proceedings are time-consuming and costly. As a result of such proceedings, our rights under the relevant patents could be narrowed or lost, and in the course of such proceedings, we may incur substantial costs, and the time and attention of our management may be diverted from the development and commercialization of our product candidates. Ex parte reexaminations were previously filed by one or more third parties against certain licensed patents in our portfolio and concluded with the claims of each reexamined patent being maintained in amended form.

We may not be able to effectively monitor unauthorized use of our intellectual property and enforce our intellectual property rights against infringement, and may incur substantial costs as a result of bringing litigation or other proceedings relating to our intellectual property rights.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products for potential infringement of our rights. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully monitor unauthorized use of our intellectual property could result in competitors offering products that incorporate our product candidates or service features, which could in turn reduce demand for our products.

We may also, from time to time, seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property.

If we choose to enforce our patent rights against a party, that party could counterclaim that our patent is invalid and/or unenforceable. The defendant may challenge our patents through proceedings before the Patent Trial and Appeal Board ("PTAB"), including inter partes and post-grant review. Proceedings to challenge patents are also available internationally, including, for example, opposition proceedings and nullity actions. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability and PTAB challenges are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the PTAB, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our product candidates.

In addition, such lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. Litigation is inherently unpredictable, and there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. Furthermore, some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our intellectual property rights.

There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could materially adversely affect the price of our common stock. Finally, any uncertainties resulting from the initiation and continuation of any litigation could materially adversely affect our ability to raise the funds necessary to continue our operations.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We have a number of international patents and patent applications and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. However, filing, prosecuting and defending patents relating to our product candidates and technology, including all of our in-licensed patent rights, in all countries throughout the world would be prohibitively expensive. We must ultimately seek patent protection on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Furthermore, the protection offered by intellectual property rights in certain countries outside of the United States may be less extensive than that in the United States. Consequently, we may not be able to prevent third parties from utilizing proprietary technology in all countries outside of the United States, even if we pursue and obtain issued patents in particular foreign jurisdictions, or from selling or importing products made using our proprietary technology in and into the United States or other jurisdictions. Such products may compete with our products, and our patent rights or other intellectual property rights may not be effective or sufficient to prevent them from competing. If such competing products arise in jurisdictions where we are unable to exercise intellectual property rights to combat them, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Changes in U.S. patent law or the patent law of other jurisdictions could decrease the certainty of our ability to obtain patents and diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. For example, in recent years the U.S. Supreme Court modified some tests used by the USPTO in granting patents, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of a challenge of any patents we obtain or license. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Those changes may materially adversely affect our patent rights and our ability to obtain issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For instance, the Leahy-Smith America Invents Act (the "America Invents Act"), enacted in 2011, included a number of significant changes to patent law in the United States. Many of the substantive changes to patent law under the America Invents Act came into effect in March 2013. For example, in March 2013, the United States transitioned from a "first-to-invent" patent system to a patent system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and how issued patents may be challenged, such as allowing third-party submission of prior art to the USPTO during patent prosecution and new post-grant administrative proceedings which can be used by third parties to attack the validity of an issued patent, including post-grant review, inter partes review and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and/or costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

In addition, the Federal Circuit and U.S. Supreme Court have ruled on several patent cases in recent years, narrowing the scope, and limiting the duration, of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own, have licensed or might obtain in the future.

Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future, which in turn could materially adversely affect our business, financial condition, results of operations and growth prospects. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unitary Patent Court (the "UPC"). As the UPC is a new court system, there is no precedent for the court or any decisions that it may take, increasing the uncertainty of any litigation. During a seven-year transitional period, patent owners may remove patents, patent applications, and supplementary protection certificates ("SPCs") from the jurisdiction of the UPC, provided that no action has been filed before the UPC, by filing a request to opt out of the jurisdiction of the UPC. Such "opted-out" patents will remain or issue as national patents in the UPC countries. Patents under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries that have ratified the UPC agreement. We cannot predict with certainty the long-term effects of any potential changes.

We may fail to obtain or enforce assignments of intellectual property rights from our employees and contractors.

While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Furthermore, our assignment agreements may not be self-executing or may be breached, and we may be forced to bring or defend claims to determine the ownership of what we regard as our intellectual property, and we may not be successful in such claims. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially adversely affect our business, financial condition, results of operations and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and product candidates could be materially diminished.

Trade secrets are difficult to protect. We rely on trade secrets to protect our proprietary information and technologies, especially where we do not believe patent protection is appropriate or obtainable, or where such patents would be difficult to enforce. We rely in part on confidentiality agreements with our employees, consultants, contractors, collaboration partners, scientific collaborators, and other advisors to protect our trade secrets and other proprietary information. We cannot guarantee that we have entered into such agreements with each party that may have had access to our proprietary information or technologies, or that such agreements, even if in place, will not be circumvented. These agreements may not effectively prevent disclosure of proprietary information or technology and may not provide an adequate remedy in the event of unauthorized disclosure of such information or technology. In addition, others may independently discover our trade secrets and proprietary information, in which case we may have no right to prevent them from using such trade secrets or proprietary information to compete with us. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could materially adversely affect our business, financial condition, results of operations and growth prospects.

The U.S. government could choose to exercise certain rights in technology developed under government-funded research, which could eliminate our exclusive use of such technology or require us to commercialize our product candidates in a way we consider sub-optimal.

The U.S. government has certain rights in some of our licensed patents (including U.S. Patent Nos. 7,435,596, 8,026,097, 11,673,937, and certain related U.S. patent applications) in accordance with the Bayh-Dole Act of 1980. These rights in certain technology developed under government-funded research include, for example, a nonexclusive, nontransferable, irrevocable, paid-up license to use those inventions for governmental purposes. In addition, the U.S. government may exercise certain "march-in rights," which require us to grant exclusive licenses to such inventions to a third party if the U.S. government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; (iii) government action is necessary to meet requirements for public use under federal regulations; or (iv) the general requirement that patented products be manufactured substantially in the United States unless domestic manufacture is not feasible has not been satisfied or waived.

The U.S. government also has the right to take title to such technology if we fail to disclose the invention of such technology to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to patent rights in any country in which a patent application is not filed within specified time limits. To the extent any of our owned or in-licensed intellectual property, now or in the future, is generated through the use of U.S. government funding, these provisions of the Bayh-Dole Act may apply.

Intellectual property generated under a government-funded program is also subject to certain reporting requirements. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States unless domestic manufacture is not feasible or the requirement is waived. If we are unable to obtain a waiver from the government agency that provided the underlying research funding, we may be limited in our ability to contract with non-U.S. product manufacturers for products related to such intellectual property.

The exercise of any of the foregoing rights of the U.S. government over technology that we own or use in the development and commercialization of our product candidates could prevent us from enjoying the exclusive use of such technology, or could cause us to incur additional expenses in the commercialization of our product candidates. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and growth prospects.

Risks Related to Commercialization

If any of our product candidates are approved for marketing and commercialization and we have not developed or secured marketing, sales and distribution capabilities, either internally or from third parties, we will be unable to successfully commercialize such products and may not be able to generate product revenue.

We currently have limited sales, marketing or distribution expertise. We will need to develop internal sales, marketing and distribution capabilities and infrastructure to commercialize any product candidate that gains FDA or other regulatory authority approval, which would be expensive and time-consuming, or enter into partnerships with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties to market products or decide to co-promote products with partners, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any product revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, if any, either on our own or through third parties, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Our product candidates, including NKX019, could be subject to regulatory limitations following approval, if and when such approval is granted.

Following approval of a product candidate, if any, we must comply with comprehensive government regulations regarding the manufacture, labeling, marketing, distribution and promotion of biologic products. We must comply with the FDA's labeling protocols, which prohibits promoting "off-label uses." We may not be able to obtain the labeling claims necessary or desirable to successfully commercialize our products, including NKX019 or other product candidates in development.

The FDA and foreign regulatory authorities could impose significant restrictions on use of an approved product including potentially restricting its use to limited clinical centers as well as through the product label, as well as on advertising, promotional and distribution activities associated with such approved product. The FDA or a foreign regulatory authority could also condition their approval on the performance of post-approval clinical trials, patient monitoring or testing, which could be time-consuming and expensive. If the results of such post-marketing trials are not satisfactory, the FDA or such foreign regulatory authority could withdraw marketing authorization or may condition continued marketing on commitments from us or our partners that may be expensive and/or time-consuming to fulfill.

In addition, if we or others identify side-effects after any of our products are on the market, if our products fail to maintain a continued acceptable safety profile after approval, if manufacturing problems occur subsequent to regulatory approval, or if we, our manufacturers or our partners fail to comply with regulatory requirements, including those mentioned above, we or our partners could be subject to the following:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned clinical trials;
- restrictions on such products' manufacturing processes;
- changes to the product label;
- restrictions on the marketing of a product;
- education requirements for prescribers;
- additional requirements prior to product distribution;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- Untitled or Warning Letters from the FDA;
- withdrawal of the product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;

- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions; or
- imposition of civil or criminal penalties.

Any one or a combination of these penalties could prevent us from achieving or maintaining market acceptance of the affected product, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating any revenue or profit from the sale of such product and could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, third-party payors may impose limitations on centers and personnel that may administer our products, including but not limited to requiring third-party accreditation to be obtained before the use of our products is reimbursed in such a center, which could materially adversely affect our potential commercial success and lead to slower market acceptance.

The market opportunities for our product candidates, if and when approved, may be limited, and if such market opportunities are smaller than we expect, our revenues could be materially adversely affected and our business could suffer.*

Our initial clinical trials have been evaluating NKX019 and NKX101 in relapsed/refractory patients who have been previously treated with other anti-cancer therapies. We are enrolling patients in a clinical trial to evaluate NKX019 in patients with refractory LN. We do not know at this time whether either NKX019 or NKX101 or any of our product candidates will be safe for use in humans or whether they will demonstrate any autoimmune or anti-cancer activity. If the activity is sufficient, we may initially seek approval of any product candidates we develop as a therapy for patients who have received one or more prior treatments. Depending on the activity we note in the initial clinical trials, we plan to conduct additional clinical trials in less heavily pretreated populations in order to expand use of our product candidates in a broader group of patients and increase market opportunities. However, there is no guarantee that product candidates we develop, even if approved for later lines of therapy, would be approved for earlier lines of therapy, and, prior to any such approvals, we will have to conduct additional clinical trials.

The number of patients who have the specific diseases we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited. Potentially addressable patient populations for our product candidates are only estimates. These estimates could prove to be incorrect, and the estimated number of potential patients in the United States and elsewhere could be lower than expected. It may also be that such patients may not be otherwise amenable to treatment with our product candidates, or patients could become increasingly difficult to identify and access for a variety of reasons including other drugs being approved, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

The commercial success of any of our product candidates will depend upon such product candidate's degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Our product candidates may not be commercially successful. Even if requisite approvals are obtained from the FDA in the United States and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance by physicians, patients and healthcare payors of cell therapy products in general, and our product candidates in particular, as medically necessary, cost-effective and safe. Physicians, patients, healthcare payors and others in the medical community may not accept any product that we commercialize. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of cell therapy products and, in particular, our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;

- the cost of treatment relative to alternative treatments, and the availability of coverage or reimbursements by government and private payors to enable patients to afford our product candidates;
- the clinical indications for which the product candidate is approved by the FDA;
- the willingness of physicians to refer patients and prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the nature, prevalence and severity of any side effects;
- product labeling or product insert requirements imposed by the FDA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the timing of market introduction of competitive products;
- adverse publicity concerning our product candidates or favorable publicity about competing products and treatments;
- sufficient third-party payor coverage, any limitations in terms of center or personnel training requirement imposed by third parties and adequate reimbursement;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts; and
- potential product liability claims.

Even if a product candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after such product is launched. Our product candidates may not achieve broad market acceptance.

Furthermore, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market such products and to generate product revenue.

We expect the cost of a single administration of one of our cell therapy product candidates to be substantial, when and if they achieve regulatory approval. We expect that there is likely to be a significant copay associated with our cell therapy products given the overall cost and that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our products, if approved, will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third-party payor could depend upon several factors, including the third-party payor's determination that use of a product is (i) a covered benefit under its health plan, (ii) safe, effective and medically necessary, (iii) appropriate for the specific patient, (iv) cost-effective and (v) neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved drug products. In the United States, third-party payors, including government payors such as Medicare and Medicaid, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. Medicare and Medicaid are increasingly used as models for the development of private payors' and government payors' coverage and reimbursement policies. Currently, few cell therapy products have been approved for coverage and reimbursement by the Centers for Medicare and Medicaid Services ("CMS"), the agency responsible for administering Medicare. It is difficult to predict what third payors, including CMS, will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, since there is no body of established protocols and precedents for these types of drug products. Moreover, reimbursement agencies in other countries, such as those in Europe, may be more conservative than CMS.

Third-party patient assistance programs, including copay assistance programs, that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives have resulted in significant civil and criminal settlements. While copay assistance programs are common within the industry, the Office of Inspector General at the U.S. Department of Health and Human Services has taken the position that such programs may violate the Anti-Kickback Statute. It is difficult to predict whether new legislation or regulatory action will restrict copay assistance programs and there is a risk that if these copay assistance programs are curtailed, higher cost treatments will be less accessible to patients and less likely to gain market acceptance.

Outside the United States, international operations vary significantly by country and are subject to extensive government price controls and other market regulations, and increasing emphasis on cost-containment initiatives in the European countries, Canada and other countries could place pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. It can also take a significant amount of time after approval of a product to secure pricing and reimbursement for such product in many countries outside the United States. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues.

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs could limit coverage and the level of reimbursement for our product candidates. Payors are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price, and Actual Acquisition Cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. Furthermore, most third-party payors currently require additional accreditation for approved cell therapy drugs, which limits the centers that can administer the drugs, and similar limitations may also be imposed on the product candidates that we are developing. We expect to experience pricing pressures in connection with the sale of our product candidates, if any, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and on prescription drugs and surgical procedures in particular, has become intense. As a result, increasingly high barriers to entry are developing for new drug products such as ours.

Healthcare reform initiatives and other administrative and legislative proposals may harm our business.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the "ACA") was enacted, which includes measures that have significantly changed the way healthcare is financed by both governmental and private payors. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drug agents or biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct, comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been legislative, judicial, and executive challenges to certain aspects of the ACA, including efforts to repeal or replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandates," and the Bipartisan Budget Act of 2018 (the "BBA") among other things, amends the ACA to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Further, the 2020 federal spending package eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer. Congress could continue to consider other legislation to repeal or replace certain elements of the ACA, and it is unclear how other efforts, if any, to challenge, repeal or replace the ACA, and other healthcare reform measures, will impact our business.

On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Court of Appeals for the Fifth Circuit court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. Thereafter, on March 2, 2020, the U.S. Supreme Court agreed to hear this case. Oral argument in the case took place on November 10, 2020. On June 17, 2021, the U.S. Supreme Court dismissed the case without specifically ruling on the constitutionality of the ACA, finding that the plaintiffs lacked standing to bring the action.

Prior to the Supreme Court's decision, an executive order was issued to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

Other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, among other things, providers are subject to Medicare payment reductions of 2% per fiscal year which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 pursuant to the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). Further, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment center, and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. Payment adjustments for the Medicare quality payment began in 2019. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

There have also been a number of proposals in the United States, at both the federal and state level, to control the escalating cost of healthcare, including the cost of drug treatments, patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and we expect that coverage and reimbursement for new therapies will be increasingly restricted. For example, certain states, including California, have implemented state-level cost containment strategies, which could adversely impact adoption of higher-cost medicines that are new to the market. Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more

transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Most significantly, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. The IRA includes provisions that will, among others: (i) direct CMS to negotiate the price of certain single-source prescription drugs reimbursed under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law; (ii) impose requirements on drug manufacturers to provide rebates to CMS under Medicare Part B and Medicare Part D as a penalty for price increases that outpace inflation; (iii) cap Medicare Part D beneficiaries' annual out-of-pocket drug expenses to \$2,000 starting in 2025, effectively eliminating the "donut hole" for Medicare Part D; and (iv) delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. The IRA also extends enhanced subsidies for individuals purchasing coverage in a health insurance marketplace through plan year 2025. The effect of the IRA on our business and the healthcare industry in general is not yet known, but we continue to evaluate its potential impact. At the state level, individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Furthermore, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs could restrict the amount that we are able to charge for our drug products, which could render our product candidates, if approved, commercially unviable and materially adversely affect our ability to raise additional capital on acceptable terms.

Obtaining and maintaining marketing approval or commercialization of our product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing approval of our product candidates in other jurisdictions.

Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

If we market approved products outside the United States, we expect that we will be subject to additional risks in commercialization, including:

- different regulatory requirements for approval of therapies in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, and other public health crises, illnesses, epidemics or pandemics.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply. Any of the foregoing difficulties, if encountered, could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our business operations and relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable fraud and abuse and other healthcare laws and regulations, which could expose us to penalties.

These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, the Health Information Technology for Economic and Clinical Health Act, the U.S. Physician Payments Sunshine Act and its implementing regulations, U.S. state laws and regulations, including, state anti-kickback and false claims laws, laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, laws requiring the registration of pharmaceutical sales representatives, laws governing the privacy and security of health information in certain circumstances, and similar healthcare laws and regulations in other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will also involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Any of the foregoing could significantly harm our business, financial condition, results of operations and growth prospects.

We may fail to comply with evolving global privacy laws.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, there are a broad variety of data protection and security laws and regulations that have been enacted by federal, state, and local governments, including personal data privacy laws, health information privacy laws, data breach notification laws, and consumer protection laws. For example, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH, and its implementing rules and regulations. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. There are a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General may all review privacy and data security protections for consumers.

New laws also are being enacted and considered at both the state and federal levels. For example, the California Consumer Privacy Act (the "CCPA"), which went into effect on January 1, 2020, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA also allows for statutory fines for noncompliance (up to \$7,500 per violation) and includes a private right of action for certain data breaches. Although there are some exemptions for clinical trial data and health information, the CCPA may impact our business activities and increase our compliance costs and potential liability. In addition, the California Privacy Rights Act (the "CPRA"), which became operative on January 1, 2023, expanded the CCPA, including by expanding consumers' rights with respect to certain sensitive personal data. The CPRA also created the new California Privacy Protection Agency to implement and enforce the CCPA and the CPRA, which could increase compliance costs. Similar laws have passed in Virginia, Utah, Connecticut and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. Additionally, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, if we conduct clinical trials in the European Economic Area ("EEA"), we may be subject to additional privacy laws. The General Data Protection Regulation, (EU) 2016/679 ("GDPR") imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing privacy and data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so we do not expect to operate in a uniform legal landscape in the EU. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.

In the event we conduct clinical trials in the EEA, we must also ensure that we implement and maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current and, in particular, future data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

Risks Related to Our Common Stock

The market price for our common stock may be volatile, which could contribute to the loss of all or part of your investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control.

Factors affecting the trading price of our common stock may include, but are not limited to:

- our decision to initiate a clinical study, not to initiate a clinical study or to terminate an existing clinical study;

- delays in the announcement of initial data or clinical results from our clinical trials or expectations that such delays may occur;
- data or clinical results from our clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval for our products;
- success or failure of competitive products, immunotherapy drugs or cellular therapies more generally;
- adverse developments concerning our manufacturers or our strategic partnerships;
- adverse safety or other clinical results, such as those that have occurred in the past or that may occur in the future, related to cellular therapies being developed by other companies that are or may be perceived to be similar to our cellular therapies;
- operating and stock price performance of other companies that investors deem comparable to us;
- sales of substantial amounts of common stock by our directors, executive officers or significant stockholders or the perception that such sales could occur;
- the ongoing conflicts in the Middle East and Ukraine;
- general economic and political conditions such as recessions, inflationary pressures, interest rates, fuel prices, elections, drug pricing policies, international currency fluctuations, acts of war or terrorism, and other public health crises, illnesses, epidemics or pandemics; and
- other factors discussed in these risk factors.

Any of the factors listed above could materially adversely affect your investment in our common stock, and our common stock may trade at prices significantly below the initial public offering price or the price at which you purchased the stock, which could contribute to a loss of all or part of your investment. In such circumstances the trading price of our common stock may not recover and may experience a further decline.

In addition, broad market and industry factors could materially adversely affect the market price of our common stock, irrespective of our operating performance. The stock market in general, and Nasdaq and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the particular companies affected. The trading prices and valuations of these stocks, and of ours, may not be predictable. For instance, technical factors in the public trading market for our common stock may produce price movements that may or may not comport with macro, industry or company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as may be expressed on financial trading and other social media sites), the amount and status of short interest in our common stock, access to margin debt, and trading in options and other derivatives on our common stock. In addition, the trading prices for common stock of other biopharmaceutical and biotechnology companies may be highly volatile in the event of a pandemic, epidemic, or outbreak of infectious disease, such as an outbreak of a COVID-19 variant. A loss of investor confidence in the market for biotechnology or pharmaceutical stocks or the stocks of other companies which investors perceive to be similar to us, the opportunities in the biotechnology and pharmaceutical market or the stock market in general, could depress our stock price regardless of our business, financial condition, results of operations or growth prospects.

Concentration of ownership of our shares of common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.*

As of November 4, 2024, our directors and executive officers, and entities affiliated with them, as well as holders of more than 5% of our outstanding shares of common stock, in the aggregate beneficially own 56% of our common stock (based on 70,568,754 shares of our common stock outstanding and 3,000,031 shares that could be issued upon the exercise of pre-funded warrants). These stockholders, acting together, are able to control or significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

Some of these persons or entities may have interests different than those of our other investors. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares were sold in the IPO and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly.*

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of stockholders intend to sell shares of our common stock, could reduce the market price of our common stock. As of November 4, 2024, we had 73,568,785 shares of common stock outstanding (including pre-funded warrants).

Holders of an aggregate of 9,837,634 shares of common stock, including with respect to shares of our convertible preferred stock that converted into shares of our common stock upon the completion of the IPO, have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 under the Securities Act, or until the rights terminate pursuant to the terms of the stockholders agreement between us and such holders. We have also registered all shares of common stock subject to equity awards issued or reserved for future issuance under our equity compensation plans on registration statements on Form S-8, and these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates under Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a negative impact on the trading price of our common stock.

We are an “emerging growth company” under the JOBS Act and a “smaller reporting company” and we rely on exemptions from certain disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, as a result of which our common stock may be less attractive to investors.

We take advantage and may continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including: not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important.

We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of our IPO, (b) in which we have total annual gross revenue of at least \$1.235 billion or (c) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30; and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company” as defined by applicable rules of the SEC. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company and would be permitted to continue to take advantage of many of the same reporting exemptions, including exemption from compliance with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act as long as we do not otherwise also qualify as an “accelerated filer” or “large accelerated filer” for SEC reporting purposes and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive if we rely on emerging growth company or smaller reporting company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Our severance and change in control agreements with our executive officers may require us to pay severance benefits to any of those persons who are terminated, which could materially adversely affect our financial condition or results of operations.

Our executive officers are parties to agreements that contain certain change in control and severance provisions. The agreements provide for cash payments for severance and other benefits in the event of a termination of employment that is not in connection with a change in control of us. They also provide for cash payments for severance and other benefits and acceleration of stock options vesting in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and could materially adversely affect the market price of our common stock. The payment of these severance benefits, and in particular, pursuant to multiple agreements at the same time, could materially adversely affect our financial condition and results of operations. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Our ability to use our net operating loss carryovers and certain other tax attributes may be limited.

As described above under “*We have incurred significant losses since our inception, and we expect to continue to incur significant losses for the foreseeable future.*” we have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. Under the Internal Revenue Code of 1986 (the “Code”), a corporation is generally allowed a deduction for net operating losses (“NOLs”) carried over from a prior taxable year. Under that provision, we can carry forward our NOLs to offset our future taxable income, if any, until such NOLs are used or expire, in the case of NOLs generated prior to 2018. The same is true of other unused tax attributes, such as tax credits. The amounts of our unused carryovers of NOLs and tax credits as of December 31, 2017, and a description of the valuation allowance we have recorded with respect to those items, are set forth below under “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In addition, under the Tax Act, the amount of post-2017 NOLs that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The Tax Act generally eliminates the ability to carry back any NOL to prior taxable years, while allowing post-2017 unused NOLs to be carried forward indefinitely.

Furthermore, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, Sections 382 and 383 of the Code limit the corporation’s ability to use carryovers of its pre-change NOLs, credits and certain other tax attributes to reduce its tax liability for periods after the ownership change. Our issuance of common stock pursuant to our IPO may result in a limitation under Sections 382 and 383 of the Code, either separately or in combination with certain prior or subsequent shifts in the ownership of our common stock. As a result, our ability to use carryovers of our pre-change NOLs and credits to reduce our future U.S. federal income tax liability may be subject to limitations. This could result in increased U.S. federal income tax liability for us if we generate taxable income in a future period. Limitations on the use of NOLs and other tax attributes could also increase our state tax liability. The use of our tax attributes will also be limited to the extent that we do not generate positive taxable income in future tax periods. To the extent our ability to utilize our NOLs and other tax assets going forward is limited, in part or altogether, our tax liability for future periods may be greater than expected, and our business, financial condition, results of operations and growth prospects may be materially adversely affected.

Under the Tax Act’s amendment to Section 174 of the Code, beginning with tax years that start after December 31, 2021, research and development expenses must be capitalized and amortized over five or fifteen years, as applicable. This tax law change has increased our effective tax rate and our cash tax payable in the taxable year 2022. If the requirement to capitalize Section 174 expenditures is not repealed or otherwise modified, it may also impact our effective tax rate and our cash tax liability in future years.

We do not expect to pay any cash dividends to the holders of our common stock for the foreseeable future.

We currently intend to invest our future earnings, if any, to fund our growth. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that our common stock will appreciate in value or even maintain the price at which our stockholders have purchased our common stock. Investors seeking cash dividends should not purchase our common stock.

Provisions in our certificate of incorporation, our bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation, bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our certificate of incorporation and bylaws include provisions that:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- establish a classified board of directors such that not all members of the board are elected at one time, which may delay the ability of our stockholders to change the membership of a majority of our board of directors;
- specify that only our board of directors, the Chairperson of our board of directors, our Chief Executive Officer or the President, or holders of greater than 10% of our common stock can call special meetings of our stockholders;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;

- provide that a majority of directors then in office, even though less than a quorum, may fill vacancies on our board of directors;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our Certificate of Incorporation and bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit your opportunity to receive a premium for your shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our certificate of incorporation includes a forum selection clause, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our Certificate of Incorporation provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware (or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for any:

- derivative action or proceeding brought on our behalf;
- action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;
- action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or
- other action asserting a claim against us that is governed by the internal affairs doctrine.

This exclusive forum provision is intended to apply to claims arising under Delaware state law and is not intended to apply to claims brought pursuant to the Securities Exchange Act of 1934, as amended (the "Exchange Act") or the Securities Act of 1933, as amended (the "Securities Act"), or any other claim for which the federal courts have exclusive jurisdiction. This exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

Our certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. The Delaware Supreme Court recently determined that the exclusive forum provision of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is permissible and enforceable under Delaware law, reversing an earlier decision from the Court of Chancery of the State of Delaware that had ruled that such provisions were not enforceable. Nevertheless, there is uncertainty as to whether a federal district court would enforce any exclusive forum provision with respect to claims under the Securities Act.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Certificate of Incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially adversely affect our business, financial condition, results of operation and growth prospects.

General Risk Factors

Computer system interruptions or security breaches of our information systems could significantly disrupt our product development programs and our ability to operate our business.*

Our internal computer systems, cloud-based computing services and those of our current and future collaborators, third party service providers, and other contractors or consultants (collectively, our "information systems") are vulnerable to damage or interruption from computer viruses, ransomware, malware, data corruption, cyber-based attacks, phishing attacks, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. These computer systems may also experience disruptions or outages due to internal or third-party mistakes or technical errors, including due to software updates. Such information system disruptions, even if inadvertent, may limit or disable our access to our systems or access by our collaborators, third party service providers, or other contractors or consultants to their systems, which could disrupt our business. While we have taken steps to protect our information systems and the data maintained in those systems, we have, from time to time, experienced cyber incidents of varying degrees, although none of these cyber incidents have had a material adverse impact on our business, financial condition or results of operations. Our business is becoming increasingly dependent upon these information systems, including as a result of remote working policies following the COVID-19 pandemic. It is possible that in the future our safety and security measures will not prevent the improper functioning or damaging of our systems, or the improper access or disclosure of personally identifiable information, in particular as cyber-based attacks become increasingly sophisticated, and any such event could materially and adversely impact our business, financial condition or results of operations. If a significant system disruption, failure, accident, security breach or other cyber incident were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, the disclosure of protected personally identifiable patient information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. To the extent that any disruption, security breach or other cyber incident were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

Furthermore, federal, state and international laws and regulations, such as the GDPR, which took effect in May 2018, and the CCPA which took effect on January 1, 2020, as well as the CPRA, which took effect on January 1, 2023 and made a number of significant amendments to the CCPA, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information systems security efforts fail or if our privacy practices do not meet the requirements of such laws. Other states are considering similar laws that could impact our use of research data with respect to individuals in those states. There are extensive documentation obligations and transparency requirements, which may impose significant costs on us.

Any computer system interruptions or security breaches of our information systems could result in a disruption of our operations, damage to our reputation, investigations, claims or lawsuits and we may also be subject to liability under relevant contractual obligations and laws and regulations protecting personal data and may be required to expend significant resources to defend, remedy and/or address any cybersecurity incidents and claims, investigations, penalties, fines, damages or settlements arising from cybersecurity incidents. We may not have adequate insurance coverage to compensate it for any losses that may occur.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business, results of operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties, such as those resulting from the current and future conditions in the banking system and the global financial markets. For instance, inflation has negatively impacted us and could continue to negatively impact us by increasing our cost of labor (through higher wages), commercial support, construction, manufacturing and clinical supply expenditures. Current inflationary pressures, if sustained, could have a negative impact on our operations. In addition, interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect our ability to raise capital in order to fund our operations, if needed. Financial conditions affecting the banking system and financial markets may threaten our ability to access our cash, as well as our access to letters of credit or other funding necessary to support our business, which may require us to find additional sources of cash or funding on short notice. Similarly, these macroeconomic factors could affect the ability of our third-party manufacturers, contractors or suppliers to manufacture materials required for our product candidates on a cost effective basis, if at all.

Any acquisitions or strategic collaborations may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities or subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to:

- scrutiny by the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ"), including the potential challenge of a proposed merger or acquisition by the FTC or DOJ;
- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent or unknown liabilities;
- assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel;
- adequately prosecuting and maintaining protection of any acquired intellectual property rights;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties about our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired drugs, intellectual property rights, technologies, and/or businesses sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we engage in acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses or acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our growth or limit access to technology or drugs that may be important to the development of our business.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a period of volatility or decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could materially adversely affect our business, financial condition, results of operation and growth prospects.

If securities analysts do not publish research or reports about our business or if they publish negative reports or downgrade our stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may materially adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules of the SEC and those of Nasdaq have imposed various requirements on public companies including that we establish and maintain effective disclosure and financial controls. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We may, as a result of regulatory changes, be subject to additional requirements, which may require us to incur significant additional costs to comply, including the implementation of significant additional internal controls processes and procedures regarding matters that have not been subject to such controls in the past, and impose increased oversight obligations on our management and board of directors.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures following an initial transition period available to public companies. In particular, we must evaluate our systems and procedures, and test our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting in the later of our second Annual Report on Form 10-K or the first Annual Report on Form 10-K following the date on which we are no longer an emerging growth company unless we are a smaller reporting company and do not otherwise also qualify as an “accelerated filer” or “large accelerated filer” for SEC reporting purposes. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we do not comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

To successfully implement our business plan and comply with Section 404, we must prepare timely and accurate financial statements. We expect that we will need to continue to improve existing procedures and controls, and implement new operational and financial systems, to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer, and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could materially adversely affect the trading prices for our common stock and our ability to access the capital markets.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would materially adversely affect our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. When we lose our status both as an emerging growth company and a smaller reporting company, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. Any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could materially adversely affect the trading price of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Changes to, or interpretations of, financial accounting standards may affect our results of operations and could cause us to change our business practices.

We prepare our financial statements in accordance with U.S. GAAP. These accounting principles are subject to interpretation by the Financial Accounting Standards Board, the SEC and various bodies formed to interpret and create accounting rules and regulations. Changes in accounting rules can have a significant effect on our reported financial results and may affect our reporting of transactions completed before a change is announced. Changes to those rules or the questioning of current practices may materially adversely affect our financial results, including those contained in this filing, or the way we conduct our business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities during the period covered by this report.

Repurchase of Shares of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the quarter ended September 30, 2024, none of our directors or officers adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-rule 10b5-1 trading arrangement," as each item is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1(A)	Amended and Restated Certificate of Incorporation of Nkarta, Inc.	8-K	001-39370	3.1	7/14/2020
3.1(B)	Amendment to Restated Certificate of Incorporation of Nkarta, Inc.	8-K	001-39370	3.1	6/9/2023
3.1(C)	Second Amendment to Restated Certificate of Incorporation of Nkarta, Inc.	8-K	001-39370	3.1	6/13/2024
3.2	Amended and Restated Bylaws of Nkarta, Inc.	8-K	001-39370	3.2	7/14/2020
10.1*#	Employment Offer between Nkarta, Inc. and Nadir Mahmood.				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32 ⁺	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	Inline XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

* Filed herewith.

#Indicates management contract or compensatory plan.

⁺This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 thereunto duly authorized.

Nkarta, Inc.

Date: November 7, 2024

By: _____
/s/ Paul J. Hastings
Paul J. Hastings
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2024

By: _____
/s/ Alyssa Levin
Alyssa Levin
Chief Financial and Business Officer
(Principal Financial Officer and Principal Accounting Officer)



Nkarta, Inc.
1150 Veterans Boulevard
South San Francisco, CA 94080 USA

July 11, 2024

Nadir Mahmood, Ph.D.

Via Electronic Delivery

Dear Nadir,

I am pleased to offer you a position with Nkarta, Inc. (the "Company") as President reporting to Paul Hastings, Chief Executive Officer. Your employment with the Company will commence on July 29, 2024 (the "Start Date"). Effective as of the Start Date, you will receive an annual base salary of \$530,000 (the "Base Salary"), which will be paid in accordance with the Company's then existing payroll procedures.

You agree that your services as President will be primarily performed at the Company's headquarters and manufacturing facilities in South San Francisco, California. Intermittent travel in the U.S. or abroad may be required, and pre-approved expenses related to transportation and lodging for such travel will be reimbursed by the Company, subject to and in accordance with the Company's expense policies.

Each year during the term of your employment, you will be eligible for a bonus of up to fifty percent (50%) of your then existing Base Salary based on achievement of performance objectives to be determined by the Board of Directors or a committee thereof (the "Board"). Any bonuses will be subject to your continued employment with the Company through the date the bonus is paid, in no event later than March 15 of the calendar year following the calendar year as to which the bonus relates. As an employee, you will also be eligible for standard Company benefits in accordance with Company policy, subject in each case to the generally applicable terms and conditions of the applicable benefit plan and to the determinations of any person or committee administering such plan. You will be entitled to paid time off in accordance with the Company's time-off policy, the timing and duration of such time off to be mutually and reasonably agreed to between you and the Company. The Company will also reimburse any of your expenses associated with Company business, subject to and in accordance with the Company's expense policies. You should note that the Company may modify salaries, benefits and its policies from time to time as it deems necessary or appropriate.

If you decide to join the Company, the Company will recommend that the Board grant you an option (the "Option") to purchase 550,000 shares (subject to customary adjustments for stock splits, reverse splits, stock dividends and similar events after the date hereof) of the Company's common stock ("Common Stock") at a price per share equal to the closing price (in regular trading) of a share of Common Stock on the date of grant of the Option (or, if the date of grant of the Option is not a trading day, as of the most recent trading day prior to the date of grant of the Option). Twenty-five percent (25%) of the Option will vest and be exercisable on the first

anniversary of the Start Date, subject to your continuing employment with the Company through that date, and none of the Option will vest before such date. The remaining Option will vest monthly over the next thirty-six (36) months in equal installments, subject in each case to your continuing employment with the Company through the applicable vesting date. The Option will be granted under the Company's equity incentive plan and will be subject to such further terms and conditions as set forth in such plan and in a written stock option agreement to be entered into by the Company and you to evidence the Option.

Effective as of your Start Date, the Company will offer you a Severance Agreement in the form that the Company has entered into with the CEO of the Company (the "Severance Agreement"). Your severance period under the Severance Agreement will be twelve months for an Involuntary Termination (as defined in the Severance Agreement) not in connection with or within one year following a Change in Control (as defined in the Severance Agreement) and eighteen months for an Involuntary Termination in connection with or within one year following a Change in Control.

The Company is excited about your joining and looks forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes at will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and with or without notice. We request that, in the event of resignation, you give the Company at least two (2) weeks' advance notice.

If you terminate, or if the Company terminates, your employment for any reason (with or without cause), then (except as otherwise provided in the circumstances in your Severance Agreement) you will be entitled to receive only: (i) any earned but unpaid base salary as of the date of termination; (ii) reimbursement for all reasonable and pre-approved necessary expenses incurred by you in connection with your performance of services on behalf of the Company while you are employed with the Company (subject to providing reasonable and timely documentation of such expenses and to the extent such expenses are reimbursable under the Company's expense policies), payable in accordance with applicable Company policies and procedures; and (iii) your vested and unpaid benefits (if any) pursuant to any Company benefit plan, payable in accordance with the terms of the applicable plan.

The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any. In addition, your position and the compensation levels provided for in this letter are subject to the approval of the Board.

For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Please bring such documentation with you on your Start Date or our employment relationship with you may be terminated.

During the course of your employment with Company, you shall perform your job responsibilities entirely within the United States and at the work location address(es) on file with the Company's People team, unless its during brief periods of travel (<2 weeks) required for

your job or you receive prior written approval from both your manager and the Company's People team to move your work to a new state or to work temporarily from a location outside of the United States.

We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing, and will not interfere with your performance of, the duties of your position and you represent that such is the case. Moreover, you agree that, while you are employed with the Company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the period of your employment, nor will you engage in any other activities that conflict with your obligations to the Company. Similarly, you agree not to bring any third-party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

As a condition of your employment and prior to the Start Date, you are also required to sign the Company's At Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement ("Confidentiality Agreement") which requires, among other provisions, the assignment of patent rights to any invention made during your employment at the Company, non-disclosure of Company proprietary information, and that in the event of any dispute or claim relating to or arising out of our employment relationship, you and the Company agree that any and all disputes between you and the Company will be fully and finally resolved by binding arbitration. Please note that we must receive your signed Confidentiality Agreement before your first day of employment. Your continued employment with the Company is subject to your ongoing compliance with your obligations under the Confidentiality Agreement and your compliance with all other Company policies, as they are in effect from time to time.

This letter and all of your rights and obligations hereunder are personal to you and may not be transferred or assigned by you at any time. The Company may assign its rights under this letter to a parent or affiliated company or to an entity that assumes the Company's obligations hereunder in connection with a sale or transfer of all or a substantial portion of the Company's business or assets.

To accept the Company's offer, please sign and date this letter agreement in the space provided below and return it to the sender before the deadline indicated below. This letter, along with the Confidentiality Agreement set forth the terms of your employment with the Company and supersede any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by authorized officer of the Company and you.

This offer of employment will expire if we don't receive your signed acceptance by the end of the day on **Monday, July 15, 2024**.

I look forward to your favorable reply and to welcoming you back to Nkarta, Inc. as President.

Sincerely,

/s/ Paul Hastings
Paul Hastings, CEO

Date: 7/11/2024

Agreed to and accepted:

/s/ Nadir Mahmood
Nadir Mahmood, Ph.D.

Date: 7/11/2024

Enclosures

At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement

