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 March 31, 2023

OR

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

For the transition period from _____ to _____

Commission file number: 001-36327

Neoleukin Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**98-0542593**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

188 East Blaine Street, Suite 450
Seattle, Washington 98102
(Address of principal executive offices, including zip code)
(Registrant's telephone number, including area code): (866) 245-0312

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, par value $0.000001	**NLTX**	**The Nasdaq Capital 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 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, a 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 May 4, 2023, there were 42,828,346 shares of the registrant's common stock outstanding.

NEOLEUKIN THERAPEUTICS, INC.

Quarterly Report on Form 10-Q

For the Quarter Ended March 31, 2023

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Except as otherwise indicated herein or as the context otherwise requires, references in this report to, "the Company," "we," "us," "our" and similar references refer to Neoleukin Therapeutics, Inc. (formerly Aquinox Pharmaceuticals, Inc.), a Delaware corporation. The name "Neoleukin" is a trademark of the Company in the United States. This report also contains references to registered marks, trademarks, and trade names of other companies that are property of their respective holders.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

NEOLEUKIN THERAPEUTICS, INC.

Condensed Balance Sheets
(Unaudited)
(In thousands of U.S. dollars, except per share and share amounts)

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 35,494	$ 37,887
Short-term investments	47,942	58,497
Other current assets	2,200	2,750
Total current assets	85,636	99,134
Property and equipment, net	2,489	6,163
Operating lease right-of-use assets	9,430	9,715
Other non-current assets	905	936
Total assets	$ 98,460	$ 115,948
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,421	$ 9,547
Operating lease liabilities	1,431	1,375
Finance lease liabilities	304	140
Total current liabilities	7,156	11,062
Non-current operating lease liabilities	9,940	10,322
Non-current finance lease liabilities	7	233
Total liabilities	17,103	21,617
Stockholders' equity		
Common stock - $0.000001 par value - authorized, 100,000,000 as of March 31, 2023 and December 31, 2022; issued and outstanding, 42,818,346 as of March 31, 2023 and 42,648,346 as of December 31, 2022	—	—
Preferred stock - $0.000001 par value - authorized, 5,000,000 as of March 31, 2023 and December 31, 2022; issued and outstanding, 0 as of March 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	546,598	545,407
Accumulated other comprehensive income (loss)	18	(21)
Accumulated deficit	(465,259)	(451,055)
Total stockholders' equity	81,357	94,331
Total liabilities and stockholders' equity	$ 98,460	$ 115,948

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

NEOLEUKIN THERAPEUTICS, INC.

Condensed Statements of Operations and Comprehensive Income (Loss)
(Unaudited)
(In thousands of U.S. dollars, except per share and share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 7,690	$ 10,701
General and administrative	4,027	4,664
Impairment of property and equipment	3,418	—
Total operating expenses	15,135	15,365
Loss from operations	(15,135)	(15,365)
Interest income	945	13
Other income (loss), net	(14)	1
Net loss	$ (14,204)	$ (15,351)
Comprehensive income (loss):		
Unrealized gain on available-for-sale securities	39	—
Comprehensive loss	$ (14,165)	$ (15,351)
Net loss per share – basic and diluted	$ (0.26)	$ (0.28)
Basic and diluted weighted average common shares outstanding	55,420,912	55,143,537

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

NEOLEUKIN THERAPEUTICS, INC.

Condensed Statements of Cash Flows
(Unaudited)
(In thousands of U.S. dollars)

	Three Months Ended March 31,	
	2023	**2022**
Operating activities		
Net loss	$ (14,204)	$ (15,351)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,191	2,446
Depreciation and amortization	329	411
Impairment of property and equipment	3,418	—
Amortization of operating lease right-of-use assets	286	250
Amortization and accretion of premiums/discounts on available-for-sale securities	(531)	—
Loss on disposal of property and equipment	190	—
Changes in operating assets and liabilities:		
Other current assets and other non-current assets	552	(803)
Accounts payable and accrued liabilities	(3,938)	(769)
Operating lease liabilities	(326)	(275)
Net cash used in operating activities	(13,033)	(14,091)
Investing activities		
Purchases of property and equipment	(419)	(452)
Purchases of available-for-sale securities	(28,375)	—
Proceeds from maturities of available-for-sale securities	39,500	—
Net cash provided by (used in) investing activities	10,706	(452)
Financing activities		
Proceeds from exercise of stock options	—	134
Payments on finance lease obligations	(66)	(1)
Net cash provided by (used in) financing activities	(66)	133
Net change in cash, cash equivalents, and restricted cash during the period	(2,393)	(14,410)
Cash, cash equivalents, and restricted cash, beginning of period	38,765	143,345
Cash, cash equivalents, and restricted cash, end of period	$ 36,372	$ 128,935
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment unpaid at period-end	$ 99	$ 91

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

NEOLEUKIN THERAPEUTICS, INC.

Condensed Statements of Stockholders' Equity
(Unaudited)
(In thousands of U.S. dollars, except share amounts)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income (Loss)	Deficit	Equity
Balances, December 31, 2021	42,457,471	$ —	$ 536,362	$ —	$ (393,498)	$ 142,864
Shares issued upon exercises of stock options	36,500	—	134	—	—	134
Stock-based compensation	—	—	2,446	—	—	2,446
Net loss	—	—	—	—	(15,351)	(15,351)
Balances, March 31, 2022	42,493,971	$ —	$ 538,942	$ —	$ (408,849)	$ 130,093
Balances, December 31, 2022	42,648,346	$ —	$ 545,407	$ (21)	$ (451,055)	$ 94,331
Shares issued upon vesting of restricted stock units	170,000	—	—	—	—	—
Unrealized gain on available-for-sale securities	—	—	—	39	—	39
Stock-based compensation	—	—	1,191	—	—	1,191
Net loss	—	—	—	—	(14,204)	(14,204)
Balances, March 31, 2023	42,818,346	$ —	$ 546,598	$ 18	$ (465,259)	$ 81,357

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

NEOLEUKIN THERAPEUTICS, INC.

Notes to the Condensed Financial Statements
(Unaudited)

1. Nature of operations
Neoleukin Therapeutics, Inc. ("Neoleukin" or "the Company") has historically been a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation, and autoimmunity using *de novo* protein design technology. Based on decisions made by our Board of Directors in November 2022 and March 2023, the Company has restructured operations to significantly reduce its workforce, discontinue development of NL-201, a *de novo* protein that was in Phase 1 clinical trial for the treatment of cancer, and suspend all research and development activities in order to conserve capital and focus on other strategic alternatives for the Company. Such alternatives may include a sale, merger, divestiture of assets, licensing or other strategic transaction

2. Summary of significant accounting policies

(a) Basis of presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, these financial statements do not include all of the information and footnotes required by U.S. GAAP for complete financial statements and should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 20, 2023.

In management's opinion, the unaudited condensed financial statements reflect all adjustments (consisting of normal recurring adjustments) necessary to present fairly the financial position of the Company as of March 31, 2023, and results of operations and cash flows for all periods presented. The interim results presented are not necessarily indicative of results that can be expected for the full year ending December 31, 2023. The Company reclassified prior year interest income in the condensed statements of operations and comprehensive income (loss) to conform to current year presentation. This reclassification had no effect on net loss or comprehensive loss.

(b) Use of estimates and assumptions

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant areas requiring estimates include valuation and recognition of stock-based compensation, the incremental borrowing rate utilized in the measurement of operating and finance lease liabilities, amortization/depreciation and impairment of property and equipment, and pre-clinical, clinical, and other accruals. Actual results could differ from those estimates.

(c) Property and equipment

Property and equipment are recorded at cost and are amortized using the straight-line basis over a range of three to seven years.

The Company reviews the carrying value of property and equipment for impairment whenever events and circumstances indicate that the carrying value of an asset may not be recoverable from the estimated future cash flows expected to result from its use and eventual disposition. In cases where undiscounted expected future cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of assets. The factors considered by management in performing this assessment include current operating results, trends and prospects, the manner in which the property is used, and the effects of obsolescence, demand, competition, and other economic factors. Based on management's assessment, as a result of the corporate restructuring announced in March 2023, including the decision to suspend all research and development activities, there were indicators of impairment of certain property and equipment as of March 31, 2023. During the three months ended March 31, 2023, the Company recorded $3.4 million in impairment charges. There were no indicators of impairment of property and equipment as of December 31, 2022.

(d) Leases

At contract inception, the Company determines if the contract is or contains a lease. Lease liabilities are recognized on the lease commencement date based on the estimated present value of lease payments over the lease term. To determine the present value of the lease payments, the Company utilizes its estimated incremental borrowing rate based on information available at the lease commencement date as the interest rate implicit in the lease is typically not readily determinable. The related right-of-use assets are recorded net of any lease incentives received. Variable lease cost primarily includes building operating expenses as charged to the Company by its landlords and payments for lessor-owned assets that are not covered by a tenant improvement allowance.

The Company includes options to extend the lease in its lease liability and right-of-use asset when it is reasonably certain that it will exercise that option. None of the Company's options to extend the rental term of any of its existing leases were considered reasonably certain as of March 31, 2023.

For leases of office space and equipment, the Company has elected to not separate the lease components from the non-lease components.

For leases with a lease term of 12 months or less and which do not include an option to purchase the underlying asset, the Company has elected to recognize the lease payments in the statement of operations on a straight-line basis over the lease term.

(e) Fair value of financial instruments

The carrying amounts of certain of the Company’s financial instruments, including cash and cash equivalents, restricted cash, receivables, accounts payable and other liabilities, approximate their fair values because of their nature and/or short maturities.

Certain of the Company’s financial instruments are measured at fair value on a recurring basis. The Company determines the fair value of those financial instruments based upon the fair value hierarchy, which prioritizes valuation inputs based on the observable nature of those inputs. The three levels of the fair value hierarchy are as follows:

Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities that can be accessed on the measurement date
Level 2 - quoted prices (in non-active markets or in active markets for similar assets or liabilities), observable inputs other than quoted prices and inputs that are not directly observable but are corroborated by observable market data
Level 3 - unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities

The following table presents information about the Company's financial instruments that are measured at fair value on a recurring basis:

	March 31, 2023			
(in thousands)	**Total**	**Level 1**	**Level 2**	**Level 3**
Financial assets				
Money market funds	$ 32,084	$ 32,084	$ —	$ —
U.S. treasury securities	50,920	50,920	—	—
Total financial assets	$ 83,004	$ 83,004	$ —	$ —

(in thousands)	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Financial assets				
Money market funds	$ 33,767	$ 33,767	$ —	$ —
U.S. treasury securities	61,970	61,970	—	—
Total financial assets	$ 95,737	$ 95,737	$ —	$ —

(f) Investments

The Company's short-term investments consist entirely of investments in U.S. treasury securities. These investments are classified as available-for-sale debt securities and are therefore reported at fair value in the condensed balance sheets. Unrealized gains and losses are included in accumulated other comprehensive income (loss). There were no realized gains or losses on investments for the three months ended March 31, 2023 and March 31, 2022.

The Company assesses investments for impairment at each reporting period. An investment is considered impaired when the amortized cost basis exceeds the fair value. When this is the case, the Company assesses whether the impairment is credit-related or noncredit-related based on various factors. When an impairment, or a portion of an impairment, is considered credit-related, an allowance for credit losses is recorded. For the three months ended March 31, 2023, the Company recognized no year-to-date credit losses and no allowance for credit losses is recorded as of March 31, 2023. The aggregate fair value of investments with unrealized losses as of March 31, 2023 is $4.0 million.

(g) Net loss per share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Common stock equivalents are included in the calculation of diluted earnings per share only in periods of net income and are excluded in the calculation of diluted net loss per share in periods of net loss as their inclusion would be anti-dilutive. Outstanding pre-funded warrants as of March 31, 2023 and March 31, 2022 are 12,663,010 and are considered outstanding as of their issuance date and are included in basic and diluted net loss per share because they are fully vested and exercisable for nominal cash consideration.

(h) Accounting for stock-based compensation

The Company has issued stock options and restricted stock units ("RSUs"). The Company measures the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The cost of such award is recognized on a straight-line basis over the requisite service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. The Company utilizes newly issued shares to satisfy option exercises, the vesting of RSUs, and 2020 Employee Stock Purchase Plan ("2020 ESPP") purchases.

The Company estimates the fair value of options using the Black-Scholes option pricing model on the grant date. This approximation uses assumptions regarding a number of inputs that requires management to make significant estimates and judgments. The expected term represents the period that the Company's stock-based awards are expected to be outstanding. As the Company does not have sufficient historical experience for determining the expected term of the stock option awards granted, the Company has based its expected term for awards issued to employees on the simplified method, which represents the average period from vesting to the expiration of the stock option. In addition, the Company does not have sufficient trading history of the Company's common stock, and therefore, the expected stock price volatility for the Company's common stock was estimated by taking the average historical price volatility for industry peers. The Company has never declared or paid any cash dividends to common stockholders and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero. The risk-free interest rate was based on the yields of treasury securities with maturities similar to the expected term of the options for each option group.

The fair value of each RSU is measured using the closing price of the Company's common stock on the date of grant.

(i) Restructuring charges

The Company records costs and liabilities associated with exit and disposal activities in accordance with ASC 420, *Exit or Disposal Cost Obligations*. Restructuring charges are recorded in the period in which they are incurred. The Company evaluates and adjusts these costs as appropriate for changes in circumstances as additional information becomes available.

(j) Recently issued and recently adopted accounting standards

The Company monitors and evaluates the issuance of Accounting Standards Updates ("ASUs"). No ASUs have been issued recently which impact the Company's financial statements and disclosures.

3. Cash, cash equivalents, and restricted cash

The Company considers all highly liquid investments with an original contractual maturity or a remaining maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist of money market funds and U.S. treasury securities as of March 31, 2023 and December 31, 2022.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash in the condensed balance sheets that sum to the total of the same such amounts shown in the condensed statements of cash flows:

(in thousands)	**March 31, 2023**	**December 31, 2022**
Cash and cash equivalents	$ 35,494	$ 37,887
Restricted cash	878	878
Total cash, cash equivalents, and restricted cash	$ 36,372	$ 38,765

Restricted cash, included in other non-current assets in the condensed balance sheets, includes $0.9 million in cash deposits the Company maintains with its bank as collateral for the irrevocable letters of credit related to its lease obligations.

4. Investments

The Company's investments consist of the following:

	March 31, 2023			
(in thousands)	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash equivalents:				
Money market funds	$ 32,084	$ —	$ —	$ 32,084
U.S. treasury securities - due within 3 months	2,995	1	—	2,996
Short-term investments:				
U.S. treasury securities - due within 1 year	47,925	17	—	47,942
Total	$ 83,004	$ 18	$ —	$ 83,022

	December 31, 2022			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:				
Money market funds	$ 33,767	$ —	$ —	$ 33,767
U.S. treasury securities - due within 3 months	3,473	—	—	3,473
Short-term investments:				
U.S. treasury securities - due within 1 year	58,518	6	(27)	58,497
Total	$ 95,758	$ 6	$ (27)	$ 95,737

5. Leases

The Company enters into lease arrangements for its facilities as well as certain equipment, classified either as operating or finance leases.

The Company has an operating lease agreement, as amended by the execution of two subsequent amendments, for approximately 33,300 square feet of office space in Seattle, Washington for the Company's principal executive offices, a laboratory for research and development, and related uses. The lease commenced on January 15, 2020 and expires on February 1, 2029, with the option to extend the lease for two five-year terms. The lease provides for a tenant improvement allowance of up to $9.5 million, which has been fully utilized.

The Company has an operating lease agreement for approximately 6,272 square feet of office space in Seattle, Washington, for additional office and laboratory space for research and development and related uses. In March 2021, the Company executed an amendment to this lease pursuant to which the contractual lease term was extended through September 30, 2026, unless terminated earlier, with the option to extend the lease for an additional 28-month term. In December 2022, the Company entered into an agreement to sublease this office and laboratory space in Seattle, Washington to an unrelated third party. Pursuant to the terms of the sublease, the Company is entitled to receive up to $0.5 million in base lease payments. The term of the sublease is through August 31, 2023, with an option by the sublessee to extend such term through November 30, 2023.

As of March 31, 2023, and December 31, 2022, the Company's operating lease right-of-use assets were $9.4 million and $9.7 million, respectively. As of March 31, 2023, and December 31, 2022, the Company's finance lease right-of-use assets, included within property and equipment on the condensed balance sheets, were $0.1 million and $0.5 million, respectively.

6. Equity

(a) Common stock and pre-funded warrants

The Company is authorized to issue 100,000,000 shares of common stock with a par value of $0.000001 as of March 31, 2023 and December 31, 2022. As of March 31, 2023 and December 31, 2022, the total number of shares of common stock issued and outstanding was 42,818,346 and 42,648,346, respectively.

As of March 31, 2023, the Company had pre-funded warrants outstanding to purchase an aggregate of 12,663,010 shares of common stock. The pre-funded warrants are exercisable at any time for an exercise price of $0.000001, except that the pre-funded warrants cannot be exercised by the holders if, after giving effect thereto, the holders would beneficially own more than 9.99% of the outstanding common stock, subject to certain exceptions. However, any holder may increase or decrease such percentage to any other percentage (not in excess of 19.99%) upon at least 61 days' prior notice from the holder to the Company. The holders of the pre-funded warrants will not have the right to vote on any matter except to the extent required by Delaware law.

On November 4, 2021, the Company entered into an ATM or “at-the-market” Equity Offering Sales Agreement (the “Sales Agreement”) with BofA Securities, Inc., as agent (“BofA”), pursuant to which the Company may offer and sell, from time to time through BofA, shares of the Company’s common stock, having an aggregate offering price of up to $40.0 million. The offer and sale of the shares will be made pursuant to a shelf registration statement on Form S-3 and the related prospectus filed on December 11, 2020, and declared effective by the SEC on December 21, 2020, as supplemented by a prospectus supplement dated November 4, 2021. The Company has no obligation to sell any such shares under the Sales Agreement. Through March 31, 2023, no sales of common stock have been made pursuant to the Sales Agreement. As of March 20, 2023, we are subject to limitations on the amount of funds we can raise by selling shares of our common stock using our Form S-3, including sales under this ATM facility, to one-third of the aggregate market value of the shares of our common stock held by non-affiliates, or public float, due to the so-called "baby shelf" requirements set forth in the SEC general instructions of Form S-3. These restrictions will remain in place until such time as our public float exceeds $75 million.

(b) Stock-based compensation expense

Stock-based compensation expense is classified in the condensed statements of operations and comprehensive income (loss) as follows:

(in thousands)	**Three Months Ended March 31,**	
	2023	**2022**
Research and development expenses	$ 256	$ 1,264
General and administrative expenses	935	1,182
Total stock-based compensation expense	$ 1,191	$ 2,446

Total unrecognized compensation expense for all stock-based compensation plans was $2.0 million as of March 31, 2023. This expense is expected to be recognized over a weighted average remaining vesting period of 2.05 years.

The fair values of stock options granted are estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	Three Months Ended March 31,	
	2023	**2022**
Expected volatility	85.95 %	83.18 %
Expected dividends	0 %	0 %
Expected terms (years)	6.04	6.07
Risk free rate	3.46 %	1.95 %

(c) Stock options

A summary of the Company's stock option activity and related information for the three months ended March 31, 2023 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at December 31, 2022	8,514,381	$ 4.89	8.32	$ —
Options granted	110,500	$ 0.59		
Options exercised	—	$ —		
Options cancelled/forfeited	(3,302,276)	$ 4.86		
Outstanding at March 31, 2023	5,322,605	$ 4.83	4.58	$ 3
Exercisable as of March 31, 2023	4,195,975	$ 5.41	3.41	$ —

During the three months ended March 31, 2023, no shares of common stock were issued upon exercise of options. During the three months ended March 31, 2022, 36,500 shares of common stock were issued upon exercise of options with an aggregate intrinsic value of $0.1 million. The weighted-average grant date fair value of options granted during the three months ended March 31, 2023 and March 31, 2022 was $0.43 and $1.75 per share, respectively.

(d) Restricted stock units

A summary of the Company's RSU activity and related information for the three months ended March 31, 2023 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2022	378,500	$ 4.22
Restricted stock units granted	—	$ —
Restricted stock units vested	(180,000)	$ 4.18
Restricted stock units forfeited	(151,250)	$ 4.10
Non-vested at March 31, 2023	47,250	$ 4.75

During the quarter ended March 31, 2023, 180,000 RSUs vested. As of March 31, 2023, 170,000 shares issued upon the vesting of these RSUs are issued and outstanding. The remaining 10,000 shares relate to a RSU that vested on March 31, 2023, and such shares are not issued and outstanding as of March 31, 2023.

(e) Employee stock purchase plan

The Company's 2020 ESPP was adopted by the Company's Board of Directors in March 2020 and approved by the Company's stockholders in May 2020. A total of 759,936 shares of common stock have been reserved for issuance under the 2020 ESPP.

Subject to share and dollar limits as described in the plan, the 2020 ESPP allows eligible employees to contribute, through payroll deductions, up to 15% of their earnings for the purchase of shares of the Company's common stock at the lower of 85% of the closing price of the Company's common stock on the first trading day of the offering period or 85% of the closing price of the Company's common stock on the last trading day of the offering period. There are two six-month offering periods during each fiscal year, ending on May 15 and November 15.

As of March 31, 2023 and December 31, 2022, employee contributions included in accounts payable and accrued liabilities in the accompanying condensed balance sheet were immaterial.

7. Net loss per share

The Company excluded the following potentially dilutive shares from diluted net loss per share as the effect would have been anti-dilutive for all periods presented:

	Three Months Ended March 31,	
	2023	**2022**
Outstanding stock options	5,322,605	8,297,921
Restricted stock units	47,250	710,000
Shares issuable under 2020 ESPP	13,347	45,261
	5,383,202	9,053,182

8. Restructurings and impairment charges

November workforce reduction

On November 14, 2022, the Company announced a corporate restructuring as a result of the strategic decision to discontinue further development of NL-201. In conjunction with this decision, the Company's Board of Directors approved a restructuring plan that included a reduction of approximately 40% of the Company's workforce (the "November 2022 Reduction").

In connection with the November 2022 Reduction, the Company expects to incur aggregate restructuring charges consisting of severance payments, benefits, and other employee related costs of $1.7 million, of which $1.4 million was recognized during the fourth quarter of 2022. The remaining $0.3 million was incurred during the three months ended March 31, 2023, all of which is included in research and development expenses in the statement of operations and comprehensive income (loss). The Company expects to pay all remaining restructuring charges associated with the November 2022 Reduction by the end of the third quarter of 2023.

March workforce reduction

On March 6, 2023, the Company's Board of Directors approved a reduction in force of the Company's workforce by approximately 70% in connection with a re-prioritization of the Company’s focus on seeking strategic alternatives to maximize stockholder value (the "March 2023 Restructuring Plan").

In connection with the March 2023 Restructuring Plan, the Company expects to incur additional aggregate restructuring charges consisting of severance payments, benefits, and other employee related costs of $1.8 million, of which $1.6 million was incurred during the three months ended March 31, 2023. The remaining restructuring costs of $0.2 million are expected to be incurred during the quarter ended June 30, 2023 due to future service requirements by certain employees entitling them to receive severance benefits. Of the $1.6 million of restructuring charges incurred during the three months ended March 31, 2023, $0.6 million is included in general and administrative expenses and $1.0 million is included in research and development expenses in the condensed statement of operations and comprehensive income (loss). The Company expects to pay all remaining restructuring charges associated with the March 2023 Restructuring Plan by the end of the first quarter of 2024.

A summary of the accrued liabilities activity recorded in connection with the November 2022 Reduction and March 2023 Restructuring Plan for the three months ended March 31, 2023 is as follows (in thousands):

	Accrued at December 31, 2022	Charges	Amounts Paid	Accrued at March 31, 2023
Employee severance, benefits, and related costs				
November 2022 Reduction	$ 1,041	$ 327	$ (490)	$ 878
March 2023 Restructuring Plan	—	$ 1,640	$ (344)	$ 1,296
Total	$ 1,041	$ 1,967	$ (834)	$ 2,174

Impairment charges

As a result of the March 2023 Restructuring Plan, the Company determined that sufficient indicators existed to trigger the performance of an interim long-lived asset impairment analysis as of March 31, 2023. In the first quarter of 2023, the Company tested the recoverability of its asset groups for property and equipment using entity-specific undiscounted cash flows. Based on these undiscounted cash flows, the Company concluded the undiscounted future cash flows expected to result from the eventual disposition of its long-lived assets were less than the carrying value of the asset groups. Therefore, the Company measured the long-lived asset impairment as the amount by which the carrying value of the asset group exceeds its fair value and recorded an impairment charge of $3.4 million. The fair value of the asset group reflect the Company’s best estimate of what hypothetical market participants would use to determine a transaction price for the asset group which represents a Level 3 fair value measurement.

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

You should read the following discussion of our financial condition and results of operations in conjunction with the unaudited interim condensed financial statements and notes thereto included elsewhere in this report and our audited consolidated financial statements and notes included as part of our Annual Report on Form 10-K for the year ended December 31, 2022.

Forward-Looking Statements

The following discussion of our financial condition and results of operations 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 (the "Exchange Act"). Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events, including the timing and outcome of our exploration of potential strategic alternatives, or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this quarterly report on Form 10-Q are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this quarterly report on Form 10-Q may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. In evaluating these statements, you should specifically consider various factors, including the risks outlined under the caption "Risk Factors" set forth in Item 1A of Part II of this quarterly report on Form 10-Q, as well as those contained from time to time in our other filings with the SEC. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We have historically been a biopharmaceutical company focused on creating next generation immunotherapies for cancer, inflammation, and autoimmunity using *de novo* protein design technology. We developed sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. With our *de novo* protein design process, we have been able to design new protein scaffolds from the ground up that are capable of demonstrating specific biological properties. Through this method we are able to produce proteins that, while resembling native proteins, may have novel molecular interfaces, differential activation of specific cell types, increased stability, or improved biodistribution compared to native proteins in order to potentially deliver greater therapeutic benefit. With the introduction of machine learning to this process, we believe timelines for developing potential candidates can be accelerated. *De novo* proteins have the capacity to be cytokine receptor agonists, antagonists, or result in conditional activation of specific cytokine receptors such that they may regulate inflammation or the immune response to cancer and inflammatory conditions.

Corporate Restructurings

In November 2022, we announced a corporate restructuring as a result of the strategic decision to discontinue development of NL-201 and turn our focus to the next generation of *de novo* cytokine mimetics that further widen the therapeutic window. While we believe that there are promising developments in this field of research, we also continued to evaluate strategic alternatives in light of the challenging capital markets. In March 2023, we announced a further corporate restructuring to significantly reduce our workforce and suspend our research and development activities in order to conserve capital and focus on other strategic alternatives for the Company. Such alternatives may include a sale, merger, divestiture of assets, licensing or other strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

As a result of the restructuring plan approved by our Board of Directors, or the Board, on November 12, 2022 in connection with our decision to discontinue development of NL-201, we reduced our workforce by approximately 40%. In connection with the decision to focus on strategic alternatives, the Board adopted a second restructuring plan on March 6, 2023, further reducing our workforce by approximately 70% of our remaining employees. We expect these restructurings to be completed by the end of the second quarter of 2023.

Clinical Trial of NL-201

Our first product candidate to be taken into clinical trial was NL-201, a computationally designed CD25-independent agonist of the IL-2 and IL-15 receptors. NL-201 was designed to eliminate binding to the alpha subunit of the IL-2 receptor (also known as CD25) while enhancing binding to the beta and gamma subunits. In multiple preclinical animal models, a precursor to NL-201 demonstrated substantial antitumor activity without detectable binding to CD25, as compared to native IL-2. Following these preclinical studies, we further refined our precursor to extend its half-life, resulting in the NL-201 product candidate. We then completed multi-dose, non-GLP and GLP toxicology studies of NL-201 in rats and non-human primates, and initiated our first in-human clinical trial. This included completion of GLP in-life dosing with no unexpected toxicities observed. NL-201 was intended to be used as either a single-agent or in combination with complementary therapeutic modalities, including checkpoint inhibitors.

In May 2021, we enrolled the first patient in a Phase 1 clinical trial of NL-201 for advanced solid tumors. On May 16, 2022, we announced that we had begun dosing patients in a new arm of the clinical trial study with a combination of NL-201 and Merck's checkpoint inhibitor KEYTRUDA® (pembrolizumab). On November 12, 2022, we made the decision to discontinue development of NL-201 for strategic reasons and to focus our resources on advancing the next generation of *de novo* protein therapeutics, using the lessons we have learned from our development of NL-201. We have also discontinued plans for any future trials of NL-201, including a Phase 1 clinical trial in hematological malignancies.

Preclinical Research Programs

Following the decision to discontinue development of NL-201, we turned our focus to research into the next generation of *de novo* cytokine mimetics that further widen the therapeutic window, such as the development of targeted and conditionally activated molecules to create potent immune agonists. We have been combining our expertise in *de novo* protein design, including data gathered from the development of NL-201 and research into other novel cytokine mimetics, with advances in machine learning and neural networks to expand the scope of our design process to include more complex protein structures and create more sophisticated and dynamic structural elements than were previously possible.

Our research team has also developed other molecules using our *de novo* protein design capabilities, including potential therapeutic candidates that may be developed in the future. In 2020, we reported development of NL-CVX1, a fully *de novo* decoy protein that was designed to block infection of human cells by the SARS-CoV-2 virus. In June 2021, we suspended plans to develop this molecule as effective vaccines became widely available; however, we believe this is a powerful example of the capability of our technology to develop potential *de novo* therapies in a short time frame. In 2021, we reported preclinical data for an inhibitor of IL-2 and IL-15 activity, Neo-5171, which demonstrated in vivo anti-inflammatory activity. In December 2022, we presented data on NEO-TRA1, a precision-tuned agonist of the IL-2 receptor beta and gamma subunits that is targeted to and selectively expands T-regulatory cells, at the American Society of Hematology (ASH) meeting ASH.

Following the decision by the Board in March 2023 to further restructure the Company to conserve capital and focus on strategic alternatives, we have suspended our research and development activities.

Finances

We will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to secure adequate additional funding, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more product candidates, reduce our early stage research projects, reduce the size of our team, or delay our pursuit of potential in-licenses or acquisitions.

Based on our current business plans, we believe that our existing cash, cash equivalents, and short-term investments will be sufficient to fund our planned operations through at least 12 months following the filing date of this Form 10-Q.

Results of Operations

Operating Expenses

The following table summarizes our operating expenses for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		Change	
(in thousands)	**2023**	**2022**	**$**	**%**
Research and development	$ 7,690	$ 10,701	$ (3,011)	(28)%
General and administrative	4,027	4,664	(637)	(14)%
Impairment on property and equipment	3,418	—	3,418	*
Total operating expenses	$ 15,135	$ 15,365	$ (230)	(1)%

**Not meaningful*

Research and Development Expenses

Research and development expenses consist primarily of costs incurred under arrangements with third parties, such as contract research organizations, or CROs, manufacturing organizations, and consultants, personnel-related costs (including stock-based compensation, severance expenses, and travel expenses), facility-related costs, and lab supplies.

For the three months ended March 31, 2023, research and development expenses were $7.7 million, compared to $10.7 million for the three months ended March 31, 2022. The decrease in research and development expenses during the three months ended March 31, 2023 is primarily due to a decrease in personnel-related costs and decreases in our early stage research, manufacturing, and clinical related costs due to the decision in November 2022 to discontinue further clinical development of NL-201 and the decision in March 2023 to re-prioritize the Company’s focus to seek strategic alternatives.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs (including stock-based compensation, severance expenses, and travel expenses), facility-related costs, insurance, and professional fees for consulting, legal, and accounting services.

For the three months ended March 31, 2023, general and administrative expenses were $4.0 million, compared to $4.7 million for the three months ended March 31, 2022. The decrease in general and administrative expenses during the three months ended March 31, 2023 was primarily due to a decrease in personnel-related costs.

Workforce Reductions

On November 14, 2022, we announced a corporate restructuring as a result of the strategic decision to discontinue further development of NL-201. In conjunction with this decision, our Board of Directors approved a restructuring plan that included a reduction of approximately 40% of our workforce (the "November 2022 Reduction").

In connection with the November 2022 Reduction, we expect to incur aggregate restructuring charges consisting of severance payments, benefits, and other employee related costs of $1.7 million, of which $1.4 million was recognized during the fourth quarter of 2022. The remaining $0.3 million was incurred during the three months ended March 31, 2023, all of which is included in research and development expenses in the statement of operations and comprehensive income (loss). We expect to pay all remaining restructuring charges associated with the November 2022 Reduction by the end of the third quarter of 2023.

On March 6, 2023, our Board of Directors approved a reduction in force of our workforce by approximately 70% and a re-prioritization of the our focus to seek strategic alternatives to maximize stockholder value (the "March 2023 Restructuring Plan").

In connection with the March 2023 Restructuring Plan, we expect to incur aggregate restructuring charges consisting of severance payments, benefits, and other employee related costs of $1.8 million, of which $1.6 million was incurred during the three months ended March 31, 2023. The remaining restructuring costs of $0.2 million are expected to be incurred during the quarter ended June 30, 2023 due to future service requirements by certain employees to receive severance benefits. Of the $1.6 million of restructuring charges incurred during the three months ended March 31, 2023, $0.6 million is included in general and administrative expenses and $1.0 million is included in research and development expenses in the condensed statement of operations and comprehensive income (loss). We expects to pay all remaining restructuring charges associated with the March 2023 Restructuring Plan by the end of the first quarter of 2024.

Impairment on Property and Equipment

In March 2023, our Board approved a reduction in force of the Company's workforce by approximately 70% and a re-prioritization of the Company’s focus to seek strategic alternatives. In connection with this decision, we determined that sufficient indicators existed to trigger the performance of an interim long-lived asset impairment analysis as of March 31, 2023. We recorded an impairment charge on our property and equipment of $3.4 million for the three months ended March 31, 2023.

Interest Income

Interest income during the three months ended March 31, 2023 was $0.9 million as compared to $13 thousand during the three months ended March 31, 2022. The increase during the three months ended March 31, 2023 is due to broad increases in the interest rate environment resulting in higher interest earned on our money market fund investments. Additionally, the increase is due to purchases of U.S. treasury securities beginning in the second quarter of 2022, which yield a higher rate of interest than investments in money market funds.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Our operating activities used $13.0 million and $14.1 million of cash flows during the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $465.3 million, working capital of $78.5 million, and cash, cash equivalents, and short-term investments of $83.4 million.

On November 4, 2021, we entered into an ATM "at-the-market" Equity Offering Sales Agreement, or the Sales Agreement, with BofA Securities, Inc., or BofA, pursuant to which we may, but are not obligated to, offer and sell, from time to time, shares of our common stock with an aggregate offering price up to $40.0 million through BofA, as sales agent. No sales of our common stock have been made pursuant to this Sales Agreement to date. As of March 20, 2023, we are subject to limitations on the amount of funds we can raise by selling shares of our common stock using our Form S-3, including sales under this ATM facility, to one-third of the aggregate market value of the shares of our common stock held by non-affiliates, or public float, due to the so-called "baby shelf" requirements set forth in the SEC general instructions of Form S-3. These restrictions will remain in place until such time as our public float exceeds $75 million.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
(in thousands)	**2023**	**2022**
Net cash (used in) provided by:		
Operating activities	$ (13,033)	$ (14,091)
Investing activities	10,706	(452)
Financing activities	(66)	133
Net change in cash, cash equivalents, and restricted cash	$ (2,393)	$ (14,410)

Net cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2023 and March 31, 2022 consisted of net loss for the period adjusted for non-cash items and changes in components of operating assets and liabilities. For the three months ended March 31, 2023, a net loss of $14.2 million was adjusted for non-cash items including impairment on property and equipment of $3.4 million, stock-based compensation expense of $1.2 million, and a net decrease of $3.7 million due to changes in operating assets and liabilities. For the three months ended March 31, 2022, a net loss of $15.4 million was adjusted for non-cash items including stock-based compensation expense of $2.4 million and a net decrease of $1.8 million due to changes in operating assets and liabilities.

Net cash (used in) provided by investing activities

For the three months ended March 31, 2023, cash provided by investing activities consisted primarily of proceeds from maturities of available-for-sale securities, partially offset by purchases of available-for-sale securities and laboratory equipment. For the three months ended March 31, 2022, cash used in investing activities consisted primarily of purchases of laboratory equipment and office furnishings.

Net cash (used in) provided by financing activities

For the three months ended March 31, 2023 net cash used in financing activities consisted primarily of payments on our finance leases. For three months ended March 31, 2022, net cash provided by financing activities consisted primarily of proceeds from stock option exercises and purchases of common stock under our 2020 Employee Stock Purchase Plan.

Operating and Capital Expenditure Requirements

We have not generated product revenue or achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. As of March 31, 2023, we had approximately $83.4 million in cash, cash equivalents, and short-term investments. Based on our current business plans, we believe that our existing cash, cash equivalents, and short-term investments will be sufficient to fund our operating requirements through at least 12 months following the filing date of this Form 10-Q.. However, our future capital requirements and the period for which we expect our existing resources to support our operations, fund expansion, develop new or enhanced products, or otherwise respond to competitive pressures, may vary significantly from our expectation and we may need to seek additional funds sooner than planned. Unless and until we generate sufficient revenue to be profitable, we will seek to fund our operations through public or private equity or debt financings or other sources. If we raise additional funds through the issuance of convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a negative impact on our business, results of operations, financial condition, cash flows, and future prospects. Our future capital requirements will depend on many factors, including:

- the number and characteristics of any future product candidates we develop or may acquire;
- the scope, progress, results, and costs of researching and developing our product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates;
- the cost of manufacturing our future product candidates and any products that may achieve regulatory approval;
- the cost of commercialization activities if any product candidates or future product candidates are approved for sale, including marketing, sales and distribution costs;
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;

- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation.

Please see Item 1A of Part II of this Quarterly Report titled “Risk Factors” for additional risks associated with our substantial capital requirements.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of these financial statements in accordance with U.S. GAAP requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable 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. A summary of our significant accounting policies is presented in Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes to our significant accounting policies during the three months ended March 31, 2023.

Recent Accounting Pronouncements

See Note 2(j), *Recently issued and recently adopted accounting standards* in the Notes to Condensed Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a “smaller reporting company,” as defined by Rule 12b-2 of the Exchange Act, and pursuant to Item 305 of Regulation S-K, we are not required to provide quantitative and qualitative disclosures about market risk.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Under the supervision and with the participation of our principal executive and our principal financial officer, our management conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report.

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on management’s evaluation, our principal executive and our principal financial officer concluded that our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and financial officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in internal control over financial reporting. There have not been any changes in our internal control over financial reporting during the quarter ended March 31, 2023 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

We may from time to time be named as a party to legal claims, actions and complaints, including matters involving employment, intellectual property or others. We are not presently a party to any legal proceedings that, in the opinion of our management, would reasonably be expected to have a material adverse effect on our business, financial condition, operating results or cash flows if determined adversely to us. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

Summary of Risk Factors

An investment in our common stock involves various risks, and prospective investors are urged to carefully consider the matters discussed in the section titled “Risk Factors” prior to making an investment in our common stock. These risks include, but are not limited to, the following:

- We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future may not be successful. If we are able to complete any such transaction, it may not result in additional value to stockholders and may present additional challenges. We may also elect to pursue a dissolution and liquidation of the Company instead of a strategic transaction, which may impact the timing and amount of payments to our stockholders.
- We will require substantial additional capital to finance our operations which may not be available to us on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of our product candidates.
- The price of our common stock does not meet the requirements for continued listing on Nasdaq. If we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.
- We have incurred significant losses in every quarter since our inception and anticipate that we will continue to incur significant losses in the future.
- We have a limited operating history as a company developing therapies using *de novo* protein design technology, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We currently have no source of product revenue and may never become profitable.
- Our product candidates are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of, or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Preclinical studies and clinical trials of our product candidates may not be successful, and if we are unable to commercialize these product candidates or experience significant delays in doing so, our business will be materially harmed.
- Future clinical trials or additional preclinical studies may reveal significant adverse events not seen in our earlier preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.
- Our approach to the discovery and development of our therapeutic treatments is based on *de novo* protein design technology which is unproven and may not result in marketable products.

- We rely on and expect to continue to rely on third parties to conduct certain of our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines, or terminate the relationship, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations, and prospects.
- We rely on and expect to continue to rely on third-party manufacturers and suppliers to supply components of our product candidates. The loss of our third-party manufacturers or suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- Unfavorable global economic conditions or other geopolitical developments could adversely affect our business, financial condition, stock price, and results of operations.
- If we are not able to obtain, maintain, and enforce patent protection and other intellectual property rights for our product candidates, our Neoleukin design process technology, or other proprietary technologies we may develop, the development and commercialization of our product candidates may be adversely affected.

Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including our condensed financial statements and related notes. If any of the events described in the following risk factors occurs, our business, operating results, and financial condition could be adversely affected. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report on Form 10-Q.

Risks Related to Strategic Process and Potential Strategic Transaction

We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future may not be successful.

In November 2022, we made the strategic decision to wind down our clinical trial of NL-201, a *de novo* protein designed to mimic the therapeutic activity of the cytokines interleukin-2, or IL-2, and interleukin-15, or IL-15, for the potential treatment of various types of cancer. In connection with that decision, our Board of Directors, or Board, approved a reduction in our workforce designed to reduce our operating expenses to increase our cash runway. In March 2023, based on the challenging capital markets and resources required to bring our earlier stage programs forward to a point of potential viability, the Board approved a plan to significantly reduce the remainder of our workforce while we undertake a comprehensive assessment of strategic options to maximize stockholder value. These strategic options may include a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we may incur significant costs related to this continued evaluation. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders. In addition, we may not be able to adequately limit or avoid future liabilities, including future costs relating to the lease on our headquarters, which may impair the value of any potential transaction or present additional challenges to completing a strategic transaction.

There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly reduce or delay any future distributions to our stockholders.

We may not realize any additional value in a strategic transaction.

The market capitalization of our company is below the value of our current cash, cash equivalents and investments. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets, including NL-201 and our *de novo* protein design methodology. Further, the development and any potential commercialization of our product candidates would require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend the additional resources necessary to continue developing our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to assess strategic options, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our the orderly operation of our company.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition, disposition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or incurrence of non-recurring, impairment or other charges;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

Our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed and, whether or not such strategic transaction is completed, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, and the loss of such employees' services may adversely impact the ability to consummate such transaction. In March 2023, we implemented a further reduction in our workforce designed to substantially reduce our operating expenses while we undertake a comprehensive assessment of strategic options to maximize stockholder value. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of strategic options as well as business operations.

We may become involved in securities class action litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Risks Related to Our Financial Position and Capital Needs

We will require substantial additional capital to complete a strategic transaction and finance future operations, which may not be available to us on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of any future product candidates.

The development of biopharmaceutical product candidates is capital-intensive. As of March 31, 2023, we had approximately $83.4 million in cash, cash equivalents, and short-term investments. We have spent a significant amount of money on our operations to date, including research and development, preclinical and clinical studies. We will continue to incur costs related to the discontinued development of NL-201 and suspension of our research and development activities. Based on our current operating plan, we believe that our available cash, cash equivalents, and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months following the filing date of this Form 10-Q. However, our current operating plan does not contemplate the resumption of research and development activities or the commencement of any clinical trials, and we do not expect to be able to fully support our operations based on the assumptions of that operating plan. We announced in March 2023 that we have suspended our research and development operations so that we can focus on reviewing strategic alternatives, which may include a sale, merger, divestiture of assets, licensing or other strategic alternative, with the intention of improving stockholder value, While we expect to have adequate capital to fund our operations through this process, our future capital requirements and the period during which we expect to complete this strategic process may vary significantly from what we expect, and we may have to seek an alternate resolution to the process. In addition, even if we are successful in completing a strategic transaction, we may still need to raise additional funds for any research and development or clinical programs we may pursue in the future. Our monthly spending levels may vary, and may also be impacted by inflationary pressures in the current economic environment. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, and because we have suspended our research and development activities while we pursue strategic alternatives, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for any product candidates that ultimately may be approved for sale. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- our ability to complete a strategic transaction in a timely manner and on acceptable terms;
- the timing, cost and progress of research, preclinical, and clinical development activities;
- the number and scope of development, preclinical and clinical programs we decide to pursue;

- the terms of any collaborations and/or research and development agreements we may enter into, which may impact the cost, timing and development plans of one or more of our product candidate programs;
- our ability to maintain our current licenses and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of regulatory requirements, regulatory submissions and timing of regulatory approvals;
- the potential delays in our preclinical studies, our development programs and our ongoing and planned clinical trial activities due to the effects of global events, including macroeconomic conditions and continued supply chain disruptions;
- the impact of inflationary pressures on salaries and wages, and costs of goods and transportation expenses, among other things;
- the cost of commercialization activities if any future product candidates are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire personnel to support development of any future product candidates.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to pursue less advantageous strategic opportunities, limit future research and development, or dissolve the Company and liquidate our assets. We do not expect to realize revenue from sales of commercial products or royalties from licensed products in the foreseeable future, if at all, and, in no event would we recognize such revenues before any future product candidates are clinically tested, approved for commercialization, and successfully marketed.

We may seek the additional funding we will need to continue operating in the future through collaborations and/or licensing agreements, public or private equity offerings or debt financings, credit or loan facilities, or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we are able to raise additional funds through future debt financings, the terms of such financings are likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. 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. We also could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish some or all of our rights to certain product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

We have incurred significant losses in every quarter since our inception and anticipate that we will continue to incur significant losses in the future.

We are a biotechnology company with a limited operating history of developing next generation immunotherapies for cancer, inflammation, and autoimmunity using *de novo* protein design technology. Investment in biotechnology is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval, or become commercially viable. We do not have any products approved by regulatory authorities for marketing or commercial sale, we have not generated any revenue from product sales to date, all of our product candidates are in early stages of research and development and we have suspended our research and development activities for the near term while we focus on evaluating strategic alternatives. As a result, we are not profitable and have incurred losses in every reporting period since our inception as Aquinox in 2003. For the three months ended March 31, 2023 and March 31, 2022, we reported a net loss of $14.2 million and $15.4 million, respectively. As of March 31, 2023,we had an accumulated deficit since our inception as Aquinox of $465.3 million.

While we have taken measures to reduce our expenses in the near term, we continue to incur significant expenses related to our ongoing operations, including expenses relating to the wind down of our clinical program for NL-201 and expenses related to our ongoing corporate restructuring, and are not currently moving any of our existing product candidates toward commercialization. We therefore expect to continue to have operating losses for the foreseeable future. If we are able to complete a strategic transaction that will allow us to resume research and development activities, we may resume our work to identify, acquire, and conduct research and development of future product candidates, and potentially begin to commercialize any future products that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our financial condition. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our financial condition. If we are unable to bring any of our product candidates or future product candidates through full clinical trials for any reason, or if such product candidates or future product candidates do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

The price of our common stock does not meet the requirements for continued listing on Nasdaq. If we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

The continued listing standards of the Nasdaq Stock Market, or Nasdaq, require, among other things, that the minimum bid price of a listed company's stock be at or above $1.00. If the closing minimum bid price is below $1.00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with Nasdaq's listing rules and, if it does not regain compliance within the grace period, will be subject to delisting. On October 26, 2022, we received a notice from the Nasdaq Listing Qualifications Department notifying us that for 30 consecutive trading days, the bid price of our common stock had closed below the minimum $1.00 per share requirement. In accordance with Nasdaq's listing rules, we were afforded a grace period of 180 calendar days, or until April 24, 2023, to regain compliance with the bid price requirement. In April 2023, we applied for and were granted an additional 180 day compliance period, until October 20, 2023. In connection with our application for that additional grace period, we transferred our listing from the Nasdaq Global Market to the Nasdaq Capital Market effective April 27, 2023 and provided written notice to Nasdaq of our intention to cure the deficiency during this second compliance period by effecting a reverse stock split, if necessary. We have submitted a proposal to our stockholders at our upcoming annual meeting, to be held on June 8, 2023, seeking approval to implement a reverse stock split of our common stock in a ratio that is between 1-for-2 shares to 1-for-5 shares, with the final determination to be made by our Board of Directors. In order to regain compliance, the bid price of our common stock must close at a price of at least $1.00 per share for a minimum of 10 consecutive trading days.

If we do implement a reverse stock split to increase the per share trading price of our common stock, we cannot assure you that the per share trading price of our common stock after such reverse stock split will remain about $1.00 per share. Some stockholders may view a reverse stock split negatively. In addition, the per share trading price of our common stock may decrease due to factors unrelated to a reverse stock split, including our future performance. If we implement a reverse stock split and the per share trading price of the common stock declines, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater. The liquidity of our common stock may also be negatively impacted by a reverse stock split, as there will be fewer shares of our common stock outstanding after a reverse stock split. Moreover, if the per share market price of our common stock does not increase in proportion to the reverse stock split ratio, or following such increase does not maintain or exceed such price, then the value of our Company, as measured by our market capitalization, will be reduced. Any reduction in our market capitalization may be magnified as a result of the smaller number of total shares of common stock outstanding following such a reverse stock split.

We cannot provide any guarantee that we will regain compliance during the grace period or be able to maintain compliance with Nasdaq's listing requirements in the future. If we are not able to regain compliance during the grace period, or any extension of the grace period for which we may be eligible, our common stock will be subject to delisting. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Since we became Neoleukin Therapeutics, Inc., our operations have been primarily limited to organizing and staffing our company, acquiring product and technology rights, discovering and developing novel *de novo* proteins, and undertaking preclinical studies and early clinical development activities. We have not yet obtained regulatory approval for any product candidate. In addition, in November 2022 and March 2023, we announced corporate restructurings resulting in a wind-down of the clinical trial for our first product candidate, NL-201, the suspension of our research and development activities, and a significant reduction in our workforce with the intention of focusing on evaluation of a potential strategic alternatives, which may include a sale, merger, divestiture of assets, licensing or other strategic transaction. Consequently, evaluating our performance, viability or possibility of future success will be more difficult than if we had a longer operating history or approved products on the market.

We currently have no source of product revenue and may never become profitable.

To date, we have not generated any revenues from commercial product sales, or otherwise. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize any products that we may develop, in-license, or acquire in the future. Even if we can successfully achieve regulatory approval for any product candidates or future product candidates, we do not know when any of these products will generate revenue from product sales for us, if at all. Our ability to generate revenue from any of our product candidates or future product candidates also depends on several additional factors, including our or any future collaborators' ability to:

- complete development activities, including the necessary clinical trials;
- complete and submit Biologics License Applications, or BLAs, to the U.S. Food and Drug Administration, or FDA, and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;

- develop a commercial organization capable of sales, marketing, and distribution for any products for which we obtain marketing approval and intend to sell ourselves in the markets in which we choose to commercialize on our own;
- find suitable distribution partners to help us market, sell, and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- achieve market acceptance for our products, if any;
- establish, maintain, and protect our intellectual property rights; and
- attract, hire, and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biological product development, any future product candidates may not advance through development or achieve the endpoints of applicable clinical trials. Therefore, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or trials in addition to those that we initially anticipate for any future product candidate. Even if we can complete the development and regulatory process for any product candidates or future product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we can generate revenues from the sale of any product candidates or future product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

We will require additional capital to finance our operations which may not be available to us on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of future product candidates.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. Our operations have consumed substantial amounts of cash since inception. If we identify and advance any current or future product candidates into clinical trials and launch and commercialize any product candidates for which we receive regulatory approval, we expect research and clinical development expenses, and our selling, general and administrative expenses to increase substantially. In connection with our current strategic initiatives, we believe that our existing cash, cash equivalents, and short-term investments will be sufficient to fund our operating requirements through at least 12 months following the filing date of this Form 10-Q. However, circumstances may cause us to consume capital more rapidly than we anticipate. If we are successful in completing a strategic transaction and able to resume our research and development activities, we will require additional capital for the further development and potential commercialization of future product candidates and may also need to raise additional funds to pursue a more accelerated development of future product candidates.

If we seek to secure additional financing, fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to:

- seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available;
- relinquish, or license on unfavorable terms, our rights to any future product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly delay, scale back, or discontinue the development or commercialization of any of our future product candidates or cease operations altogether.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from resuming our development and commercialization efforts, which will have a material adverse effect on our business, operating results, and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- our ability to identify or acquire additional product candidates for development;
- the initiation, progress, timing, costs, and results of clinical trials for any future product candidates;
- the estimated costs for discontinuing the development of NL-201;
- the clinical development plans we establish for any future product candidates;
- if we in-license or acquire product candidates from third parties, the cost of in-licensing or acquisition;
- the achievement of milestones and our obligation to make milestone payments under our present or any future in-licensing agreements;
- the number and characteristics of product candidates that we discover, or in-license and develop;
- the outcome, timing, and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- the cost to establish, maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- the effects of global macroeconomic trends, including market volatility, instability in the global banking system, supply chain disruptions, inflationary pressures, unemployment rates and impacts of a potential market recession, on our business and financial results;
- the effect of competing technological and market developments;
- the costs and timing of the implementation of commercial-scale outsourced manufacturing activities; and
- the costs and timing of establishing sales, marketing, distribution, and pharmacovigilance capabilities for any product candidates for which we may receive regulatory approval in territories where we choose to commercialize products on our own.

If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our business, results of operations, financial condition and cash flows, and future prospects could be materially adversely affected.

Risks Related to Discovery, Development, and Commercialization

Product candidates in early stages of development may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of, or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Any product candidates that we have are in the early stages of development efforts. We have no products on the market, we have elected to discontinue development of NL-201, we have suspended development of all of our remaining product candidates, which are still in drug discovery stages, and we may not ever obtain regulatory approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA, and have significantly reduced our clinical trial team in connection with the discontinuation of development of NL-201. Before obtaining regulatory approval for the commercial distribution of any future product candidates, we must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Moreover, our development portfolio consists of targets and programs that are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development, and in March 2023 we suspended development of all of our current product candidates to focus on evaluation of strategic alternatives for the Company while reducing operating costs in the near term. If we are able to resume development, or if we are able to acquire or in-license additional product candidates, but we do not receive regulatory approvals for clinical testing and commercialization of such product candidates, we may not be able to continue our operations.

We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any issues that cause or require us to delay or abandon preclinical or clinical trials or delay and/or prevent regulatory approval of or our ability to commercialize product candidates, including:

- preclinical study results showing the product candidate to be less effective than desired or to have harmful or problematic side effects;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours;
- product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologics similar to our product candidates;
- a failure to demonstrate that the dose for the product candidate has been optimized;
- the inability of third-party manufacturers to successfully manufacture our products or to meet regulatory specifications;
- inability of any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials or commercial sales;
- delays in submitting INDs or comparable foreign applications, or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA, the European Medicines Agency, or EMA, or other applicable regulatory authorities regarding the scope or design of our future clinical trials;
- delays in enrolling patients in clinical trials for future product candidates;
- high drop-out rates of patients in our future clinical trial patients;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our future clinical trials;
- inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials;
- supply chain disruptions that may impact our ability to obtain materials for research and development, preclinical or future clinical testing or significantly increase our costs;

- greater than anticipated costs of development, including preclinical studies and clinical trials;
- manufacturing costs, formulation issues, pricing or reimbursement issues or other factors that no longer make a product candidate economically feasible;
- harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials;
- failure to demonstrate a benefit-risk profile acceptable to the FDA, EMA, or other applicable regulatory authorities;
- unfavorable inspection and review by the FDA, EMA, or other applicable regulatory authorities of one or more clinical trial sites or manufacturing facilities used in the testing and manufacture of any of our product candidates;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy, and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of our data by the FDA, EMA, or other applicable regulatory authorities.

Our inability to complete development of, or commercialize our product candidates, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Further, cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for advanced cancers, i.e. third-line or beyond. When cancer is detected early enough, first-line therapy, usually chemotherapy, surgery, radiation therapy, immunotherapy, hormone therapy, or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect that our product candidates will initially be targeted to second- or third-line patients, and that if those product candidates prove to be sufficiently beneficial in those initial trials, we would expect to seek subsequent approval in earlier lines of therapy. Any product candidates we develop, even if approved, may not be successfully approved for earlier lines of therapy, and, prior to any such approvals, we will likely have to conduct additional clinical trials, which are often very lengthy, expensive, and have a significant risk of failure.

Preclinical studies and clinical trials of our product candidates may not be successful, and if we are unable to commercialize these product candidates or experience significant delays in doing so, our business will be materially harmed.

Our business is heavily dependent on our ability to obtain regulatory approval of, and then successfully launch and commercialize, our product candidates. Following a corporate reorganization approved by our Board of Directors in March 2023, we have suspended all research and development activities at the present time to focus on a review of strategic alternatives. Our ability to generate commercial product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of any product candidates we may develop in the future if we are able to resume research and development or acquire or in-licenses other product candidates. If we are able to bring any of our product candidates to clinical trial, they may not be successful in those trials or, even if they are, they may not receive regulatory approval in a timely manner, or at all. Regulatory agencies, such as an FDA Advisory Committee or similar authority, may recommend non-approval or place restrictions on approval, which may also increase costs and delay commercialization. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process. For example, the Oncology Center of Excellence within the FDA has recently advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which maximizes not only the efficacy of a drug but the safety and tolerability as well. This may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection. Other recent Oncology Center of Excellence initiatives include Project FrontRunner, a framework for identifying candidate drugs for initial clinical development in the earlier lines of therapies rather than only after exhausting available treatment options. We are considering these policy changes as they relate to our programs.

Regulatory authorities may approve a product candidate for targets, disease indications, or patient populations that are not as broad as we intended or desired, approve more limited indications than requested, or require distribution restrictions or strong safety language, such as contraindications or boxed warnings. Regulatory authorities may also require Risk Evaluation and Mitigation Strategies, or REMS, or the performance of costly post-marketing clinical trials. Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We expect to seek regulatory approval to commercialize any future product candidates we may bring forward for clinical development both in the United States and in selected foreign countries. In order to market and sell our product candidates in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The approval procedure varies among countries and can involve additional testing. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may be required to expend significant resources to obtain regulatory approval, which may not be on a timely basis or successful at all, and to comply with ongoing regulations in these jurisdictions.

The success of our Neoleukin design process and our future product candidates will depend on many factors, including the following:

- successful completion of necessary preclinical studies to enable the initiation of clinical trials;
- successful enrollment of patients in, and the completion of, our clinical trials;
- obtaining adequate financing to perform the expensive clinical development programs anticipated for approval;

- receiving required regulatory authorizations for the development and approvals for the commercialization of our product candidates;
- establishing and maintaining arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and their components;
- enforcing and defending our intellectual property rights and claims;
- achieving desirable therapeutic properties for our product candidates' intended indications;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with third parties;
- acceptance of our product candidates, if and when approved, by patients, the medical community, and third-party payors;
- achieving appropriate reimbursement, pricing, and payment coverage for our product candidates;
- effectively competing with other therapies, including those that are currently in development; and
- maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory approval.

If we do not achieve any one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Future clinical trials or additional preclinical studies may reveal significant adverse events not seen in our earlier preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, we may be required to revise, pause, delay, or abandon the trials or our development efforts of one or more product candidates altogether, we may be required to have more restrictive labeling, or we may experience the delay or denial of regulatory approval by applicable regulatory authorities. We, applicable regulatory authorities, or IRBs, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Therapies involving cytokines have been known to cause side effects such as neurotoxicity and cytokine release syndrome, and there is no guarantee that these side effects can be avoided through *de novo* protein design.

Additionally, if any of our product candidates receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the product outweigh its risks, which may include, among other things, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by any of our products, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label of such product;
- we may be required to change the way such a product is administered or conduct additional clinical trials;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these developments could materially harm our business, financial condition, and prospects.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory, and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

Development of immunotherapies involves a lengthy and expensive process, with an uncertain outcome, and results of early studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any of our product candidates.

Following the decision in November 2022 to discontinue development of NL-201, all of our product candidates are now in preclinical or earlier development and their risk of failure is high. Moreover, in March 2023, we decided to suspend our research and development activities, and any future product candidates will depend on a resumption of research and development activities and may come from an acquisition or in-licensing of other assets. If we are able to resume the development of one or more product candidates, it is impossible to predict when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex, and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and the outcome is inherently uncertain. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Failure can occur at any time during the clinical trial process, or we may decide, as we did with NL-201, to stop development for strategic reasons at any time. The results of preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials, and differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier trials, and we could face similar setbacks. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products, and there can be no assurance that any of our clinical trials will ultimately be successful or support clinical development of our product candidates.

Commencement of any future clinical trials for our product candidates is subject to finalizing the trial design and receiving approval from the FDA to proceed with clinical testing or similar approval from the EMA or other comparable foreign regulatory authorities. Even after we submit our IND or comparable submissions in other jurisdictions, if the FDA, EMA, or comparable foreign regulatory authorities disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, we may be required to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials.

We may encounter substantial delays in the commencement or completion of our clinical trials, or may be required to terminate or suspend such trials, which could result in increased costs to us or delay or limit our ability to generate revenue, adversely affecting our commercial prospects.

If we are able to move any of our product candidates to the clinical trial stage, we may experience delays in initiating or completing clinical trials or may experience numerous unforeseen events during, or as a result of, any such future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any future product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to obtain regulatory authorizations to commence a clinical trial;
- we may experience issues in reaching a consensus with regulatory authorities on trial design;
- regulators or institutional review boards, ethics committees, FDA, EMA, or other applicable regulatory authorities, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from trial protocol or drop out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, which in turn may cause us to decide, or regulators to require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial, or may be adversely impacted by global supply chain issues;
- we may be unable to obtain or manufacture sufficient quantities of our product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates; and
- we may fail to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other molecules in the same class as our product candidate.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board, or the DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or other reasons related to our overall business strategy. For example, prior to our discontinuation of development of NL-201, NL-201 was subject to an FDA clinical hold, which was later lifted. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA, or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or obtaining marketing approvals. We do not know whether we will be able to bring any of our product candidates forward to clinical trial and, if we do, if any of our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our future clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, CROs, and clinical trial sites to ensure the proper and timely conduct of our future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in future clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

If we are unable to enroll a sufficient number of patients for our future clinical trials, it would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing if needed.

Preliminary, topline, and interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures, and such changes in the final data may be material.

From time to time, we may publish preliminary or topline data from our recently terminated or future clinical trials, which is based on a preliminary analysis of then-available data. Those results and any related findings and conclusions are subject to change following a more comprehensive review of the more complete data related to the particular study or trial. 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 preliminary or topline results that we report may differ from future results of the same studies or clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data we previously published. Results from prespecified interim analyses that we may conduct are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, preliminary and topline data and prespecified interim analyses should be viewed with caution until the final data are available. Adverse differences between preliminary, topline, or interim data and final data could significantly harm our reputation and business prospects.

Failure to obtain regulatory approval would prevent any future product candidates from being marketed.

In order to market and sell our products, we must obtain marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval differs substantially from jurisdiction to jurisdiction. In many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Approval by a single regulatory authority does not ensure approval by other regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities. A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our future product candidates by regulatory authorities, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of, and commercialization of, our future product candidates and affect the prices we may obtain.

The regulations that govern, among other things, marketing approvals, coverage, pricing, and reimbursement for new drug products vary from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our future product candidates, restrict or regulate post-approval activities, and affect our ability to successfully sell any product candidates for which we obtain marketing approval.

In the United States in recent years, Congress has considered reductions in Medicare reimbursement for drugs administered by physicians. The Centers for Medicare and Medicaid Services, or CMS, the agency that administers the Medicare program, also has the authority to revise reimbursement rates and to implement coverage restrictions for drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of, and reimbursement for, any approved products, which in turn could affect the price we can receive for those products. For example, on September 9, 2021, the Biden administration published a wide-ranging list of policy proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices, disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the IRA in August 2022, which will, among other things, allow the U.S. Department of Health and Human Services, or HHS, to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation.

In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in establishing their own coverage polices and reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Affordable Care Act in an effort to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. The Affordable Care Act, among other things, also expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program, imposed a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products, and enacted substantial provisions affecting compliance, which may affect our business practices with healthcare practitioners. Certain provisions of the Affordable Care Act have been subject to judicial and Congressional challenges to repeal or replace certain aspects of the Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the Affordable Care Act and in turn our business, prospects, financial condition, or results of operations.

Other legislative measures impacting federal expenditures on health care may also have an adverse impact on our business. For example, on August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension followed by reduction from May 1, 2020 through June 30, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. In addition, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Furthermore, in the past few years there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, including Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer's patient programs, and reform government program reimbursement methodologies for drug products. We cannot be sure whether additional legislative changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our future product candidates, if any, may be.

In the United States, the European Union and other potentially significant markets for our future product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional coverage, pricing, and reimbursement controls in the European Union will put additional pressure on product coverage, pricing, reimbursement, and utilization, which may adversely affect our business, results of operations, financial condition, cash flows, and future prospects. These pressures can arise from various sources, including but not limited to, rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies, and pricing in general.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Laws and regulations governing international operations may preclude us from developing, manufacturing, and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

As we expand our operations outside of the United States, we must comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We must also comply with U.S. laws applicable to the foreign operations of U.S. businesses and individuals, such as the Foreign Corrupt Practices Act, or FCPA. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment, or offering anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because in many countries hospitals are operated by the government, and therefore doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations, and executive orders also restrict the use and dissemination outside the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Even if we are able to commercialize our future product candidates, the products may not receive coverage and adequate reimbursement from third-party payors, which could harm our business.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers, health maintenance organizations, and third-party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our future product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what that level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, obtaining coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based in part on existing reimbursement amounts for lower cost drugs or may be bundled into the payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage and reimbursement determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement will be obtained or applied consistently. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

We have never marketed a drug before. If we are able to identify and develop or acquire a product candidate that is ultimately approved for sale but are unable to establish an effective sales force and marketing infrastructure or enter into acceptable third-party sales and marketing or licensing arrangements, we may be unable to generate any revenue.

We do not currently have an infrastructure for the sales, marketing, and distribution of pharmaceutical drug products, and the cost of establishing and maintaining such an infrastructure may exceed the cost-effectiveness of doing so. In addition, following the decision to discontinue development ofNL-201 in November 2022, we do not have any product candidates in clinical development. If we are able to successfully advance any of our future product candidates through clinical development to approval by the FDA and comparable foreign regulatory authorities, we will need to either build our sales, marketing and distribution operations, including managerial and other non-technical capabilities, or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing team may not be successful in commercializing our product candidates, which would negatively affect our ability to generate revenue.

We may not be successful in our efforts to expand our pipeline of product candidates and develop marketable products.

The success of our business depends in part upon our ability to discover, develop, and commercialize products, and we may fail to identify potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial, and human resources.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must choose the product candidates on which we focus our research and development efforts, which may require us to forgo or delay pursuit of opportunities with other product candidates that may ultimately have greater commercial potential. For instance, prior to November 2022, we were primarily focused on developing our lead product candidate, NL-201, and invested significant resources in the preclinical and Phase 1 clinical trial for that product candidate, but ultimately decided that our limited resources would be better spent on early stage research of the next generation *de novo* protein design and so elected to discontinue development of NL-201 even though that product candidate had demonstrated on target activity in reviews of preliminary data. In March 2023, our Board of Directors determined that continued investment in early stage *de novo* protein design was not in the best interests of our stockholders and suspended further allocation of our resources to our research and development efforts in order to focus our financial and managerial resources on pursuing a potential strategic alternative. Our resource allocation decisions may require us to make strategic decisions, which in turn may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We face substantial competition, including companies developing novel treatments and technology platforms in oncology. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of drugs is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies, and emerging biotechnology companies, as well as with technologies and product candidates being developed at academic institutions, governmental agencies, and other public and private research institutions. Our competitors have developed, are developing, or will develop product candidates and processes competitive with our product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel technology platforms that enter the market. We believe that a significant number of products are currently under development and may become commercially available in the future for the treatment of conditions for which we are trying, or may try, to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical, and interleukin and immunoregulatory therapeutics fields. Competition from many sources exists or may arise in the future. Our competitors include larger and better funded biopharmaceutical, biotechnological, and therapeutics companies, including companies focused on oncology therapeutics, as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions. Some of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our future partners. In addition, these companies compete with us in recruiting scientific and managerial talent.

Our success will depend partially on our ability to develop and commercialize therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, or less expensive than the therapeutics we develop.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales, and supply resources or experience than we have. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage, and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive, or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Any product candidates we develop that are regulated as biological products, or biologics, may be subject to competition sooner than anticipated.

Our product candidates may face competition from other products that are the same as or similar to ours. For any product candidates that are biological products, if the FDA or comparable foreign regulatory authorities approve biosimilar versions of those product candidates, or such authorities do not grant our products appropriate periods of regulatory exclusivity, the sales of those products could be adversely impacted.

The Biologics Price Competition and Innovation Act of 2009, or the BPCIA, was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar biological products (both highly similar and interchangeable biosimilar biological products). The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the first licensure date of the reference product licensed under a BLA. The law is complex and some provisions are still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

A biological product submitted for licensure under a BLA is eligible for a period of exclusivity that commences on the date of its licensure, unless its date of licensure is not considered a date of first licensure because it falls within an exclusion under the PBCIA. Our biological product candidates may qualify for the BPCIA's 12-year period of exclusivity, but there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. There is also a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. For example, there have been efforts to decrease this period of exclusivity to a shorter timeframe—future proposed budgets, international trade agreements, and other arrangements or proposals may affect periods of exclusivity. Most states have enacted substitution laws that permit substitution of only interchangeable biosimilars. The extent to which a highly similar biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If we decide to pursue accelerated approval for any of our product candidates, it may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. If we are unable to obtain approval under an accelerated pathway, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approvals.

In the future, we may decide to pursue accelerated approval for one or more of our product candidates. Under the FDA's accelerated approval program, the FDA may approve a drug or biological product for a serious or life-threatening disease or condition that provides a meaningful advantage over available therapies based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. For products granted accelerated approval, post-marketing confirmatory trials are required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence, and the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If we were to pursue accelerated approval for a product candidate for a disease or condition, we would do so on the basis that there is no available therapy for that disease or condition. If standard of care were to evolve or if any of our competitors were to receive full approval on the basis of a confirmatory trial for a drug or biological product for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, the disease or condition would no longer qualify as one for which there is no available therapy, and accelerated approval of our product candidate would not occur. Many cancer therapies rely on accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials.

Moreover, the FDA may withdraw approval of any product candidate approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with such product;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, the Oncology Center of Excellence has recently announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post-marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies. Furthermore, in addition, Congress is considering various proposals to potentially make changes to the accelerated approval pathway, including proposals to increase the likelihood of withdrawal of approval in such circumstances.

Risks Related to Our Reliance on Third Parties

We rely on and expect to continue to rely on third parties to conduct certain of our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations, and prospects.

We rely on third-party clinical investigators, CROs, clinical data management organizations, and consultants to assist or provide the design, conduct, supervision, and monitoring of preclinical studies and clinical trials of our product candidates, including certain third parties who will continue to assist in the wind-down of our NL-201 Phase 1 clinical trial. To the extent we rely on these third parties, we will have less control over the timing, quality, and other aspects of certain preclinical studies and clinical trials than we would have had we conducted them on our own. Although we have agreements governing the activities of third parties, consultants are not and will not be our employees, and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful, or timely in conducting our development work, preclinical studies or clinical trials, which could result in such work being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy applicable legal and regulatory requirements or meet expected deadlines, our development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The FDA generally requires preclinical studies to be conducted in accordance with Good Laboratory Practices, or GLPs, and clinical trials to be conducted in accordance with Good Clinical Practices, or GCPs, including for designing, conducting, recording, and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. If we or any of our third-party service providers fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional studies. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

We rely on and expect to continue to rely on third-party manufacturers and suppliers to supply components of our product candidates. The loss of our third-party manufacturers or suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution, or quality testing. We therefore must rely on third-party contract manufacturers to manufacture bulk drug substances, drug products, raw materials, samples, components, or other materials and reports, and conduct fill-finish services. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. Our third-party manufacturers may prioritize another customer's needs in front of ours, especially in the event of a global pandemic. Additionally, raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects, may be in short supply, and may significantly increase in price. There can be no assurance that our preclinical and clinical development product supplies will not be limited, or that they will be available at acceptable prices, if at all. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, global supply chain disruption may hamper our ability to source materials needed for our research and development, including our preclinical trial programs, may increase our costs due to scarcity or may require us to buy materials on spec in advance of when we need it, which may impact our ability to budget or forecast expenditures, and may also hamper our ability to complete our preclinical trials on time, or at all.

The manufacturing process for a product candidate is subject to review by the FDA, EMA, or other applicable regulatory authorities. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices, or cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or other applicable regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates and approval may be delayed. Moreover, although we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements, we are responsible for ensuring that our products comply with regulatory requirements. If any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do in a timely manner or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to repeat some of the development program. The costs and delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA, EMA, or other applicable regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance, and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs, or maintain a compliance status acceptable to the FDA, EMA, or other applicable regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. For example, the global outbreak of the COVID-19 pandemic resulted in extended shutdowns of businesses in the United States, Canada, and many other countries and had ripple effects to businesses around the world. Global health concerns, such as the COVID-19 pandemic, and the ensuing impacts on financial markets and supply chain logistics could also result in adverse effects to our manufacturing operations, including our ability to source raw materials and reagents. If our contract manufacturers were to encounter any of these difficulties, our ability to provide our product candidates to patients in preclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

Our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our products for patients, if approved, could be delayed or stopped.

Our product candidates are biopharmaceuticals, and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated, and subject to multiple risks. Our contract manufacturers must comply with legal requirements, cGMPs, and guidelines for the bulk manufacturing, fill-finish services, packaging, and storage of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our contract manufacturers may have limited experience in the manufacturing of cGMP batches.

Manufacturing biopharmaceuticals is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. 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 at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our third-party manufacturers' facilities are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny approval of our application until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. For example, certain resins used in the manufacture of biopharmaceuticals have recently experienced limited availability. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product, or provide fill-finish services, to specifications acceptable to the FDA, EMA, or other applicable regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations, and prospects.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task, and our third-party manufacturers may not have the necessary capabilities to complete the implementation, manufacturing, and development process. If we are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. Our *de novo* protein product candidates may not demonstrate sufficient long-term stability to support a BLA submission or obtain approval, or the product shelf life may be limited by stability results. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse development affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, prospects, financial condition, and results of operations.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes 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 future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

We may, in the future, seek to enter into collaborations with other third parties for the discovery, development, and commercialization of our product candidates. If our collaborators cease development efforts under our collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products, and we may never receive milestone payments or future royalties under these agreements.

We expect a significant portion of our future revenue and cash resources to be derived from collaboration agreements or other similar agreements into which we may enter in the future for research, development, and commercialization of other therapeutic technologies or product candidates. Biopharmaceutical companies are our likely future collaborators for any marketing, distribution, development, licensing, or broader collaboration arrangements. If we fail to enter into future collaborations on commercially reasonable terms, or at all, or such collaborations are not successful, we may not be able to execute our strategy to develop certain targets, product candidates, or disease areas that we believe could benefit from the resources of either larger biopharmaceutical companies or those specialized in a particular area of relevance.

Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development services, and resulting options to acquire any licenses of successful product candidates, and the achievement of milestones, contingent payments, and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our collaboration agreements will be substantially less than expected.

With respect to future collaboration agreements, we expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates may pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished, or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Moreover, to the extent that any of our future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may have conflicts with our collaborators that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations, or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a collaborator to pay us milestone payments or royalties we believe are due to us under a collaboration, which could require us to raise additional capital; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses, and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, and out- or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. In addition, a significant number of recent business combinations among large pharmaceutical companies has resulted in a reduced number of potential future strategic partners. Our collaborators may 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. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA, or other applicable regulatory authorities, 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. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing, and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

We cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition, or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty, and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership, and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations, and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

Risks Related to Our Business and Operations

We may experience difficulties in preparing our operations for potential future growth, which could adversely affect our business.

As of March 31, 2023, we had approximately 12 full-time employees, after taking into account a further corporate restructuring that we announced in March 2023, that reduced our headcount by approximately 70% of the workforce in place at that time and which was largely completed prior to March 31, 2023. We have also announced a shift to focusing on strategic alternatives for the Company and a suspension of our research and development programs in connection with that restructuring. If we are successful in completing a strategic transaction in the future, we expect that we will need to invest in additional growth for the Company, which may include potentially expanding our development and regulatory capabilities, contracting with other organizations to provide manufacturing and other capabilities for us, and managing additional relationships with collaborators or partners, suppliers, and other organizations. Our ability to prepare for future growth will require us to continue to improve our operational, financial, and management controls, reporting systems, and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.

We have experienced high turnover in the past year, and will rely on our remaining employees to execute any strategic alternatives the Board may approve under the current plan. The changes in our strategic direction and in our workforce may make retention of our current personnel both more important and more challenging. We cannot guarantee that we will be able to retain key employees necessary to carry out our revised strategic plan, and if such employees were to leave, we may not be able to identify and hire the personnel we need to replace them. Our success largely depends on the continued service of key management, advisors, and other specialized personnel. We currently do not maintain key person insurance on any of these individuals. The loss of one or more members of our management team or other key employees or advisors could delay any strategic initiative we may elect to pursue, and have a material and adverse effect on our business, financial condition, results of operations, and prospects. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty.
Further, the reductions in workforce announced in November 2022 and March 2023 may also make retention of our current personnel both more important and more challenging. These workforce reductions resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel.

We also recently underwent a leadership transition, which may be viewed negatively by employees, investors and/or our strategic partners. Moreover, any attrition associated with this transition could significantly delay or prevent the achievement of certain business objectives, and adversely impact our stock price.

If we are successful in completing a strategic transaction, we will need to retain the key managers, scientists and personnel necessary for the future growth of the Company following such transaction. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We also face competition for personnel from other companies, universities, public and private research institutions, government entities, and other organizations. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical, and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation, and commercialization. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates will be limited which could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Our relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors are and will be subject, directly and indirectly, to applicable anti-kickback, fraud and abuse, privacy, transparency, and other healthcare laws and regulations, which could expose us to penalties, including without limitation, civil, criminal, and administrative sanctions, civil penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, integrity obligations, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations.

As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid, or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our future arrangements with third-party payors and customers who are in a position to purchase, recommend, and/or prescribe our product candidates for which we obtain marketing approval. These broadly applicable fraud and abuse and other healthcare laws and regulations may constrain our future business or financial arrangements and relationships with healthcare professionals, principal investigators, consultants, customers, and third-party payors and other entities, including our marketing practices, educational programs, and pricing policies. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which, among other things, prohibits persons from knowingly and willfully soliciting, offering, receiving, providing, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, and, among other things, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent, or from knowingly making a false statement to improperly avoid, decrease, or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items, or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as health plans, healthcare clearinghouses, and healthcare providers;

- the federal Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), physician assistants, certain types of advance practice nurses, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members; and
- analogous local, state, and foreign laws and regulations, including: state anti-kickback and false claims laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; local, state, and foreign laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities and file reports relating to pricing and marketing information and/or register their pharmaceutical sales representatives; and local, state, and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our internal operations and any business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Recent healthcare reform legislation has also strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute, such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to penalties, including without limitation, significant civil, criminal, and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity obligations, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any physicians or other healthcare 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. Moreover, we expect there will continue to be federal, state, local and foreign laws and regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future drug candidates and programs because our research and development pipeline may be insufficient, our drug candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our drug candidates could also delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market.

Our employees, independent contractors, principal investigators, CROs, consultants, vendors, and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, CROs, consultants, vendors, and collaboration partners, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state data privacy and security, fraud and abuse and other healthcare laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Specifically, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct for our directors, officers, and employees, but it is not always possible to identify and deter misconduct by employees and other third parties, 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, results of operations, financial condition, and cash flows from future prospects, including the imposition of significant fines or other sanctions.

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

We will face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercialize any of our product candidates. If we cannot successfully defend ourselves against claims that our 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 candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any product candidates that we may develop.

We currently maintain product liability insurance coverage for our clinical trials, but the amount may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage for each new clinical trial we begin and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders, and harm our business, results of operations, financial condition, and cash flows and future prospects.

We may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our future product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our stockholders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets, or investors. Furthermore, future acquisitions could pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products, or technologies;
- increases to our expenses;
- the failure to discover undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete any acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition.

Our ability to use our U.S. net operating losses to offset future taxable income will be subject to Section 382 limitations and may be limited by other factors.

As of December 31, 2022, we had U.S. net operating losses, or NOLs, of $124.9 million, for federal tax purposes, for which we have recorded a full valuation allowance, and R&D credit carryovers of $3.9 million, which may be offset by future taxable income. The R&D credit carryforwards and certain of our NOL carryforwards will expire in various years beginning in 2028 if not used. Unused losses incurred in taxable years beginning on or prior to December 31, 2017 will carry forward to offset future taxable income, if any, until such unused losses expire. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, unused U.S. federal NOLs generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal NOLs (particularly those generated in taxable years beginning after December 31, 2020) is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. Furthermore, use of certain of our NOLs and R&D credit carryforwards will be subject to annual limitations on their use as a result of ownership changes under the rules of Sections 382 and 383 of the Internal Revenue Code, or the Code that have historically occurred. Based on our Section 382 analysis to date, we underwent ownership changes in August 2015 and August 2019. As a result of these ownership changes, we believe that certain of our NOLs will be likely to expire before they are able to be used under Section 382. In addition, we may experience ownership changes in the future as a result of future changes in our stock ownership, some of which changes are outside of our control, and as a result, our ability to utilize NOL and R&D credit carryforwards could become further limited under Sections 382 and 383, and the tax benefits related to our NOLs and R&D credits may be diminished or lost. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition, cash flow and future prospects. As a result, even if we attain profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

Risks Related to Intellectual Property

If we are not able to obtain, maintain, and enforce patent protection and other intellectual property rights for our product candidates, our Neoleukin design process technology, or other proprietary technologies we may develop, the development and commercialization of our product candidates may be adversely affected.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. Under our License Agreement with the University of Washington, dated July 8, 2019, as amended on October 29, 2020, effective July 24, 2020, and again on December 27, 2021, effective December 15, 2021, we have an exclusive license to develop and commercialize products covered by patent applications with claims covering the composition of matter of certain molecule families as well as methods of using the computational algorithms that form the basis of the Neoleukin design process. However, we may not be able to apply for patents on certain aspects of our product candidates or methods in a timely fashion or at all. Further, we may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce, and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing, and prosecution of all patent applications that we license from third parties, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Patents we currently hold, or in the future may obtain, may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our future issued or granted patents will not later be found to be invalid or unenforceable or that any future issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a large number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The process of obtaining patents is time consuming, expensive and sometimes unpredictable.

Once granted, for a given period after allowance or grant patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation action in court or before patent offices or similar proceedings, during which time third parties can raise objections against such initial grant. Such proceedings may continue for a protracted period of time and an adverse determination in any such proceedings could reduce the scope of the allowed or granted claims thus attacked, or could result in our patents being invalidated in whole or in part, or being held unenforceable, which could allow third parties to commercialize our product candidates and compete directly with us without payment to us. In addition, there can be no assurance that:

- others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors, or our future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our licensors, or our future collaborators are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed;
- any issued patents that we own or have licensed or that we may license in the future will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop additional proprietary technologies that are patentable;
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations, and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

If we or our licensors or collaborators fail to maintain patent applications and later-issued patents covering our product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations, and prospects. In addition, if the breadth or strength of protection provided by our patent applications and later-issued patents is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We could be required to incur significant expenses to strengthen our intellectual property rights, and our intellectual property rights may be inadequate to protect our competitive position.

The patent prosecution process is expensive and time-consuming, and we or our future potential licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future potential licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We may also elect not to continue pursuing prosecution of our patents in one or more countries if we determine that the value of the protection we are seeking is outweighed by the cost, or if we determine that our resources would be better allocated in a different way. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. 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 expiration of the patent. However, the applicable authorities, including the FDA 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 this occurs, 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. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our patent applications and the enforcement or defense of our issued patents may be impacted by the application of or changes in U.S. and foreign standards.

The standards that the USPTO and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our product candidates. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the validation enforceability, or term of our patent. For example, the U.S. Supreme Court has recently modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U.S. patent system have come into force under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, which was signed into law in September 2011. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

While we cannot predict with certainty the impact the Leahy-Smith Act or any potential future changes to the U.S. or foreign patent systems will have on the operation of our business, the Leahy-Smith Act and such future changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

Obtaining and maintaining any patent protection we may receive will depend on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our future licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may be subject to claims by third parties claiming ownership of what we regard as our own intellectual property, which may prevent, delay or otherwise interfere with our product discovery and development efforts.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. In addition, third parties may from time to time make claims over what we regard as our intellectual property, or we may get into disputes with licensors or licensees of our intellectual property rights over the interpretation of the license terms. If a third party claims that we infringe, misappropriate or otherwise violate their intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims that, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights or proprietary technology to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates;

- the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time; and
- there could 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 have a substantial adverse effect on the price of our common stock.

Our licensors may have the right to terminate their license agreements with us or pursue damages or other legal remedies. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful and could result in a finding that such patents are unenforceable or invalid.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. If a defendant were to prevail on a legal assertion of invalidity and/ or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Conversely, we may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings), or we may choose to challenge a third party's patent in patent opposition proceedings in the Canadian Intellectual Property Office, or CIPO, the European Patent Office, or EPO, or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, CIPO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. Any of the foregoing could have a material adverse effect on our business financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturing organizations, consultants, advisors and other third parties. We also generally enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not currently clear how the FDA's disclosure policies may change in the future, if at all.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or future collaborators may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Intellectual property rights do not necessarily provide sufficient protection of our technology or address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- It is possible that there are prior public disclosures that could invalidate our owned or exclusively licensed patents, as the case may be, or parts of our owned or exclusively licensed patents.
- It is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours.
- It is possible that our owned or exclusively licensed patents or patent applications omit one or more individuals that should be listed as inventors or include one or more individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or such omitted individuals may grant licenses to third parties.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and exclusive licenses.

The growth of our business may depend in part on our ability to acquire, license or use third-party proprietary rights.

For example, our product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties we identify as necessary or important in our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be nonexclusive, which means our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

We sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Inventions contained within some of our in-licensed patents and patent applications may have been made using U.S. government funding or other non-governmental funding. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations. We rely on our licensors to ensure compliance with applicable obligations arising from such funding, such as timely reporting, an obligation associated with in-licensed patents and patent applications. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents. For example, the government could have certain rights in such in-licensed patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non-commercial purposes. In addition, our rights in such in-licensed government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly.

Risks Related to Ownership of Our Common Stock

Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance, resulting in substantial losses for investors.

The trading price of our common stock has been, and is likely to continue to be, volatile for the foreseeable future. The trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials, including both safety and efficacy, of any of our current or future product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our future product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions, such as market volatility and economic uncertainty due to rising interest rates, instability in the global banking system, inflation, and the ongoing conflict in Ukraine.

In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks or any of a broad range of other risks, including those described in this "Risk Factors" section and elsewhere in this report, could have a dramatic and material adverse impact on the market price of our common stock.

Some provisions of our charter documents 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.

Provisions in our amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that:

- permit our Board to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our Board, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by the Board or by such person or persons requested by a majority of the Board to call such meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. 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 the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

The exclusive forum provisions in our certificate of incorporation and bylaws may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims.

Our certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or the DGCL, our certificate of incorporation, or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act of 1933, as amended, or the Securities Act, inasmuch as 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 rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

In April 2020, we amended and restated our bylaws to provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in ourcertificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

We are no longer an "emerging growth company," however, we are still a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

Although we ceased to be an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, on December 31, 2019, we are a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. As a smaller reporting company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We cannot predict if investors will find our common stock less attractive because we may rely on these 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.

We may become a "large accelerated filer" and have to comply with more rigorous disclosure and reporting requirements and regulations.

If we cease to be a "smaller reporting company" or a "non-accelerated filer" in the future, we may be subject to certain disclosure requirements that are applicable to other public companies that had not been applicable to us previously. These requirements include:

- compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting once we are an accelerated filer or large accelerated filer;
- compliance with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and
- full disclosure and analysis obligations regarding executive compensation.

There can be no assurance that we will be able to comply with the applicable regulations in a timely manner, if at all. Inability to comply with these regulations could impact our ability to raise additional capital.

General Risk Factors

We may be subject to securities litigation, which is expensive and could divert management attention.

The trading price of our common stock has been and will continue to be volatile. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our principal stockholders, directors and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates together beneficially own a majority of our outstanding voting stock. These stockholders are able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders are able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our business, results of operations, financial condition and cash flows and future prospects, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures and that we furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we are not an accelerated filer or large accelerated filer, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 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 and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we fail to identify and to remediate any significant deficiencies or material weaknesses that may be identified, or encounter problems or delays in the implementation of internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Stock Market, or Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, 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. 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 or insufficient disclosures due to error or fraud may occur and not be detected.

Our internal computer and information systems, or those used by our CROs, or other contractors or consultants, may fail or suffer security incidents (e.g., cyber-attacks) or other technical failures, which could result in a material disruption of our development programs and may result in extensive and costly legal compliance requirements.

Our *de novo* protein technology depends on sophisticated computational facilities and storage of vast amounts of data which could be lost or stolen. In the ordinary course of our business, we collect, store, and transmit confidential information, including intellectual property, proprietary business information and personal information. Despite the implementation of appropriate security measures, our internal computer and information systems and those of our current and any future CROs, and other contractors or consultants may become vulnerable to damage from security incidents (such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or information technology incidents caused by threat actors, technological vulnerabilities or human error), natural disasters, terrorism, war, including the recent conflict between Russia and Ukraine, and telecommunication and electrical failures.

While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach 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 significantly delayed.

Our internal and outsourced information technology systems and infrastructure are also vulnerable to damage from natural disasters, terrorism, war, including the ongoing conflict in Ukraine, telecommunication and electrical failures. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud-based systems during the COVID-19 pandemic, could compromise our ability to perform our day-to-day operations, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

Although we devote resources to protect our information systems, we realize that cyberattacks resulting in a security incident are a threat, and there can be no assurance of our efforts will prevent information security breaches that would result in business, legal, financial, or reputational harm to the Company, or would have a material adverse effect on our results of operations and financial condition. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. The COVID-19 pandemic is generally increasing the attack surface available to criminals, as more companies and individuals, including many of our service providers, work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing.

Federal, state, and foreign government requirements include obligations of companies to notify regulators and/or individuals of security breaches involving personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a security breach could impact our reputation and cause us to incur significant costs. Any failure to prevent or mitigate security breaches or improper access to, use, disclosure or other misappropriation of our data or consumers' personal data could result in significant legal liability, such as under state breach notification laws, federal law (including HIPAA/HITECH), and international law (e.g., GDPR). Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight. Our failure to comply with such laws or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, member base and revenue. Further, if we are unable to generate or maintain access to essential patient samples or data for our research and development and manufacturing activities for our programs, our business could be materially adversely affected.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, global health crises such as the COVID-19 pandemic and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We do not carry insurance for all categories of risk that our business may encounter. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters. Further, any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, results of operations, financial condition and cash flows from future prospects.

Unfavorable global economic conditions or other geopolitical developments could adversely affect our business, financial condition, stock price, and results of operations.

In addition, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis of 2007-2008 caused extreme volatility and disruptions in the capital and credit markets. Likewise, the capital and credit markets may be adversely affected by the recent conflict between Russia and Ukraine, and the possibility of a wider European or global conflict, and global sanctions imposed in response thereto. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Further, the conflict in Ukraine could increase incidences of cybersecurity attacks against companies in the United States as retaliation for sanctions levied against Russia, which could increase our risk of being the subject of such an attack. We cannot anticipate all of the ways in which the foregoing, and the current economic climate, financial market conditions and geopolitical developments generally, could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

Moreover, there has been recent turmoil in the global banking system. For example, in March 2023, one of our banking partners, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. On March 27, 2023, First-Citizens Bank & Trust Company assumed all of SVB’s customer deposits and certain other liabilities and acquired substantially all of SVB's loans and certain other assets from the FDIC. While we only had a minimal amount of our cash directly at SVB and, since that date, the FDIC has stated that all depositors of SVB will be made whole, and First-Citizens Bank & Trust Company has assumed our deposits from SVB, there is no guarantee that the federal government would guarantee all depositors if such financial institutions were to fail, as they did with SVB depositors, in the event of further bank closures and continued instability in the global banking system.

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

As a public company, we have incurred and will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses will likely increase even more given we are no longer an “emerging growth company.” We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time-consuming and costly. The increased costs will increase our net loss. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. 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.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

We have in the past and may in the future grant rights to some of our stockholders that require us to register the resale of our common stock or other securities on behalf of these stockholders and/or facilitate public offerings of our securities held by these stockholders, including in connection with potential future acquisition or capital-raising transactions. For example, in connection with our public offering of common stock on September 19, 2016, we entered into a registration rights agreement with the Baker Entities that together, based on information available to us, collectively beneficially owned approximately 45.1% of our common stock as of September 19, 2016. Under the registration rights agreement, we agree that, if at any time and from time to time after December 19, 2016, the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act, we would be obligated to effect such registration. On January 6, 2017, pursuant to the registration rights agreement, we registered for resale, from time to time, up to 10,536,092 shares of our common stock held by the Baker Entities. Our registration obligations under this registration rights agreement cover all shares now held or hereafter acquired by the Baker Entities, would be in effect for up to ten years, and would include our obligation to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future. If the Baker Entities or any other holders of registration rights with respect to our common stock, by exercising their registration and/or underwriting rights or otherwise, sell a large number of our shares, or the market perceives that the Baker Entities or such holders intend to sell a large number of our shares, this could adversely affect the market price of our common stock. We have registered all currently reserved shares of common stock that we may issue under our equity compensation plans and intend to register in the future any additional reserved or issued shares of common stock. These registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We have also filed a shelf registration statement covering the sale of up to $400.0 million of any combination of our common stock, preferred stock, debt securities, or warrants and may conduct one or more sales of securities pursuant to such registration statement, from time to time. In November 2021, we entered into an ATM “at-the-market” Equity Offering Sales Agreement, or Sales Agreement, with BofA Securities, Inc., or BofA, pursuant to which, from time to time, we may offer and sell through BofA up to $40.0 million of the common stock registered under the shelf registration statement pursuant to one or more “at the market” offerings. Sales of our common stock under the Sales Agreement with BofA could be subject to business, economic or competitive uncertainties and contingencies, many of which may be beyond our control, and which could cause actual results from the sale of our common stock to differ materially from expectations.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, including the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our stockholders. New investors could also gain rights, preferences, and privileges senior to those of holders of our common stock.

Pursuant to our 2014 Equity Incentive Plan, as amended, or 2014 Plan, our compensation committee is authorized to grant equity-based incentive awards to our directors, executive officers, and other employees and service providers, including officers, employees and service providers of our subsidiaries and affiliates. Future option grants and issuances of common stock under our 2014 Plan may have an adverse effect on the market price of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, or our business. If one or more of the securities or industry analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Number	Description
EX-10.1	Separation Agreement dated March 31, 2023, by and between Neoleukin Therapeutics, Inc. and Priti Patel.
EX-10.2	Separation Agreement dated March 6, 2023 and effective March 31, 2023, by and between Neoleukin Therapeutics, Inc. and Jonathan Drachman.
EX-10.3	Employment Agreement Amendment dated as of April 3, 2023 and effective March 31, 2023, by and between Neoleukin Therapeutics, Inc. and Donna Cochener.
EX-10.4	Employment Agreement dated August 3, 2023 by and between Neoleukin Therapeutics, Inc. and Sean Smith.
EX-10.5	Employment Agreement Amendment dated as of April 3, 2023 and effective March 31, 2023, by and between Neoleukin Therapeutics, Inc. and Sean Smith.
EX-31.1	Certification of Interim Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a).
EX-31.2	Certification of Interim Chief Financial Officer (Principal Financial Officer) pursuant to Rule 13a-14(a).
EX-32.1#	Certification of Interim Chief Executive Officer and Interim Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
#	This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

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.

Neoleukin Therapeutics, Inc.
(Registrant)

Date: May 8, 2023

/s/ Donna M. Cochener

Donna M. Cochener
Interim Chief Executive Officer
(Principal Executive Officer)

Neoleukin Therapeutics, Inc.
(Registrant)

Date: May 8, 2023

/s/ Sean Smith

Sean Smith
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

SEPARATION AGREEMENT AND RELEASE

This Separation Agreement and Release (this "**Agreement**") is made and entered into by and between Priti Patel, M.D. ("**Employee**") and Neoleukin Therapeutics, Inc. (the "**Company**"). The parties agree as follows:

1. **Separation Date**. Employee acknowledges that the last date of Employee's employment relationship with or service to the Company or any of its Affiliates in any capacity is March 31, 2023 (the "**Separation Date**"). Employee claims and will claim no further right to employment by Company or its Affiliates beyond the Separation Date. For purposes of this Agreement, "**Affiliate**" means any entity currently existing or subsequently organized or formed that directly or indirectly controls, is controlled by, or is under common control with the Company, whether through the ownership of voting securities, by contract, or otherwise. By signing below, Employee acknowledges and agrees that Employee's termination constitutes a termination without "Cause" unrelated to a "Change of Control" within the meaning of Section 6.2 of Employee's Executive Employment Agreement with the Company dated April 14, 2021 (the "***Employment Agreement***").

2. **Earned Payments and Benefits**. Employee represents and agrees that the Company has paid to Employee all compensation, wages, bonuses, and benefits owed to Employee through the Separation Date by virtue of Employee's employment with the Company. The Company will issue Employee's final paycheck by the first regular payroll date following the Separation Date. Any funds maintained in Company's 401(k) plan will be handled in accordance with the terms of that plan. By signing below, Employee acknowledges that the Company does not owe Employee any other amounts. Employee acknowledges that Employee must promptly submit for reimbursement all final outstanding expenses, if any.

3. **Separation Consideration**. In consideration of Employee's waiver, release, and covenants in this Agreement, and provided that this Agreement becomes effective and irrevocable no later than the sixtieth (60^{th}) day following the Separation Date, the Company agrees to the following:

a. **Severance**: In accordance with the terms of Section 6.2 of the Employment Agreement, The Company will provide Employee with the equivalent of nine (9) months of Employee's base salary in effect as the Separation Date (the "**Severance**"). The Severance will be paid to Employee in the form of salary continuation, payable on the Company's regular payroll dates, subject to standard payroll deductions and withholdings, commencing on the first regular payroll date on or following the 60^{th} day after the Separation Date, with the first payment to include those payments that would have occurred earlier but for the 60-day delay.

b. **COBRA:** Employee's health insurance benefits through the Company will end on March 31, 2023, as a result of her separation. Employee may exercise whatever rights Employee may have under Consolidated Omnibus Budget Reconciliation Act (COBRA) for continuation of medical benefits under the Company's medical plan, including electing to continue health insurance coverage for Employee and her qualifying dependents under COBRA. Employee is solely responsible for the proper and timely election of COBRA continuation coverage and payment of the related premiums for COBRA continuation coverage, except that if Employee timely elects COBRA continuation coverage, then, in accordance with the terms of Section 6.2 of the Employment Agreement, the Company will pay Employee's COBRA premiums to continue Employee's coverage (including coverage for eligible dependents, if applicable) through the period starting on Employee's Separation Date and ending on the earliest to occur of: (a) nine (9) months following Employee's Separation Date; (b) the date Employee becomes eligible for group health insurance coverage through a new employer; or (c) the date Employee ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Employee becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during this time period, Employee must immediately notify the Company of such event. The Company is not responsible for any loss or termination of COBRA coverage due to Employee's failure to timely notify the

Company in writing of the COBRA election, premium amount, changes to premium amounts, premium payment due dates, or the party to which premium payments are to be made. Employee understands that if she enrolls in COBRA coverage but such coverage is terminated prior to the end of the COBRA coverage continuation period, she or her eligible dependents may not be immediately eligible to enroll in other group or individual coverage. In addition, notwithstanding the foregoing, if the Company in its sole discretion determines that it cannot provide the COBRA benefits under this Section 3(b) without potentially violating applicable law or giving rise to any excise taxes or penalties under applicable law, the Company shall in lieu thereof provide to Employee a taxable monthly payment in an amount equal to the monthly COBRA premium, less applicable withholdings, that Employee would be required to pay for COBRA continuation coverage for the remainder of the period under this Section 3(b) for which Employee was otherwise eligible for the COBRA payments.

c. **Retention Bonus**: The Company agrees to pay Employee, no later than the second payroll date following the Effective Date (as defined below), a retention bonus payment in the gross amount of $57,703.49, less applicable state and federal payroll deductions, which equals fifty percent (50%) of Employee's annual base salary earned from January 1, 2023 through March 31, 2023.

d. **Acceleration of Equity Vesting and Extended Exercise Period**: The Company agrees to accelerate the vesting of a portion of the August 2022 Option and the April 2021 RSU (each as defined below) and to extend the exercise period of the Accelerated August 2022 Option Shares (as defined below) to twelve (12) months following the Separation Date, each as described in Section 5.

Employee will not earn vacation or sick leave, or other benefits based upon the above payments. Employee acknowledges that the consideration provided in this Section 3, in whole or in part, constitutes adequate consideration for Employee's waiver, release, and covenants set forth in this Agreement. Except as specified in this Agreement, Company has no obligation to provide, and will not provide, further payments or benefits of any kind to Employee.

4. **Company Property**. Employee represents and warrants that Employee has turned over all property that Employee received from the Company or that Employee generated in the course of Employee's relationship with the Company (collectively "**Company Property**"), and that Employee has not provided any Company Property to anyone without the Company's authorization. Company Property includes, without limitation, equipment, materials, designs, prototypes, samples, products, documents, computers, electronic media, keys, credit cards, lists and databases indicating parties who have relationships with the Company, and all copies thereof.

5. **Equity**.

1. **Accelerated Vesting**. Pursuant to Employee's Stock Option Agreements with the Company dated August 2, 2022 (the "**August 2022 Options**")[1], August 3, 2021, and April 30, 2021, and the Company's 2014 Equity Incentive Plan (hereafter collectively referred to as the "**Stock Option Agreements**"), Employee was granted options to purchase 775,000 shares of the Company's common stock (the "**Options**"). The Options will have vested as to 247,396 shares (the "**Vested Option Shares**") and will have remained unvested as to 527,604 shares (the "**Unvested Option Shares**"), in each case of the Separation Date. Pursuant to Employee's Restricted Stock Unit Agreements with the Company dated February 1, 2022 and April 30, 2021 (the "**April 2021 RSUs**")[2] and the Company's 2014 Equity Incentive Plan (collectively, the "**Restricted Stock Unit Agreements**" and collectively with the Stock Option Agreements, the "**Equity Agreements**"), Employee was granted restricted stock units with respect to 90,000 shares of the Company's common stock (the "**RSUs**"), of which 45,000 shares will remain unvested as of the

[1] The August 2022 Options were granted with respect to 250,000 shares (of which 250,000 shares remain unvested and unexercised) at an exercise price of $0.99.
[2] The April 2021 RSUs were granted with respect to 20,000 shares (of which 10,000 remain unvested).

Separation Date (the "**Unvested RSUs**"). Upon Employee's termination of employment on the Separation Date, the Unvested Option Shares and Unvested RSUs will be forfeited for no consideration on the Separation Date and will not be eligible for continued vesting. However, if Employee executes this Agreement and it becomes effective on its terms, (i) the Company agrees to accelerate the vesting of 100,000 of the Unvested Option Shares subject to the August 2022 Options (the "**Accelerated August 2022 Option Shares**"), which Accelerated August 2022 Option Shares will be considered Vested Option Shares for purposes of Section 5(b) below and (ii) the Company agrees to accelerate the vesting of 10,000 of the shares subject to the April 2021 RSUs.

2. **Post-Termination Exercise Period Extension**. Per the Stock Option Agreements, Employee will have three (3) months following Employee's termination of Continuous Service (as defined in the Stock Option Agreement) to exercise the Vested Option Shares. After this date, Employee will no longer have a right to exercise the Vested Option Shares. However, if this Agreement becomes effective, the post-termination exercise period of the Accelerated August 2022 Option Shares will be extended to the twelve (12)-month anniversary of the Separation Date. Further, please note that if Employee does not exercise the unexercised Vested Option Shares within three (3) months of the Separation Date, all of the unexercised Vested Option Shares will cease to have incentive stock option status and will instead be considered nonqualified stock options. Employee should consult Employee's accountant or tax advisor with respect to this matter.

3. **Equity Agreement Amendment**. The Equity Agreements are hereby amended consistent with this Section 5. Employee's rights concerning the Options and RSUs will continue to be governed by the Equity Agreements (as amended herein); provided that, notwithstanding anything to the contrary in the Equity Agreements, Employee's termination of Continuous Service (as defined in the Equity Agreements) shall be deemed to have occurred on the Separation Date, even if Employee continues to provide services in a consultant or advisory role following the Separation Date and Employee acknowledges and agrees that the Options and RSUs will cease vesting on the Separation Date notwithstanding any continued services following the Separation Date.

6. **Waiver and Release**. On behalf of Employee and Employee's marital community, if any, heirs, executors, administrators, and assigns, Employee expressly waives, releases, and acknowledges satisfaction of all claims of any kind against the Company and its present, former, and future Affiliates, related entities, predecessors, successors, and assigns, and all of their present, former, and future officers, directors, stockholders, partners, members, employees, agents, representatives, and attorneys, in their individual and representative capacities (collectively the "**Released Parties**"). Except as stated below, this waiver and release is comprehensive and includes any and all rights, actions, claims (including claims to attorneys' fees), causes of action, disputes, damages, expenses or costs, whether known or unknown, based upon acts or omissions occurring or that could be alleged to have occurred at or before Employee's execution of this Agreement ("**Released Claims**"). Released Claims include, without limitation, all claims for wages, compensation, including claims for separation benefits, acceleration or other compensation under the Employment Agreement, stock or stock options (including claims relating to continued vesting under the Equity Agreements), employee benefits, and damages of any kind whatsoever arising out of any: contract, express or implied; tort; covenant of good faith and fair dealing; estoppel or misrepresentation; defamation; discrimination; harassment; retaliation; wrongful termination or any legal restriction on the Company's right to terminate Employee's employment; any federal, state, local, or other governmental statute, ordinance, or regulation, including, without limitation and as amended from time to time, the Age Discrimination in Employment Act ("**ADEA**"), the Older Worker's Benefit Protection Act of 1990 ("**OWBPA**"), Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Employee Retirement Income Security Act of 1974 ("**ERISA**"), the Family and Medical Leave Act, the Fair Credit Reporting Act, the Occupational Safety and Health Act ("**OSHA**"), the California Fair Employment and Housing Act, the California Labor Code, including without limitation Sections 98.6, 98.7, and 132a, and the California Family Rights Act. Employee acknowledges and agrees that included in the General Release of claims are any and all claims that have been or may be asserted by Employee or by any other person or entity on Employee's behalf in any class

or collective action relating to Employee's employment and/or termination of employment with Employer. Excluded from this waiver and release are claims that arise after this Agreement is executed, claims of vested rights under ERISA, unemployment compensation claims, workers' compensation claims, claims challenging the validity of this Agreement under the ADEA, claims for breach or enforcement of this Agreement, claims for indemnity under California Labor Code section 2802, and/or any other claim that may not be lawfully released under this Agreement.

7. **Waiver of Unknown Claims.** Employee has read and understands the provisions of Section 1542 of the California Civil Code, which provides as follows:

> "A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

Employee understands that Section 1542 gives Employee the right not to release existing claims of which Employee is presently unaware, unless Employee voluntarily chooses to waive this right. Employee nevertheless hereby voluntarily waives the rights described in Section 1542 and elects to assume all risks for claims that now exist in Employee's favor, known or unknown.

8. **Proceedings and Covenant Not to Sue**. Employee represents and warrants that Employee is the sole owner of all Released Claims and has not assigned, transferred, or otherwise disposed of Employee's right or interest in those matters. Employee further represents and warrants that neither Employee nor anyone acting on Employee's behalf has filed any complaints, charges, or lawsuits against any of the Released Parties with any governmental agency or court with respect to any Released Claims. Employee promises never to file or prosecute any lawsuit based on any Released Claims (whether as a named plaintiff or class member) and agrees to immediately cause the withdrawal or dismissal with prejudice of any such lawsuit, if filed by Employee or anyone acting on Employee's behalf.

9. **Protected Rights.**

1. Employee understands that nothing in this Agreement, including the General Release and Waiver and Release, Covenant Not to Sue, and Non-disparagement sections contained herein, limits, impedes or restricts Employee's ability to file a charge or complaint with the Equal Employment Opportunity Commission, the National Labor Relations Board (the "**NLRB**"), the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local government agency or commission ("**Government Agencies**"). Employee further understand that this Agreement does not limit Employee's ability to communicate with any Government Agencies or otherwise participate and/or assist in any investigation or proceeding that may be conducted by any Government Agency, including providing documents (including this Agreement) or other information, without notice to the Company. This Agreement does not limit Employee's right to receive an award for information provided to any Government Agencies.

2. Further, nothing in the Non-disparagement or Confidential Information sections, or otherwise in this Agreement, shall prohibit Employee from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that Employee has reason to believe is unlawful.

10. **Non-disparagement; References**. Subject to the Protected Rights section above, and otherwise to the fullest extent permitted by applicable law, Employee agrees that he will not, directly or indirectly, disparage or make negative remarks regarding the Released Parties or their products, services, agents, representatives, directors, officers, shareholders, attorneys, employees, vendors, affiliates, successors or assigns, or any person acting by, through, under or in concert with any of them, with any written or oral statement, including, but not limited to, any statement posted on social media (including online company review sites) or otherwise on the Internet, whether or not made anonymously or with

attribution. Nothing in this section shall prohibit Employee from providing truthful information in response to a subpoena or other legal process. Any reference requests regarding Employee's performance shall be directed to the Company's People Team, who shall only confirm Employee's dates of employment and job title consistent with the Company's policy.

11. **Confidential Information**. Subject to the Protected Rights section above, Employee will hold in strictest confidence and not use, disclose, or give to others, either directly or indirectly, any Confidential Information. "**Confidential Information**" means trade secrets and all other information about or relating to the business of the Company or any of its Affiliates that is not generally available to the public and is deemed proprietary or confidential by the Company or any of its Affiliates, whether recorded or merely remembered. Confidential Information also includes information relating to third parties that Employee learned of or obtained in the course of Employee's employment with the Company that is not generally available to the public or that the Company or any of its Affiliates is obligated to treat as confidential.

Employee represents and warrants that Employee has not disclosed or revealed, either directly or indirectly, or used in any way Confidential Information, except as authorized by the Company. The obligations under this provision are in addition to any obligations imposed under prior agreements between Employee and Company (such as Employee's Invention Assignment and Confidentiality, and Non-Competition Agreement (the "**Confidentiality Agreement**")), and under federal or state laws, including, without limitation, the federal Defend Trade Secrets Act ("**DTSA**").

12. **No Admission of Wrongdoing**. Nothing in this Agreement will be construed as an admission of wrongdoing or liability by Employee, the Company, or any Released Parties.

13. **Arbitration**. Except for any claim for injunctive relief arising out of a breach of a party's obligations to protect the other's proprietary information, the parties agree to arbitrate, in San Francisco, California through JAMS, any and all disputes or claims arising out of or related to the validity, enforceability, interpretation, performance or breach of this Agreement, whether sounding in tort, contract, statutory violation or otherwise, or involving the construction or application or any of the terms, provisions, or conditions of this Agreement. Any arbitration may be initiated by a written demand to the other party. The arbitrator's decision shall be final, binding, and conclusive. The parties further agree that this Agreement is intended to be strictly construed to provide for arbitration as the sole and exclusive means for resolution of all disputes hereunder to the fullest extent permitted by law. The parties expressly waive any entitlement to have such controversies decided by a court or a jury.

14. **Governing Law; Attorney's Fees**. This Agreement will be governed by the laws of the State of California, excluding its conflict of law provisions. If any action is brought to enforce the terms of this Agreement, the prevailing party will be entitled to recover its reasonable attorneys' fees, costs and expenses from the other party, in addition to any other relief to which the prevailing party may be entitled.

15. **Severability and Construction**. If any provision of this Agreement constitutes a violation of any law or is or becomes unenforceable or void, then such provision will be deemed modified to the extent necessary so that it is no longer in violation of law, unenforceable, or void, and such provision will otherwise be enforced to the fullest extent permitted by law. If such modification is not possible, such provision (with the exception of Section 6), to the extent that it is in violation of law, unenforceable, or void, will be deemed severable from the remaining provisions of this Agreement, which will remain binding. This Agreement will not be construed against any party as its drafter.

16. **Entire Agreement; Amendment**. This Agreement, together with the Equity Agreements, as amended herein, set forth the entire agreement and understanding between the parties and supersedes any prior oral or written agreements or understandings between them regarding its subject matter, including the Employment Agreement, except for the Confidentiality Agreement (or other similarly titled agreement), which will remain in full force and effect, with the exception of any post-employment non-competition provision, including Sections14(a)-(c) of the Confidentiality Agreement. The Company agrees that any previously executed post-employment non-competition provision with Employee will not be enforced.

This Agreement may only be modified through a written document, signed by an authorized representative of each of the parties, in which the parties expressly agree to modify it. This Agreement may be executed in one or more counterparts, all of which together will constitute one Agreement, and each of which separately will constitute an original document.

17. **Consideration and Revocation Periods**. This Agreement was presented to Employee on March 31, 2023 (the "**Date Presented**"). Employee has twenty-one (21) days after the Date Presented to review and consider this Agreement (the "**Consideration Period**"). Employee may not sign the Agreement before the Separation Date. Employee may otherwise sign the Agreement before the Consideration Period has elapsed, however, in which case Employee will waive the remainder of the Consideration Period. To accept, Employee must either (a) sign and deliver the Agreement through DocuSign using the link provided by the Company, or (b) sign and deliver the Agreement to Donna Cochener by hand or by e-mail to dcochener@neoleukin.com. Employee is entitled to revoke this Agreement for a period of seven (7) days after Employee signs it (the "**Revocation Period**"). To revoke, Employee must deliver a notice revoking Employee's acceptance to Donna Cochener, by hand or by e-mail to dcochener@neoleukin.com, before the Revocation Period has elapsed. This Agreement will become effective on the eighth day after Employee's acceptance and signature (the "**Effective Date**"), provided that Employee has not timely revoked the Agreement.

18. **Knowing and Voluntary Agreement**. Employee hereby warrants and represents that: (a) Employee has carefully read this Agreement and finds that it is written in a manner that Employee understands; (b) Employee knows the contents hereof; (c) Employee has been advised to consult with Employee's attorney regarding this Agreement and its effects and has done so or knowingly and voluntarily waived the right to do so; (d) Employee understands that Employee is giving up all Released Claims, including under the ADEA, and all damages and disputes that have arisen before Employee executes this Agreement, except as provided herein; (e) Employee has had ample time to review and analyze this entire Agreement; (f) Employee did not rely upon any representation or statement concerning the subject matter of this Agreement, except as expressly stated in the Agreement; (g) Employee has been given at least twenty-one (21) days to consider this Agreement before signing it; (h) Employee has seven (7) days to revoke this Agreement after signing it; (i) Employee understands this Agreement's final and binding effect; and (j) Employee has signed this Agreement as Employee's free and voluntary act.

19. **Taxes**. All payments made by the Company under this Agreement to Employee or for the benefit of Employee will be made less applicable withholdings and deductions. This Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended ("**Section 409A**"), including the exceptions thereto, and will be construed and administered in accordance with such intent. The parties intend that any payments and other benefits provided under this Agreement that may be excluded from Section 409A as separation pay due to an involuntary separation from service, as a short-term deferral, or otherwise, shall be exempt from Section 409A to the maximum extent possible. To the extent Section 409A is applicable to such payments and benefits, the parties intend that this Agreement (and such payments and benefits) comply with the deferral, payout and other limitations and restrictions imposed under Code Section 409A. Notwithstanding anything to the contrary in this Agreement, if at the time the Employee's employment terminates, she is a "specified employee," as defined for purposes of Section 409A, any and all amounts payable under this Agreement on account of such separation from service that would (but for this provision) be payable within six (6) months following the date of termination, shall instead be paid on the next regular payroll date following the expiration of such six (6) month period or, if earlier, upon Employee's death (except to the extent of amounts that do not constitute a deferral of compensation within the meaning of Treasury Regulation Section 1.409A-1(b), but only to the extent Section 409A is applicable to such payments and benefits. For purposes of Section 409A, each payment made under this Agreement shall be treated as a separate payment, and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments. However, the Company makes no representations that the payments and benefits provided under this Agreement comply with, or are exempt from, Section 409A, and in no event will the Company have any liability to Employee or any other person relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of Section 409A.

The parties hereby execute this Agreement on the dates written below.

NEOLEUKIN THERAPEUTICS, INC.

_____
Donna Cochener, General Counsel
SVP Legal

Date:_____

PRITI PATEL, M.D.

_____
Priti Patel, M.D.

Date:_____

SEPARATION AGREEMENT AND RELEASE

This Separation Agreement and Release (this "**Agreement**") is made and entered into by and between Jonathan G. Drachman, MD ("**Employee**") and Neoleukin Therapeutics, Inc. (the "**Company**"). The parties agree as follows:

1. **Separation Date; Transition Period and Services**. Employee acknowledges that the last date of Employee's employment relationship with or service to the Company or any of its Affiliates in any capacity is March 31, 2023 (the "**Separation Date**"). Between now and the Separation Date (the "**Transition Period**"), Employee agrees to carry out the duties and responsibilities of Employee's position as directed principally by the Company's Board of Directors (the "**Board**"), to whom Employee will continue to report, and to provide other transition services as may reasonably be requested by the Company, including transition of the responsibilities, duties, and knowledge relative to Employee's position (the "**Transition Services**").

2. **Resignation from Officer and Director Positions**. By signing below, Employee hereby resigns, effective as of the Separation Date, (a) from all officer positions of the Company and its Affiliates that Employee may hold, including, without limitation, Chief Executive Officer, and (b) as a member of the Board and the Board of Directors of any of the Company's Affiliates, and any committee thereof on which Employee may be on, which resignations Employee confirms by executing the resignation letter attached hereto as Exhibit A and returning the executed letter to the Company concurrently with this Agreement. Employee claims and will claim no further right to employment by Company or its Affiliates beyond the Separation Date. For purposes of this Agreement, "**Affiliate**" means any entity currently existing or subsequently organized or formed that directly or indirectly controls, is controlled by, or is under common control with the Company, whether through the ownership of voting securities, by contract, or otherwise.

3. **Continued Employment; Other Release Consideration**. In exchange for Employee's agreement to the general release and waiver of claims and covenant not to sue set forth below and Employee's other promises herein, the Company agrees to continue Employee's employment on the following terms:

1. **Compensation and Benefits**: During the Transition Period, the Company will continue to pay Employee's current base salary and Employee will continue to be eligible to participate in benefits customarily afforded to other employees, including participation in the Company-sponsored health benefits plan and continued equity vesting, to the fullest extent allowed by the governing plans, agreements, or policies.

2. **Separation Compensation**: Provided that Employee cooperatively and diligently provides the Transition Services as determined by the Company in good faith and in its sole discretion, then in exchange for Employee's agreement to the waiver and release and covenant not to sue set forth in Exhibit B (the "**Second Release**"), and provided that the Second Release becomes effective and irrevocable no later than the sixtieth (60^{th}) day following the Separation Date, the Company agrees as follows:

    1. **Severance**: The Company will provide Employee with the equivalent of twelve (12) months of Employee's base salary in effect as the Separation Date (the "**Severance**"). The Severance will be paid to Employee in the form of salary continuation, payable on the Company's regular payroll dates, subject to standard payroll deductions and withholdings, commencing on the first regular payroll date on or following the 60th day after the Separation Date, with the first payment to include those payments that would have occurred earlier but for the 60-day delay.

    2. **COBRA**: Employee's health insurance benefits through the Company will end on March 31, 2023, as a result of his separation. Employee may exercise whatever rights Employee may have under Consolidated Omnibus Budget Reconciliation Act (COBRA) for continuation of medical benefits under the

Company's medical plan, including electing to continue health insurance coverage for Employee and his qualifying dependents under COBRA. Employee is solely responsible for the proper and timely election of COBRA continuation coverage and payment of the related premiums for COBRA continuation coverage, except that if Employee timely elects COBRA continuation coverage, then, the Company will pay Employee's COBRA premiums to continue Employee's coverage (including coverage for eligible dependents, if applicable) through the period starting on Employee's Separation Date and ending on the earliest to occur of: (a) twelve (12) months following Employee's Separation Date; (b) the date Employee becomes eligible for group health insurance coverage through a new employer; or (c) the date Employee ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Employee becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during this time period, Employee must immediately notify the Company of such event. The Company is not responsible for any loss or termination of COBRA coverage due to Employee's failure to timely notify the Company in writing of the COBRA election, premium amount, changes to premium amounts, premium payment due dates, or the party to which premium payments are to be made. Employee understands that if he enrolls in COBRA coverage but such coverage is terminated prior to the end of the COBRA coverage continuation period, he or his eligible dependents may not be immediately eligible to enroll in other group or individual coverage. In addition, notwithstanding the foregoing, if the Company in its sole discretion determines that it cannot provide the COBRA benefits under this Section 3(b) without potentially violating applicable law or giving rise to any excise taxes or penalties under applicable law, the Company shall in lieu thereof provide to Employee a taxable monthly payment in an amount equal to the monthly COBRA premium, less applicable withholdings, that Employee would be required to pay for COBRA continuation coverage for the remainder of the period under this Section 3(b) for which Employee was otherwise eligible for the COBRA payments.

3. **Unearned Bonus**. The Company agrees to pay Employee, no later than the second payroll date following the Effective Date (as defined below), a lump sum payment in the gross amount of $56,772.03, less applicable state and federal payroll deductions, which equals 100% of Employee's unearned target annual bonus for 2023, pro-rated at 3/12ths (based on three (3) months of service during 2023).

4. **Acceleration of Equity Vesting and Extended Exercise Period**: The Company agrees to accelerate the vesting of the August 2022 Option (as defined below) and to extend the exercise period of all outstanding Vested Option Shares (as defined below) to eighteen (18) months following the Separation Date, each as described in Section 6.

Employee will not earn vacation or sick leave, or other benefits based upon the above payments in this Section 3(b). Employee acknowledges that the consideration provided in this Section 3(b), in whole or in part, constitutes adequate consideration for Employee's waiver, release, and covenants set forth in this Agreement. Except as specified in this Agreement, Company has no obligation to provide, and will not provide, further payments or benefits of any kind to Employee.

4. **Earned Payments and Benefits**. The Company will issue Employee's final paycheck by the first regular payroll date following the Separation Date, including all compensation, wages, bonuses, and benefits owed to Employee through the Separation Date by virtue of Employee's employment with the Company. Any funds maintained in Company's 401(k) plan will be handled in accordance with the terms of that plan. By signing below, Employee acknowledges that the Company does not owe Employee

any other amounts, except as otherwise may become payable under this Agreement. Employee acknowledges that Employee must promptly submit for reimbursement all final outstanding expenses, if any.

5. **Company Property**. Employee represents and warrants that no later than the Separation Date, Employee will turn over all property that Employee received from the Company or that Employee generated in the course of Employee's relationship with the Company (collectively "**Company Property**"), and that Employee has not provided any Company Property to anyone without the Company's authorization. Company Property includes, without limitation, equipment, materials, designs, prototypes, samples, products, documents, computers, electronic media, keys, credit cards, lists and databases indicating parties who have relationships with the Company, and all copies thereof.

6. **Equity**.

a. **Accelerated Vesting**. Pursuant to Employee's Stock Option Agreements with the Company dated August 2, 2022 (the "**August 2022 Options**[1]"), August 3, 2021, August 10, 2020, and August 31, 2019, and the Company's 2014 Equity Incentive Plan (hereafter collectively referred to as the "**Stock Option Agreements**"), Employee was granted options to purchase 2,820,000 shares of the Company's common stock (the "**Options**"). The Options will have vested as to 1,907,708 shares (the "**Vested Option Shares**") and will have remained unvested as to 912,292 shares (the "**Unvested Option Shares**"), in each case of the Separation Date. Upon Employee's termination of employment on the Separation Date, the Unvested Option Shares will be forfeited for no consideration on the Separation Date and will not be eligible for continued vesting. However, if Employee executes this Agreement and it becomes effective on its terms, the Company agrees to accelerate the vesting of 100% of the Unvested Option Shares subject to the August 2022 Options (the "**Accelerated August 2022 Option Shares**"), which Accelerated August 2022 Option Shares will be considered Vested Option Shares for purposes of Section 6(b) below.

b. **Post-Termination Exercise Period Extension**. Per the Stock Option Agreements, Employee will have three (3) months following Employee's termination of Continuous Service (as defined in the Stock Option Agreement) to exercise the Vested Option Shares. After this date, Employee will no longer have a right to exercise the Vested Option Shares. However, if this Agreement becomes effective, the post-termination exercise period of the Vested Option Shares will be extended to the eighteen (18)-month anniversary of the Separation Date. Further, please note that if Employee does not exercise the unexercised Vested Option Shares within three (3) months of the Separation Date, all of the unexercised Vested Option Shares will cease to have incentive stock option status and will instead be considered nonqualified stock options. Employee should consult Employee's accountant or tax advisor with respect to this matter.

c. **Stock Option Amendment**. The Stock Option Agreements are hereby amended consistent with this Section 6. Employee's rights concerning the Options will continue to be governed by the Stock Option Agreement; provided that, notwithstanding anything to the contrary in the Stock Option Agreements, Employee's termination of Continuous Service (as defined in the Stock Option Agreements) shall be deemed to have occurred on the Separation Date, even if Employee continues to provide services in a consultant or advisory role following the Separation Date.

7. **Waiver and Release**.

a. On behalf of Employee and Employee's marital community, if any, heirs, executors, administrators, and assigns, Employee expressly waives, releases, and acknowledges satisfaction of all claims of any kind against the Company and its present, former, and

[1] The August 2022 Options were granted with respect to 350,000 shares (of which 350,000 remain unexercised) at an exercise price of $0.99.

future Affiliates, related entities, predecessors, successors, and assigns, and all of their present, former, and future officers, directors, stockholders, partners, members, employees, agents, representatives, and attorneys, in their individual and representative capacities (collectively the "**Released Parties**"). Except as stated below, this waiver and release is comprehensive and includes any and all rights, actions, claims (including claims to attorneys' fees), causes of action, disputes, damages, expenses or costs, whether known or unknown, based upon acts or omissions occurring or that could be alleged to have occurred at or before Employee's execution of this Agreement ("**Released Claims**"). Released Claims include, without limitation, all claims for wages, compensation, including claims for separation benefits, acceleration or other compensation under Employee's Amended and Restated Executive Employment Agreement with the Company dated April 15, 2020 (the "**Employment Agreement**"), stock or stock options (including claims relating to continued vesting under the Stock Option Agreements), employee benefits, and damages of any kind whatsoever arising out of any: contract, express or implied; tort; covenant of good faith and fair dealing; estoppel or misrepresentation; defamation; discrimination; harassment; retaliation; wrongful termination or any legal restriction on the Company's right to terminate Employee's employment; any federal, state, local, or other governmental statute, ordinance, or regulation, including, without limitation and as amended from time to time, Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Employee Retirement Income Security Act of 1974 ("**ERISA**"), the Family and Medical Leave Act, the Fair Credit Reporting Act, the Washington Law Against Discrimination, and any other legal limitation on the employment relationship. Excluded from this waiver and release are claims that arise after this Agreement is executed, claims of vested rights under ERISA, unemployment compensation claims, worker's compensation claims, claims for breach or enforcement of this Agreement, and any other claim that may not be lawfully released under this Agreement.

b. Employee hereby acknowledges that he is aware of the principle that a general release does not extend to claims that the releasor does not know or suspect to exist in his or her favor at the time of executing the release, which, if known by him or her, must have materially affected his or her settlement with the releasee. With knowledge of this principle, Employee hereby agrees to expressly waive any rights Employee may have to that effect.

8. **Proceedings and Covenant Not to Sue**. Employee represents and warrants that Employee is the sole owner of all Released Claims and has not assigned, transferred, or otherwise disposed of Employee's right or interest in those matters. Employee further represents and warrants that neither Employee nor anyone acting on Employee's behalf has filed any complaints, charges, or lawsuits against any of the Released Parties with any governmental agency or court with respect to any Released Claims. Employee promises never to file or prosecute any lawsuit based on any Released Claims (whether as a named plaintiff or class member) and agrees to immediately cause the withdrawal or dismissal with prejudice of any such lawsuit, if filed by Employee or anyone acting on Employee's behalf. Nothing in this paragraph shall prohibit or impair Employee or the Company from complying with all applicable laws, nor shall this Agreement be construed to obligate either party to commit (or aid or abet in the commission of) any unlawful act.

9. **Protected Rights.**

Employee understands that nothing in this Agreement, including the Waiver and Release, Covenant Not to Sue, and Confidential Information sections contained herein, limits, impedes or restricts Employee's ability to file a charge or complaint with the Equal Employment Opportunity Commission, the National Labor Relations Board (the "**NLRB**"), the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local government agency or commission ("**Government Agencies**"). Employee further understands that this Agreement does not limit Employee's ability to communicate with any Government Agencies or otherwise participate and/or assist in any investigation or proceeding that

may be conducted by any Government Agency, including providing documents (including this Agreement) or other information, without notice to the Company. This Agreement does not limit Employee's right to receive an award for information provided to any Government Agencies.

2. Further, nothing in the Confidential Information section, or otherwise in this Agreement, shall prohibit Employee from discussing or disclosing workplace or work-related conduct (including conduct at the workplace, at work-related events coordinated by or through the Company, between employees, or between the Company and an employee, whether on or off the employment premises) that Employee reasonably believed, under Washington state, federal, or common law, to be illegal discrimination, illegal harassment, illegal retaliation, a wage and hour violation, sexual assault, or that is recognized as against a clear mandate of public policy.

10. **Confidential Information**. Subject to the Protected Rights section above, Employee will hold in strictest confidence and not use, disclose, or give to others, either directly or indirectly, any Confidential Information. "**Confidential Information**" means trade secrets and all other information about or relating to the business of the Company or any of its Affiliates that is not generally available to the public and is deemed proprietary or confidential by the Company or any of its Affiliates, whether recorded or merely remembered. Confidential Information also includes information relating to third parties that Employee learned of or obtained in the course of Employee's employment with the Company that is not generally available to the public or that the Company or any of its Affiliates is obligated to treat as confidential.

Employee represents and warrants that Employee has not disclosed or revealed, either directly or indirectly, or used in any way Confidential Information, except as authorized by the Company. The obligations under this provision are in addition to any obligations imposed under prior agreements between Employee and Company (such as Employee's Employee Invention Assignment, Confidentiality and Non-Competition Agreement (the "**Confidentiality Agreement**")), and under federal or state laws, including, without limitation, Washington's Uniform Trade Secrets Act and the federal Defend Trade Secrets Act ("**DTSA**").

11. **No Admission of Wrongdoing**. Nothing in this Agreement will be construed as an admission of wrongdoing or liability by Employee, the Company, or any Released Parties.

12. **Arbitration**. Except for any claim for injunctive relief arising out of a breach of a party's obligations to protect the other's proprietary information, the parties agree to arbitrate, in Seattle, Washington through JAMS, any and all disputes or claims arising out of or related to the validity, enforceability, interpretation, performance or breach of this Agreement, whether sounding in tort, contract, statutory violation or otherwise, or involving the construction or application or any of the terms, provisions, or conditions of this Agreement. Any arbitration may be initiated by a written demand to the other party. The arbitrator's decision shall be final, binding, and conclusive. The parties further agree that this Agreement is intended to be strictly construed to provide for arbitration as the sole and exclusive means for resolution of all disputes hereunder to the fullest extent permitted by law. The parties expressly waive any entitlement to have such controversies decided by a court or a jury.

13. **Governing Law; Attorney's Fees**. This Agreement will be governed by the laws of the State of Washington, excluding its conflict of law provisions. If any action is brought to enforce the terms of this Agreement, the prevailing party will be entitled to recover its reasonable attorneys' fees, costs and expenses from the other party, in addition to any other relief to which the prevailing party may be entitled.

15. **Severability and Construction**. If any provision of this Agreement constitutes a violation of any law or is or becomes unenforceable or void, then such provision will be deemed modified to the extent necessary so that it is no longer in violation of law, unenforceable, or void, and such provision will otherwise be enforced to the fullest extent permitted by law. If such modification is not possible, such provision (with the exception of Section 7), to the extent that it is in violation of law, unenforceable, or void, will be deemed severable from the remaining provisions of this Agreement, which will remain binding. This Agreement will not be construed against any party as its drafter.

16. **Entire Agreement; Amendment**. This Agreement, together with Exhibits A and B hereto and the Stock Option Agreements, as amended herein, set forth the entire agreement and understanding between the parties and supersedes any prior oral or written agreements or understandings between them regarding its subject matter, including the Employment Agreement, except for the Confidentiality Agreement (or other similarly titled agreement), which will remain in full force and effect. Nothing in the Confidentiality Agreement prohibits Employee from disclosing or discussing conduct that they reasonably believe, under federal, state, or common law, to be illegal discrimination, illegal harassment, illegal retaliation, a wage and hour violation, sexual assault, or that is recognized as against a clear mandate of public policy.

This Agreement may only be modified through a written document, signed by an authorized representative of each of the parties, in which the parties expressly agree to modify it. This Agreement may be executed in one or more counterparts, all of which together will constitute one Agreement, and each of which separately will constitute an original document.

17. **Consideration Period**. This Agreement was presented to Employee on March 8, 2023 (the "**Date Presented**"). Employee has five (5) business days after the Date Presented to review and consider this Agreement (the "**Consideration Period**"). The offer set forth in this Agreement, if not accepted by Employee before the end of the Consideration Period, will automatically expire. To accept, Employee must either (a) sign and deliver the Agreement through DocuSign using the link provided by the Company, or (b) sign and deliver the Agreement to Donna Cochener by hand or by e-mail to dcochener@neoleukin.com. This Agreement will become effective on the date it is signed by both parties (the "**Effective Date**").

18. **Knowing and Voluntary Agreement**. Employee hereby warrants and represents that: (a) Employee has carefully read this Agreement and finds that it is written in a manner that Employee understands; (b) Employee knows the contents hereof; (c) Employee has been advised to consult with Employee's attorney regarding this Agreement and its effects and has done so or knowingly and voluntarily waived the right to do so; (d) Employee understands that Employee is giving up all Released Claims, and all damages and disputes that have arisen before Employee executes this Agreement, except as provided herein; (e) Employee has had ample time to review and analyze this entire Agreement; (f) Employee did not rely upon any representation or statement concerning the subject matter of this Agreement, except as expressly stated in the Agreement; (g) Employee has been given five (5) business days to consider this Agreement before signing it; (h) Employee understands this Agreement's final and binding effect; and (i) Employee has signed this Agreement as Employee's free and voluntary act.

19. **Taxes**. All payments made by the Company under this Agreement and the Second Release to Employee or for the benefit of Employee will be made less applicable withholdings and deductions. This Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended ("**Section 409A**"), including the exceptions thereto, and will be construed and administered in accordance with such intent. The parties intend that any payments and other benefits provided under this Agreement that may be excluded from Section 409A as separation pay due to an involuntary separation from service, as a short-term deferral, or otherwise, shall be exempt from Section 409A to the maximum extent possible. To the extent Section 409A is applicable to such payments and benefits, the parties intend that this Agreement (and such payments and benefits) comply with the deferral, payout and other limitations and restrictions imposed under Code Section 409A. Notwithstanding anything to the contrary in this Agreement, if at the time the Employee's employment terminates, he is a "specified employee," as defined for purposes of Section 409A, any and all amounts payable under this Agreement on account of such separation from service that would (but for this provision) be payable within six (6) months following the date of termination, shall instead be paid on the next regular payroll date following the expiration of such six (6) month period or, if earlier, upon Employee's death (except to the extent of amounts that do not constitute a deferral of compensation within the meaning of Treasury Regulation Section 1.409A-1(b), but only to the extent Section 409A is applicable to such payments and benefits. For purposes of Section 409A, each payment made under this Agreement shall be treated as a separate payment, and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments. However, the Company makes no representations that the payments and benefits provided under this Agreement comply with, or are exempt from, Section 409A, and in no event will the Company have any liability to Employee or any

other person relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of Section 409A.

[SIGNATURE PAGE FOLLOWS]

The parties hereby execute this Agreement on the dates written below.

NEOLEUKIN THERAPEUTICS, INC.

_____
Todd Simpson
Chairman of the Board of Directors

Date:_____

JONATHAN G. DRACHMAN, MD

_____
Jonathan G. Drachman, MD

Date:_____

EXHIBIT A

RESIGNATION LETTER

March 8, 2023

Neoleukin Therapeutics, Inc.

Re: Resignation from Board of Directors and Officer Positions

To the Board of Directors:

Effective as of March 31, 2023, I hereby voluntarily resign as the Chief Executive Officer of Neoleukin Therapeutics, Inc. (the "**Company**"), and from any other positions I may hold with the Company and any of its affiliates. Effective as of March 31, 2023, I hereby voluntarily resign as a member of the Company's Board of Directors as well as the Board of Directors of any of the Company's affiliates (together, the "**Board**"), and as a member of each committee thereof on which I may serve. I acknowledge that I hold no other director, officer, or employee positions with the Company or any of its affiliates. I further acknowledge that I am not resigning from the Board due to any disagreement with the Company over any matter related to the Company's operations, policies and practices.

Sincerely,

_____

Jonathan G. Drachman, MD

EXHIBIT B

SECOND RELEASE

This General Release of All Claims and Covenant Not to Sue (the "**Second Release**") is entered into between Jonathan G. Drachman, MD ("**Employee**") and Neoleukin Therapeutics, Inc. (the "**Company**") (collectively, "**the parties**").

WHEREAS, Employee and the Company entered into an agreement regarding Employee's transition and separation from employment with the Company (the "**Separation Agreement**," to which this Second Release is attached as Exhibit B);

WHEREAS, on March 31, 2023, Employee's employment with the Company terminated (the "**Separation Date**");

WHEREAS, the Company has determined that Employee cooperatively and diligently provided the Transition Services (as defined in the Separation Agreement);

WHEREAS, this agreement serves as the Second Release, pursuant to the Separation Agreement; and

WHEREAS, Employee and the Company desire to mutually, amicably and finally resolve and compromise all issues and claims surrounding Employee's employment and separation from employment with the Company;

NOW THEREFORE, in consideration for the mutual promises and undertakings of the parties as set forth below, Employee and the Company hereby enter into this Second Release.

1. **Acknowledgment of Payment of Wages**: The Company will pay Employee for all wages, salary, accrued vacation (if applicable), bonuses, reimbursable expenses previously submitted by Employee, and any similar payments due Employee from the Company as of the Separation Date. By signing below, Employee acknowledges that the Company does not owe Employee any other amounts, except as may become payable under the Separation Agreement and the Second Release.

2. **Return of Company Property**: Employee hereby warrants to the Company that Employee has returned to the Company all property or data of the Company of any type whatsoever that has been in Employee's possession, custody or control.

3. **Consideration**: In exchange for Employee's agreement to this Second Release and Employee's other promises in the Separation Agreement and herein, the Company agrees to provide Employee with the consideration set forth in Section 3(b) of the Separation Agreement. By signing below, Employee acknowledges that Employee is receiving the consideration in exchange for waiving Employee's rights to claims referred to in this Second Release and Employee would not otherwise be entitled to the consideration.

4. **Waiver and Release**:

1. On behalf of Employee and Employee's marital community, if any, heirs, executors, administrators, and assigns, Employee expressly waives, releases, and acknowledges satisfaction of all claims of any kind against the Company and its present, former, and future Affiliates, related entities, predecessors, successors, and assigns, and all of their present, former, and future officers, directors, stockholders, partners, members, employees, agents, representatives, and attorneys, in their individual and representative capacities (collectively the "**Released Parties**"). Except as stated below, this waiver and release is comprehensive and includes any and all rights, actions, claims (including claims to attorneys' fees), causes of action, disputes, damages, expenses or costs, whether known or unknown, based upon acts or omissions occurring or that could be alleged to have occurred at or before Employee's execution of this Second Release ("**Released Claims**"). Released Claims include, without limitation, all claims for wages, compensation, including claims for separation benefits, acceleration or other compensation under Employee's Amended and Restated Executive Employment Agreement with the Company dated April 15, 2020 (the "**Employment Agreement**"), stock or stock options (including claims relating to continued vesting under the Stock Option Agreements), employee benefits, and damages of any kind whatsoever arising out of any: contract, express or implied; tort; covenant of good faith and fair dealing; estoppel or misrepresentation; defamation; discrimination; harassment; retaliation; wrongful termination or any legal restriction on the Company's right to terminate Employee's employment; any federal, state, local, or other governmental statute, ordinance, or regulation, including, without limitation and as amended from time to time, the Age Discrimination in Employment Act ("**ADEA**"), the Older Worker's Benefit Protection Act of 1990 ("**OWBPA**"), Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Employee Retirement Income Security Act of 1974 ("**ERISA**"), the Family and Medical Leave Act, the Fair Credit Reporting Act, the Washington Law Against Discrimination, and any other legal limitation on the employment relationship. Excluded from this waiver and release are claims that arise after this Second Release is executed, claims of vested rights under ERISA, unemployment compensation claims, worker's compensation claims, claims challenging the validity of this Second Release under the ADEA and/or the OWBPA, claims for breach or enforcement of this Second Release, and any other claim that may not be lawfully released under this Second Release.

2. Employee hereby acknowledges that he is aware of the principle that a general release does not extend to claims that the releasor does not know or suspect to exist in his or her favor at the time of executing the release, which, if known by him or her, must have materially affected his or her settlement with the releasee. With knowledge of this principle, Employee hereby agrees to expressly waive any rights Employee may have to that effect.

5. **Covenant Not to Sue**: Employee represents and warrants that Employee is the sole owner of all Released Claims and has not assigned, transferred, or otherwise disposed of Employee's right or interest in those matters. Employee further represents and warrants that neither Employee nor anyone acting on Employee's behalf has filed any complaints, charges, or lawsuits against any of the Released Parties with any governmental agency or court with respect to any Released Claims. Employee promises never to file or prosecute any lawsuit based on any Released Claims (whether as a named plaintiff or class member) and agrees to immediately cause the withdrawal or dismissal with prejudice of any such lawsuit, if filed by Employee or anyone acting on Employee's behalf. Nothing in this paragraph shall prohibit or impair Employee or the Company from complying with all applicable laws, nor shall this Second Release be construed to obligate either party to commit (or aid or abet in the commission of) any unlawful act.

6. Protected Rights:

a. Employee understands that nothing in this Second Release, including the Waiver and Release, Covenant Not to Sue, and Non-disparagement sections contained herein,

limits, impedes or restricts Employee's ability to file a charge or complaint with the Equal Employment Opportunity Commission, the National Labor Relations Board (the "**NLRB**"), the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local government agency or commission ("**Government Agencies**"). Employee further understands that this Second Release does not limit Employee's ability to communicate with any Government Agencies or otherwise participate and/or assist in any investigation or proceeding that may be conducted by any Government Agency, including providing documents (including this Second Release) or other information, without notice to the Company. This Second Release does not limit Employee's right to receive an award for information provided to any Government Agencies.

2. Further, nothing in the Non-disparagement section, or otherwise in this Second Release, shall prohibit Employee from discussing or disclosing workplace or work-related conduct (including conduct at the workplace, at work-related events coordinated by or through the Company, between employees, or between the Company and an employee, whether on or off the employment premises) that Employee reasonably believed, under Washington state, federal, or common law, to be illegal discrimination, illegal harassment, illegal retaliation, a wage and hour violation, sexual assault, or that is recognized as against a clear mandate of public policy.

7. **Non-disparagement; References**: Subject to the Protected Rights section above, and otherwise to the fullest extent permitted by applicable law, Employee agrees that he will not, directly or indirectly, disparage or make negative remarks regarding the Released Parties or their products, services, agents, representatives, directors, officers, shareholders, attorneys, employees, vendors, affiliates, successors or assigns, or any person acting by, through, under or in concert with any of them, with any written or oral statement, including, but not limited to, any statement posted on social media (including online company review sites) or otherwise on the Internet, whether or not made anonymously or with attribution. Nothing in this section shall prohibit Employee from providing truthful information in response to a subpoena or other legal process.

8. **Consideration and Revocation Periods**: Employee understands that Employee may take until the Separation Date to consider this Second Release (the "**Consideration Period**"). Employee may not sign the Second Release before the Separation Date. To accept, Employee must either (a) sign and deliver the Second Release through DocuSign using the link provided by the Company, or (b) sign and deliver the Second Release to Donna Cochener by hand or by e-mail to dcochener@neoleukin.com. Employee is entitled to revoke this Second Release for a period of seven (7) days after Employee signs it (the "**Revocation Period**"). To revoke, Employee must deliver a notice revoking Employee's acceptance to Donna Cochener, by hand or by e-mail to dcochener@neoleukin.com, before the Revocation Period has elapsed. This Second Release will become effective on the eighth day after Employee's acceptance and signature (the "**Effective Date**"), provided that Employee has not timely revoked the Second Release.

9. **Knowing and Voluntary Second Release**: Employee hereby warrants and represents that: (a) Employee has carefully read this Second Release and finds that it is written in a manner that Employee understands; (b) Employee knows the contents hereof; (c) Employee has been advised to consult with Employee's attorney regarding this Second Release and its effects and has done so or knowingly and voluntarily waived the right to do so; (d) Employee understands that Employee is giving up all Released Claims, including under the ADEA, and all damages and disputes that have arisen before Employee executes this Second Release, except as provided herein; (e) Employee has had ample time to review and analyze this entire Second Release; (f) Employee did not rely upon any representation or statement concerning the subject matter of this Second Release, except as expressly stated in the Second Release; (g) Employee has been given at least twenty-one (21) days to consider this Second Release before signing it; (h) Employee has seven (7) days to revoke this Second Release after signing it; (i) Employee understands this Second Release's final and binding effect; and (j) Employee has signed this Second Release as Employee's free and voluntary act.

10. **Other Terms of Separation Second Release Incorporated Herein**: All other terms of the Separation Agreement, to the extent not inconsistent with the terms of this Second Release, are hereby incorporated in this Second Release as though fully stated herein and apply with equal force to this Second Release, including, without limitation, the provisions on Arbitration, Governing Law, and Attorneys' Fees.

The parties hereby execute this Second Release on the dates written below.

NEOLEUKIN THERAPEUTICS, INC.

_____
Todd Simpson
Chairman of the Board of Directors

Date:_____

_____
Todd Simpson
Chairman of the Board of Directors
Date:_____

JONATHAN G. DRACHMAN, MD

_____
Jonathan G. Drachman, MD

Date:_____

_____
Jonathan G. Drachman, MD
Date:_____

AMENDMENT NO. 1
TO
EMPLOYMENT AGREEMENT

This Amendment No. 1 (this "**Amendment**"), dated as of April 3, 2023, amends that certain Employment Agreement (the "**Agreement**"), dated as of March 4, 2022, by and between Neoleukin Therapeutics, Inc., a Delaware corporation (the "**Company**"), and Donna Cochener (the "**Executive**"). All capitalized terms not defined herein shall have the meanings assigned to them in the Agreement.

On March 31, 2023, Executive was appointed as the Company's Interim Chief Executive Officer. In connection with such appointment, the Company and Executive hereby agree to amend the Agreement as follows:

1. Section 1.2 of the Agreement shall be replaced in its entirety as follows:

"**1.2 Position**. Executive shall serve as the Company's Interim Chief Executive Officer and General Counsel. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company."

2. Section 1.3 of the Agreement shall be replaced in its entirety as follows:

"**1.3 Duties and Location**. Executive shall perform such duties as are typically performed by a Chief Executive Officer and General Counsel. Executive will report to the Company's Board of Directors. Executive's primary office location shall be the Company's office located in Seattle, Washington."

3. Effective as of March 31, 2023, the Company shall pay Executive a Base Salary at a rate equal to $450,000 per annum.

4. Section 2.2 of Agreement shall be replaced in its entirety as follows:

"**2.2 Bonus**. Executive will be entitled to an annual bonus equal to the greater of (i) Executive's target annual bonus (equal to $219,375 for 2023, which is pro-rated for salary increases in 2023 and calculated using a target bonus percentage of 50%) or (ii) Executive's actual annual bonus based on corporate and individual performance in 2023, if performance is determinable (the "**Annual Bonus**"), payable in a lump sum (subject to applicable withholdings) on or shortly following the earlier to occur of (x) December 31, 2023 (subject to Executive's continued employment through December 31, 2023, and payable by March 15, 2024,) and (y) a termination of Executive's employment without Cause or Executive's resignation for Good Reason (payable within 60 days of such termination); provided that, in the event the Annual Bonus is payable under 2.2(y), receipt of the Annual Bonus will be subject to the requirements of Section 7 of the Agreement and the Annual Bonus will be pro-rated for the number of days of calendar year worked through the date of termination.

Subject to Executive's continued employment with the Company, Executive shall be eligible for an annual bonus with respect to 2024, and the Company and Executive shall negotiate in good faith such annual bonus, including the amount and any applicable corporate and individual performance metrics."

5. A new Section 2.3 shall be added as follows:

"**2.3 Retention Bonus**. Executive will be entitled to a Retention Bonus equal to $219,375 (the "**Retention Bonus**"), which is equal to Executive's target annual bonus for 2023, payable in a lump sum (subject to applicable withholdings) on or shortly following the earliest to occur of (i) a termination of Executive's employment without Cause or Executive's resignation for Good Reason (payable within 60 days of such termination of employment), (ii) the consummation of a

Change of Control (subject to Executive's continued employment through the Change of Control and payable within 10 days following the Change of Control), or (iii) December 31, 2023 (subject to Executive's continued employment through December 31, 2023 and payable by January 10, 2024); provided that, in the event the Retention Bonus is payable under 2.3(i), receipt of the Retention Bonus will be subject to the requirements of Section 7 of the Agreement."

6. A new Section 2.4 shall be added as follows:

"**2.4. Post-Termination Exercise Period following a Change of Control**. Notwithstanding anything to the contrary in Executive's Stock Option Agreements with the Company, following a Change of Control, the post-termination exercise period of any then-outstanding and vested stock options (including stock options for which vesting is accelerated pursuant to Section 6.3(iv)) held by Executive will be extended to fifteen (15) months following Executive's termination of Continuous Service (as defined in the Company's 2014 Equity Incentive Plan (the "**Plan**")) for any reason (other than a termination for Cause); provided such termination occurs on or following a Change of Control and subject to the earlier termination of Executive's stock options pursuant to the Plan and the applicable Stock Option Agreements. Further, please note that if Executive does not exercise any unexercised vested stock options within three (3) months of the date of termination of employment, any such unexercised vested options will cease to have "incentive stock option" status and will instead be considered "nonqualified stock options." Executive should consult Executive's account or tax advisor with respect to this matter."

7. The first clause of Section 6.3 shall be replaced in its entirety as follows:

"In the event Executive's employment with the Company is terminated by the Company without Cause or Executive resigns for Good Reason during the period commencing six (6) months prior to and ending twelve (12) months following a Change of Control; provided that if Executive
has such a qualifying termination within the six (6)-month period prior to a Change of Control,
the Change of Control must occur prior to March 1st of the calendar year following the calendar
year in which the date of employment termination occurs and provided further that Executive remains in compliance with the terms of this Agreement and the Confidentiality Agreement and subject to Section 7 below, the Company, or its successor, as the case may be, shall provide the Executive with the following severance benefits:"

8. Section 6.3(i) of the Agreement shall be replaced in its entirety as follows:

"The Company shall pay Executive, as severance, the equivalent of fifteen (15) months of Executive's base salary in effect as of Executive's employment termination, less any severance previously provided under Section 6.2(i) (the "**Severance**"). This Severance will be paid in a lump sum within 60 days after Executive's termination of employment or, if applicable, subsequent Change of Control; provided that in no events will the Severance be paid later than March 15th of the calendar year following the calendar year in which such termination of employment occurs."

9. Section 6.3(ii) of the Agreement shall be amended to provide that references to twelve (12) months with respect to COBRA premiums will now refer to fifteen (15) months with respect to COBRA premiums, less any COBRA premiums previously provided under Section 6.2(ii), and the following sentence will be added to the end of Section 6.3(ii):

"Notwithstanding the foregoing, the Company may, in its discretion, provide any remaining monthly payments in a fully taxable lump sum cash payment equal to the aggregate amount of the applicable COBRA premiums over the remainder of the COBRA premium periods, subject to applicable tax withholdings and payable as soon as practicable and in all events prior to March 15 of the calendar year following the calendar year in which the termination of employment occurs."

10. Section 6.3(iii) of the Agreement shall be replaced in its entirety as follows:

"The Company shall pay Executive an amount equal to $281,250, which represents 15 months of Executive's 2023 target annual bonus (or, if the qualifying termination occurs during 2024, the Company shall pay Executive an amount equal to 15 months of Executive's 2024 target annual bonus) payable in a lump sum, less deductions and withholdings, at the same time as the severance payment described in Section 6.3(i) above. For the avoidance of doubt, the amount payable pursuant to this Section 6.3(iii) shall not be subject to proration based on the portion of the year elapsed as of the termination date."

11. 10.3(e) (prior to the proviso) shall be replaced in its entirety by the following:

"(e) the approval by the stockholders of the Company of a complete liquidation, dissolution or winding-up of the Company."

12. Notwithstanding anything to the contrary in the Agreement or otherwise, Executive's new role and any associated changes in position, authority, responsibilities and/or duties shall not constitute Good Reason under this Agreement nor shall any changes in position, authorities, responsibilities and/or duties during a dissolution, liquidation or winding-up of the Company.

Except as otherwise set forth herein the Agreement will remain unmodified and in full force and effect.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the first day written above.

THE COMPANY:

Neoleukin Therapeutics, Inc.

By:
Name:
Title:

THE EXECUTIVE

Donna Cochener

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "**Agreement**"), made between Neoleukin Therapeutics, Inc., a Delaware corporation (the "**Company**"), and **Sean Smith** (the "**Executive**" and, collectively with the Company, the "**Parties**"), is entered into as of August 3, 2022 (the "**Effective Date**").

Whereas, the Company desires to continue to employ Executive to provide services to the Company and wishes to provide Executive with certain compensation and benefits in return for such services; and

Whereas, Executive wishes to continue to be employed by the Company and to provide services to the Company in return for certain compensation and benefits.

Now, Therefore, in consideration of the mutual promises and covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1. Employment by the Company.

1.1 Employment. This Agreement shall govern the terms of Executive's employment with the Company, effective as of the Effective Date set forth above.

1.2 Position. Executive shall serve as the Company's **Vice President, Finance**. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company. At such times as the Company does not have an acting Chief Financial Officer, Executive shall also serve as Principal Accounting Officer of the Company.

1.3 Duties and Location. Executive shall perform such duties as are typically performed by a Vice President of Finance and Principal Accounting Officer. Executive will report to the Company's Principal Financial Officer. Executive's primary office location shall be the Company's office located in Seattle, Washington.

1.4 Policies and Procedures. The employment relationship between the Parties shall be governed by the general employment policies and practices of the Company, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Salary. For services to be rendered hereunder, Executive shall receive a base salary at the rate of Three Hundred Fifteen Thousand Dollars ($315,000) per year (such base salary, as may be increased (but not decreased) from time to time, the **"Base Salary"**), subject to standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule.

2.2 Bonus. Executive will be eligible for an annual discretionary bonus of up to 35% of Executive's Base Salary (the **"Annual Bonus"**). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Company's Board of Directors (the **"Board"**) or the compensation committee thereof in its sole discretion based upon the Company's achievement of objectives and milestones as to 60% of the Annual Bonus and Executive's achievement of objectives and milestones as to 40% of the Annual Bonus, to be determined on an annual basis by the Board or the compensation committee thereof. Annual Bonuses are typically paid no later than March 15th of the year following the applicable bonus year. Executive will not be eligible for, and will not earn, any Annual Bonus (including a prorated bonus) if Executive's employment terminates for any reason before any Annual Bonus is paid, except as otherwise expressly provided in Section 6.3 below.

3. Standard Company Benefits. Executive shall be entitled to participate in all employee benefit programs for which Executive is eligible under the terms and conditions of the benefit plans that may be in effect from time to time and provided by the Company to its employees.

4. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in furtherance or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

5. [Reserved].

6. Termination of Employment; Severance.

6.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause or advance notice. In the event Executive's employment relationship is terminated for any reason, Executive shall be entitled to receive Executive's earned but unpaid Base Salary, unreimbursed business expenses properly incurred by Executive pursuant to Section 4 and any other compensation or benefit earned by or owed to (but not yet paid to) Executive through and including the date of termination, payable in a lump sum on the next regularly scheduled payroll date following the date on which Executive's employment terminated, or at such other date as shall be specified under the terms of the employee benefit plan pursuant to which such compensation or benefit is payable.

6.2 Severance Benefits for Termination Without Cause or Resignation with Good Reason Unrelated to a Change of Control. In the event Executive's employment with the Company is terminated by the Company without Cause or Executive resigns for Good Reason prior to a Change of Control (as defined below) or more than twelve (12) months following a Change of Control, provided that Executive remains in compliance with the terms of this Agreement and the Confidentiality Agreement (as defined below) and subject to Section 7 below, the Company or its successor, as the case may be, shall provide Executive with the following severance benefits:

i. The Company shall pay Executive, as severance, the equivalent of

nine (9) months of Executive's Base Salary in effect as of the date of Executive's employment termination. This severance will be paid in the form of salary continuation, payable on the Company's regular payroll dates, subject to standard payroll deductions and withholdings, starting on the 60th day after Executive's termination date, with the first payment to include those payments that would have occurred earlier but for the 60-day delay.

ii. Provided that Executive is then eligible for and timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable) through the period starting on Executive's termination date and ending on the earliest to occur of: (a) nine (9) months following Executive's termination date; (b) the date Executive becomes eligible for comparable group health insurance coverage through a new employer; or (c) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's comparable group health plan or otherwise ceases to be eligible for COBRA during this time period, Executive must immediately notify the Company of such event. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA premiums without a substantial risk of violating applicable law, the Company instead shall pay to Executive, on the first day of each calendar month, a fully taxable cash payment equal to the applicable COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the COBRA premium period. Executive may, but is not obligated to, use such payments toward the cost of COBRA premiums.

6.3 Severance Benefits for Termination Without Cause or Resignation with Good Reason Related to a Change of Control. In the event Executive's employment with the Company is terminated by the Company without Cause or Executive resigns for Good Reason during the twelve (12) month period immediately following a Change of Control, and provided that Executive remains in compliance with the terms of this Agreement and the Confidentiality Agreement and subject to Section 7 below, the Company, or its successor, as the case may be, shall provide Executive with the following severance benefits:

i. The Company shall pay Executive, as severance, the equivalent of twelve (12) months of Executive's base salary in effect as of the date of Executive's employment termination. This severance will be paid in the form of salary continuation, payable on the Company's regular payroll dates, subject to standard payroll deductions and withholdings, starting on the 60th day after Executive's termination date, with the first payment to include those payments that would have occurred earlier but for the 60-day delay.

ii. Provided that Executive is then eligible for and timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable) through the period starting on Executive's termination date and ending on the earliest to occur of: (a) twelve (12) months following Executive's termination date; (b) the date Executive becomes eligible for comparable group health insurance coverage through a new employer; or
(c) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's comparable group health plan or otherwise ceases to be eligible for COBRA during this time

period, Executive must immediately notify the Company of such event. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA premiums without a substantial risk of violating applicable law, the Company instead shall pay to Executive, on the first day of each calendar month, a fully taxable cash payment equal to the applicable COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the COBRA premium period. Executive may, but is not obligated to, use such payments toward the cost of COBRA premiums.

iii. The Company shall pay Executive an amount equal to 100% of Executive's target annual bonus, payable in a lump sum, less deductions and withholdings, at the same time as the first severance payment described in Section 6.3(i) above. For the avoidance of doubt, the amount payable pursuant to this Section 6.3(iii) shall not be subject to proration based on the portion of the year elapsed as of the date of termination.

iv. The vesting of all unvested equity-based incentive compensation awards then held by Executive shall be accelerated such that 100% of the shares underlying such awards shall be deemed immediately vested and exercisable; *provided that*, in the case of any unvested equity-based incentive compensation awards that are subject to performance-based vesting terms as of the date of such termination, the treatment of such performance-based vesting conditions shall be governed by the applicable equity plan and award agreement.

6.4 Termination for Cause; Resignation Without Good Reason; Death or Disability.

i. If Executive resigns without Good Reason or the Company terminates Executive's employment for Cause, Executive shall not be entitled to receive any payments or benefits under this Agreement, other than as set forth in Section 6.1. In addition, Executive shall resign from all positions and terminate any relationships as an employee, advisor, officer or director with the Company and any of its affiliates, each effective on the date of termination.

ii. Executive's employment shall terminate automatically upon the death or Total Disability of Executive. "**Total Disability**" shall mean Executive's inability, with reasonable accommodation, to perform the duties of her position for a period or periods aggregating ninety (90) calendar days in any period of one hundred eighty days (180) consecutive days as a result of any medically recognized physical or mental illness, loss of legal capacity or any other cause beyond Executive's control. Executive and the Company hereby acknowledge that Executive's ability to perform the duties specified in Section 1 is the essence of this Agreement. Termination hereunder shall be deemed to be effective (a) at the end of the calendar month in which Executive's death occurs or (b) immediately upon a reasonable determination by the Board or the compensation committee thereof of Executive's Total Disability. In the case of termination of employment under this Section 6.4(ii), Executive shall not be entitled to receive any payments or benefits under this Agreement, other than as set forth in Section 6.1.

7. Conditions to Receipt of Severance Benefits. The receipt of the severance benefits set forth in Section 6.2 and Section 6.3 above shall be subject to Executive signing and

not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company and Executive (the "**Separation Agreement**") no later than 60 days following the date of termination. No severance benefits will be paid or provided unless and until the Separation Agreement becomes effective and non-revocable. Executive shall also resign from all positions and terminate any relationships as an employee, advisor, officer or director with the Company and any of its affiliates, each effective on the date of termination.

8. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**" and "**Section 409A**") provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. All payments and benefits that are payable upon a termination of employment hereunder shall be paid or provided only upon Executive's "separation from service" from the Company (within the meaning of Section 409A). For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's termination to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i), and if any of the payments upon termination set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month period measured from the date of Executive's termination with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Paragraph shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred.

9. Section 280G. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section 9, would be subject to the excise tax imposed by Section 4999 of the Code, then, Executive's severance and other benefits under this Agreement shall be payable either (i) in full, or (ii) as to such lesser amount which would result in no portion of such severance and other benefits being subject to the excise tax under Section 4999 of the Code, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999 of the Code, results in the receipt by Employee on an after-tax basis of the greatest amount of severance benefits under this Agreement, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. Any reduction shall be

made in the following manner: first a pro rata reduction of (i) cash payments subject to Section 409A as deferred compensation and (ii) cash payments not subject to Section 409A, and second a pro rata cancellation of (i) equity-based compensation subject to Section 409A as deferred compensation and (ii) equity-based compensation not subject to Section 409A. Reduction in either cash payments or equity compensation benefits shall be made prorata between and among benefits which are subject to Section 409A and benefits which are exempt from Section 409A. Unless the Company and Employee otherwise agree in writing, any determination required under this Section 9 shall be made in writing by the Company's independent public accountants (the "**Accountants**"), whose determination shall be conclusive and binding upon Employee and the Company for all purposes. For purposes of making the calculations required by this Section 9, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Employee shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section 9. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 9.

10. Definitions.

10.1 Cause. For purposes of this Agreement, **"Cause"** for termination will mean: (a) a material breach of any of Executive's obligations or duties pursuant to this Agreement or the Confidentiality Agreement, which remains uncured seven days after Executive becomes aware of the breach by formal written notification by the Company; (b) gross negligence or willful misconduct in the course of employment; (c) any action or activity that is contrary to applicable insider trading rules or any other applicable securities rules or legislation; or (d) a material act or omission involving substantial dishonesty or fraud that harms or would reasonably be expected to harm the Company.

10.2 Good Reason. For purposes of this Agreement, Executive shall have "**Good Reason**" for resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent: (a) any material and adverse change to Executive's position, authority, responsibilities, or job location in effect under this Agreement; (b) any material reduction in base salary or bonus opportunity as provided under this Agreement; (c) an assignment to Executive of any duties materially inconsistent with Executive's status as Vice President, Finance; or (d) any failure to secure the agreement of any successor entity to fully assume the Company's obligations under this Agreement. In order to resign for Good Reason, Executive must provide written notice to the Board within 60 days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, allow the Company at least 30 days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company not later than 90 days after the expiration of the cure period.

10.3 Change of Control. For purposes of this Agreement, **"Change of Control"** means the occurrence of one or more of the following: (a) a merger, a consolidation, a reorganization or an arrangement that results in a transfer of more than fifty percent (50%) of the

total voting power of the Company's outstanding securities to a person or a group of persons different from a person or a group of persons holding those securities immediately prior to such transaction (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company); (b) a direct or indirect sale or other transfer of beneficial ownership of securities of the Company possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities to a person or a group of persons different from a person or a group of persons holding those securities immediately prior to such transaction (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company); (c) a direct or indirect sale or other transfer of the right to appoint more than fifty percent (50%) of the directors of the Board or otherwise directly or indirectly control the management, affairs and business of the Company to a person or a group of persons different from a person or a group of persons holding this right immediately prior to such transaction (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company); (d) a direct or indirect sale or other transfer of all or substantially all of the assets of the Company to a person or a group of persons different from a person or a group of persons holding those assets immediately prior to such transaction (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company); or (e) a complete liquidation, dissolution or winding-up of the Company; *provided, however,* that a Change in Control will not be deemed to have occurred if such Change in Control results solely from the issuance, in connection with a bona fide financing or series of financings by the Company, of voting securities of the Company or any rights to acquire voting securities of the Company which are convertible into voting securities.

11. Proprietary Information Obligations. As a condition of employment, Executive has previously executed and shall continue to abide by the Company's standard form of Employee Invention Assignment, Confidentiality and Non-Competition Agreement (the **"Confidentiality Agreement"**).

12. Outside Activities During Employment.

12.1 Non-Company Business. Except with the prior written consent of the Board, Executive will not during the term of Executive's employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder.

12.2 No Adverse Interests. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

13. Dispute Resolution. To ensure the timely and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance, negotiation, execution, or interpretation of this Agreement, Executive's employment, or the termination of Executive's employment, including

but not limited to statutory claims, shall be resolved to the fullest extent permitted by law by final, binding and confidential arbitration, by a single arbitrator, in Seattle, Washington conducted by JAMS, Inc. ("**JAMS**") under the then applicable JAMS rules or by another arbitration provider if mutually agreed upon by Executive and Board. By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. The Company acknowledges that Executive will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. The arbitrator shall be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS' arbitration fees in excess of the amount of court fees that would be required of Executive if the dispute were decided in a court of law. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

14. General Provisions.

14.1 Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by email or fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

14.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

14.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

14.4 Complete Agreement. This Agreement, together with the Confidentiality Agreement, constitutes the entire agreement between Executive and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the Parties' agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. It is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in a writing signed by a duly authorized officer of the Company.

14.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

14.6 Headings. The headings of the paragraphs hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

14.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of his duties hereunder and he may not assign any of his rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

14.8 Tax Withholding and Indemnification. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to the Agreement.

14.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of Washington.

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IN WITNESS WHEREOF, the Parties have executed this Agreement on the day and year first written above.

NEOLEUKIN THERAPEUTICS, INC.

By: /s/ Jonathan M. Drachman
Name: Jonathan M. Drachman, M.D.
Title: Chief Executive Officer

SEAN SMITH

/s/ Sean Smith

AMENDMENT NO. 1
TO
EMPLOYMENT AGREEMENT

This Amendment No. 1 (this "**Amendment**"), dated as of April 3, 2023, amends that certain Employment Agreement (the "**Agreement**"), dated as of August 3, 2022, by and between Neoleukin Therapeutics, Inc., a Delaware corporation (the "**Company**"), and Sean Smith (the "**Executive**"). All capitalized terms not defined herein shall have the meanings assigned to them in the Agreement.

On March 31, 2023, Executive was appointed as the Company's Interim Chief Financial Officer. In connection with such appointment, the Company and Executive hereby agree to amend the Agreement as follows:

1. Section 1.2 of the Agreement shall be replaced in its entirety as follows:

"**1.2 Position**. Executive shall serve as the Company's Interim Chief Financial Officer. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company."

2. Section 1.3 of the Agreement shall be replaced in its entirety as follows:

"**1.3 Duties and Location**. Executive shall perform such duties as are typically performed by a Chief Financial Officer. Executive will report to the Company's Chief Executive Officer. Executive's primary office location shall be the Company's office located in Seattle, Washington."

3. Effective as of March 31, 2023, the Company shall pay Executive a Base Salary at a rate equal to $410,000 per annum.

4. Section 2.2 of Agreement shall be replaced in its entirety as follows:

"**2.2 Bonus**. Executive will be entitled to an annual bonus equal to the greater of (i) Executive's target annual bonus (equal to $159,167 for 2023, which is pro-rated for salary increases in 2023 and calculated using a target bonus percentage of 40% or (ii) Executive's actual annual bonus based on corporate and individual performance in 2023, if performance is determinable (the "**Annual Bonus**"), payable in a lump sum (subject to applicable withholdings) on or shortly following the earlier to occur of (x) December 31, 2023 (subject to Executive's continued employment through December 31, 2023, and payable by March 15, 2024,) and (y) a termination of Executive's employment without Cause or Executive's resignation for Good Reason (payable within 60 days of such termination); provided that, in the event the Annual Bonus is payable under 2.2(y), receipt of the Annual Bonus will be subject to the requirements of Section 7 of the Agreement and the Annual Bonus will be pro-rated for the number of days of calendar year worked through the date of termination.

Subject to Executive's continued employment with the Company, Executive shall be eligible for an annual bonus with respect to 2024, and the Company and Executive shall negotiate in good faith such annual bonus, including the amount and any applicable corporate and individual performance metrics."

5. A new Section 2.3 shall be added as follows:

"**2.3 Retention Bonus**. Executive will be entitled to a Retention Bonus equal to $159,167 (the "**Retention Bonus**"), which is equal to Executive's target annual bonus for 2023, payable in a lump sum (subject to applicable withholdings) on or shortly following the earliest to occur of (i) a termination of Executive's employment without Cause or Executive's resignation for Good Reason (payable within 60 days of such termination of employment), (ii) the consummation of

a Change of Control (subject to Executive's continued employment through the Change of Control and payable within 10 days following the Change of Control), or (iii) December 31, 2023 (subject to Executive's continued employment through December 31, 2023 and payable by January 10, 2024); provided that, in the event the Retention Bonus is payable under 2.3(i), receipt of the Retention Bonus will be subject to the requirements of Section 7 of the Agreement."

6. A new Section 2.4 shall be added as follows:

"**2.4. Post-Termination Exercise Period following a Change of Control**. Notwithstanding anything to the contrary in Executive's Stock Option Agreements with the Company, following a Change of Control, the post-termination exercise period of any then-outstanding and vested stock options (including stock options for which vesting is accelerated pursuant to Section 6.3(iv)) held by Executive will be extended to fifteen (15) months following Executive's termination of Continuous Service (as defined in the Company's 2014 Equity Incentive Plan (the "**Plan**")) for any reason (other than a termination for Cause); provided such termination occurs on or following a Change of Control and subject to the earlier termination of Executive's stock options pursuant to the Plan and the applicable Stock Option Agreements. Further, please note that if Executive does not exercise any unexercised vested stock options within three (3) months of the date of termination of employment, any such unexercised vested options will cease to have "incentive stock option" status and will instead be considered "nonqualified stock options." Executive should consult Executive's account or tax advisor with respect to this matter."

7. The first clause of Section 6.3 shall be replaced in its entirety as follows:

"In the event Executive's employment with the Company is terminated by the Company without Cause or Executive resigns for Good Reason during the period commencing six (6) months prior to and ending twelve (12) months following a Change of Control; provided that if Executive has such a qualifying termination within the six (6)-month period prior to a Change of Control, the Change of Control must occur prior to March 1st of the calendar year following the calendar year in which the date of employment termination occurs and provided further that Executive remains in compliance with the terms of this Agreement and the Confidentiality Agreement and subject to Section 7 below, the Company, or its successor, as the case may be, shall provide the Executive with the following severance benefits:"

8. Section 6.3(i) of the Agreement shall be replaced in its entirety as follows:

"The Company shall pay Executive, as severance, the equivalent of fifteen (15) months of Executive's base salary in effect as of Executive's employment termination, less any severance previously provided under Section 6.2(i) (the "**Severance**"). This Severance will be paid in a lump sum within 60 days after Executive's termination of employment or, if applicable, subsequent Change of Control; provided that in no events will the Severance be paid later than March 15th of the calendar year following the calendar year in which such termination of employment occurs."

9. Section 6.3(ii) of the Agreement shall be amended to provide that references to twelve (12) months with respect to COBRA premiums will now refer to fifteen (15) months with respect to COBRA premiums, less any COBRA premiums previously provided under Section 6.2(ii), and the following sentence will be added to the end of Section 6.3(ii):

"Notwithstanding the foregoing, the Company may, in its discretion, provide any remaining monthly payments in a fully taxable lump sum cash payment equal to the aggregate amount of the applicable COBRA premiums over the remainder of the COBRA premium periods, subject to applicable tax withholdings and payable as soon as practicable and in all events prior to March 15 of the calendar year following the calendar year in which the termination of employment occurs."

10. Section 6.3(iii) of the Agreement shall be replaced in its entirety as follows:

"The Company shall pay Executive an amount equal to $205,000, which represents 15 months of Executive's 2023 target annual bonus (or, if the qualifying termination occurs during 2024, the Company shall pay Executive an amount equal to 15 months of Executive's 2024 target annual bonus) payable in a lump sum, less deductions and withholdings, at the same time as the severance payment described in Section 6.3(i) above. For the avoidance of doubt, the amount payable pursuant to this Section 6.3(iii) shall not be subject to proration based on the portion of the year elapsed as of the termination date."

11. 10.3(e) (prior to the proviso) shall be replaced in its entirety by the following:

"(e) the approval by the stockholders of the Company of a complete liquidation, dissolution or winding-up of the Company."

12. Notwithstanding anything to the contrary in the Agreement or otherwise, Executive's new role and any associated changes in position, authority, responsibilities and/or duties shall not constitute Good Reason under this Agreement nor shall any changes in position, authorities, responsibilities and/or duties during a dissolution, liquidation or winding-up of the Company.

Except as otherwise set forth herein the Agreement will remain unmodified and in full force and effect.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the first day written above.

THE COMPANY:

Neoleukin Therapeutics, Inc.

By:
Name:
Title:

THE EXECUTIVE

Sean Smith

Exhibit 31.1

CERTIFICATIONS

I, Donna M. Cochener, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Neoleukin Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2023

/s/ Donna M Cochener

Donna M Cochener
Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Sean Smith, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Neoleukin Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2023

/s/ Sean Smith

Sean Smith
Interim Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

NEOLEUKIN THERAPEUTICS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Neoleukin Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Donna M. Cochener, Interim Chief Executive Officer of the Company, and Sean Smith, Interim Chief Financial Officer of the Company, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of May 8, 2023.

/s/ Donna M. Cochener	/s/ Sean Smith
Donna M. Cochener *Interim Chief Executive Officer* *(Principal Executive Officer)*	Sean Smith *Interim Chief Financial Officer* *(Principal Financial Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Neoleukin Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.