

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2020

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number: 001-36327

**Neoleukin Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

98-0542593  
(I.R.S. Employer  
Identification No.)

360-1616 Eastlake Avenue East  
Seattle, Washington 98102  
(Address of principal executive offices, including zip code)

(Registrant's telephone number, including area code): (206) 732-2133

Securities registered pursuant to Section 12(b) of the Act:

Title of each class  
Common Stock, par value \$0.000001

Trading Symbol(s)  
NLTX

Name of each exchange on which registered  
The Nasdaq Global 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 November 4, 2020, there were 41,894,382 shares of the registrant's common stock outstanding.

**Neoleukin Therapeutics, Inc.**  
**Quarterly Report on Form 10-Q**  
**For the Quarter Ended September 30, 2020**

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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 registered 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 Consolidated Financial Statements**

**NEOLEUKIN THERAPEUTICS, INC.**

**Condensed consolidated balance sheets**

(Unaudited)

(In thousands of U.S. dollars, except per share and share amounts)

	<b>September 30, 2020</b>	<b>December 31, 2019</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 201,150	\$ 143,093
Other current assets	5,439	503
<b>Total current assets</b>	<b>206,589</b>	<b>143,596</b>
Property and equipment, net	3,303	2,060
Operating lease right-of-use assets	10,398	770
Intangible asset, net	403	567
Other non-current assets	997	30
<b>Total assets</b>	<b>\$ 221,690</b>	<b>\$ 147,023</b>
<b>Liabilities</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 9,522	\$ 4,125
Operating lease liabilities	321	556
Finance lease liabilities	49	62
<b>Total current liabilities</b>	<b>9,892</b>	<b>4,743</b>
Non-current operating lease liabilities	11,350	447
Non-current finance lease liabilities	108	146
<b>Total liabilities</b>	<b>21,350</b>	<b>5,336</b>
<b>Stockholders' equity</b>		
Share capital:		
Common stock - \$0.000001 par value - authorized, 100,000,000 as of September 30, 2020 and December 31, 2019; issued and outstanding, 41,876,590 as of September 30, 2020 and 37,996,849 as of December 31, 2019.	—	—
Preferred stock - \$0.000001 par value - authorized, 5,000,000 as of September 30, 2020 and December 31, 2019; nil issued and outstanding as of September 30, 2020 and December 31, 2019.	—	—
Additional paid-in capital	520,506	441,216
Accumulated deficit	(320,166)	(299,529)
<b>Total stockholders' equity</b>	<b>200,340</b>	<b>141,687</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 221,690</b>	<b>\$ 147,023</b>

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

NEOLEUKIN THERAPEUTICS, INC.

Condensed consolidated statements of operations

(Unaudited)

(In thousands of U.S. dollars, except per share and share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
<b>Operating loss</b>				
Research and development	\$ 6,216	\$ 1,420	\$ 16,557	\$ (471)
Acquired in-process research and development	—	47,716	—	47,716
General and administrative	3,860	10,380	12,359	15,358
Gain on sale of Aquinox Canada	(7,826)	—	(7,826)	—
Total operating loss	2,250	59,516	21,090	62,603
Other income, net	1	384	453	1,262
<b>Net loss</b>	<b>\$ (2,249)</b>	<b>\$ (59,132)</b>	<b>\$ (20,637)</b>	<b>\$ (61,341)</b>
Net loss per common stock – basic and diluted	\$ (0.04)	\$ (2.26)	\$ (0.41)	\$ (2.51)
Basic and diluted weighted average common shares outstanding	54,121,676	26,185,839	50,896,014	24,429,893

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

## NEOLEUKIN THERAPEUTICS, INC.

## Condensed consolidated statements of cash flows

(Unaudited)

(In thousands of U.S. dollars)

	Nine Months Ended September 30,	
	2020	2019
<b>Operating activities</b>		
Net loss	\$ (20,637)	\$ (61,341)
Adjustments to reconcile net cash used in operating activities:		
Stock-based compensation	3,393	7,017
Acquired in-process research and development	—	47,716
Depreciation and amortization	578	180
Loss on disposal of property and equipment	180	—
Amortization of operating lease right-of-use assets	784	76
Write-off of right-of-use asset upon lease termination	113	—
Unrealized foreign exchange loss	—	20
Changes in operating assets and liabilities:		
Other current assets and other non-current assets	(5,026)	(453)
Accounts payable and accrued liabilities	5,125	(3,828)
Operating lease right-of-use assets	(169)	—
Operating lease liabilities	313	(145)
Net cash used in operating activities	<u>(15,346)</u>	<u>(10,758)</u>
<b>Investing activities</b>		
Acquisition of Former Neoleukin, net of cash acquired	—	191
Purchase of property and equipment	(1,566)	(97)
Net cash provided by (used in) investing activities	<u>(1,566)</u>	<u>94</u>
<b>Financing activities</b>		
Proceeds from issuance of common stock and pre-funded warrants, net of commissions of \$4.6 million	71,675	—
Payment of offering costs	(355)	—
Proceeds from exercise of stock options	4,576	40
Payment on finance lease obligations	(49)	(7)
Net cash provided by financing activities	<u>75,847</u>	<u>33</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	—	9
Net change in cash, cash equivalents and restricted cash during the period	58,935	(10,622)
Cash, cash equivalents and restricted cash, beginning of period	143,093	76,928
<b>Cash, cash equivalents and restricted cash, end of period</b>	<u>\$ 202,028</u>	<u>\$ 66,306</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Purchases of property and equipment unpaid at period-end	271	—
Operating lease liabilities arising from obtaining ROU asset	10,618	515

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

NEOLEUKIN THERAPEUTICS, INC.

Condensed consolidated statements of stockholders' equity

(Unaudited)

(In thousands of U.S. dollars, except share amounts)

	Common Stock		Non-Voting Convertible Preferred Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Number	Amount	Number	Amount			
Balances, December 31, 2019	37,996,849	\$ —	—	\$ —	\$ 441,216	\$ (299,529)	\$ 141,687
Options exercised	376,311	—	—	—	3,392	—	3,392
Restricted stock units vested	13,000	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	683	—	683
Net loss	—	—	—	—	—	(8,642)	(8,642)
Balances, March 31, 2020	38,386,160	\$ —	—	\$ —	\$ 445,291	\$ (308,171)	\$ 137,120
Options exercised	98,882	—	—	—	303	—	303
Restricted stock units vested	1,500	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,022	—	1,022
Net loss	—	—	—	—	—	(9,746)	(9,746)
Balances, June 30, 2020	38,486,542	\$ —	—	\$ —	\$ 446,616	\$ (317,917)	\$ 128,699
Issuance of common stock and pre-funded warrants, net of commissions and offering expenses	3,262,471	—	—	—	71,320	—	71,320
Options exercised	106,077	—	—	—	882	—	882
Restricted stock units vested	21,500	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,688	—	1,688
Net loss	—	—	—	—	—	(2,249)	(2,249)
Balances, September 30, 2020	41,876,590	\$ —	—	\$ —	\$ 520,506	\$ (320,166)	\$ 200,340

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

**NEOLEUKIN THERAPEUTICS, INC.**

**Condensed consolidated statements of stockholders' equity**

(Unaudited)

(In thousands of U.S. dollars, except share amounts)

	Common Stock		Non-Voting Convertible Preferred Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Number	Amount	Number	Amount			
Balances, December 31, 2018	23,537,368	\$ —	—	\$ —	\$ 302,759	\$ (230,087)	\$ 72,672
Stock-based compensation	—	—	—	—	1,078	—	1,078
Net loss	—	—	—	—	—	(2,208)	(2,208)
Balances, March 31, 2019	23,537,368	\$ —	—	\$ —	\$ 303,837	\$ (232,295)	\$ 71,542
Stock-based compensation	—	—	—	—	788	—	788
Net loss	—	—	—	—	—	(1)	(1)
Balances, June 30, 2019	23,537,368	\$ —	—	\$ —	\$ 304,625	\$ (232,296)	\$ 72,329
Issuance of common stock for Former Neoleukin common stock	4,589,771	—	—	—	15,055	—	15,055
Issuance of convertible preferred stock for Former Neoleukin common stock	—	—	101,927	—	33,432	—	33,432
Options exercised	13,104	—	—	—	40	—	40
Stock-based compensation	—	—	—	—	5,151	—	5,151
Net loss	—	—	—	—	—	(59,132)	(59,132)
Balances, September 30, 2019	28,140,243	\$ —	101,927	\$ —	\$ 358,303	\$ (291,428)	\$ 66,875

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

**Notes to the condensed consolidated financial statements**  
(Unaudited)

**1. Nature of operations**

Neoleukin Therapeutics, Inc. (“Neoleukin” or “the Company”) is a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using *de novo* protein design technology. Neoleukin uses sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins.

**2. Summary of significant accounting policies****(a) Basis of presentation**

The accompanying unaudited condensed consolidated financial statements are presented in United States (“U.S.”) dollars and 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 consolidated financial statements do not include all of the information and footnotes required for complete consolidated 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, 2019, filed with the Securities and Exchange Commission on March 12, 2020.

In management’s opinion, the unaudited condensed consolidated financial statements reflect all adjustments (including reclassifications and normal recurring adjustments) necessary to present fairly the financial position as of September 30, 2020, 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 a full year.

**(b) Use of estimates and assumptions**

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant areas requiring estimates include valuation and recognition of stock-based compensation, leases, amortization and depreciation of property, plant and equipment and intangible assets, and pre-clinical and other accruals. Actual results could differ from those estimates.

**(c) Reclassification**

The Company reclassified prior year amortization of operating lease right-of-use assets, depreciation and amortization, and changes in operating lease liabilities in the condensed consolidated statements of cash flows to conform to current year presentation. This reclassification had no effect on net cash used in operating activities.

**(d) Leases**

At contract inception, the Company determines if the contract is a lease or contains a lease. Operating leases are recorded as operating lease right-of-use assets, operating lease liabilities and non-current operating lease liabilities. Finance leases are recorded as finance lease right-of-use assets, finance lease liabilities and non-current finance lease liabilities.

Right-of-use assets and 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 rate implicit in the lease is not readily determinable. The 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.

For leases of office space with a lease term 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.

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



**(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.

At September 30, 2020, and December 31, 2019, the Company had \$108.3 million and \$40.0 million in money market funds, respectively. Money market funds are level one financial instruments as they are valued at fair value, which is the closing price reported by the fund sponsor from an actively traded exchange.

**(f) Earnings (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 such as outstanding stock options and unvested restricted stock units are included in the calculation of diluted earnings per share only in periods of net income. Such common stock equivalents are excluded in the calculation of diluted net loss per share in periods of net loss as inclusion of such amounts would be anti-dilutive. Outstanding pre-funded warrants of 12,663,010 are considered outstanding as of their issuance date and are included in the basic and diluted net loss per share calculation because they are fully vested and exercisable at any time for a nominal cash consideration.

**(g) Asset acquisitions**

At the time of acquisition, the Company determines if a transaction should be accounted for as a business combination or acquisition of assets.

For an acquisition of assets, the cost of acquiring the asset group, including transaction costs, is allocated to the acquired assets and assumed liabilities based on their relative fair values without giving rise to goodwill. Acquired in-process research and development assets are expensed if management determines that the assets do not have an alternative future use. Other long-lived intangible assets are recorded at the acquired cost and amortized using the straight-line method over their estimated useful life.

The intangible asset is tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. The Company recognizes an impairment loss when carrying amount is not recoverable and the estimated fair value of the intangible asset is less than its carrying value.

**(h) Recently issued and recently adopted accounting standards**

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12 "Simplifying the Accounting for Income Taxes." The objective of the standard is to improve areas of GAAP by removing certain exceptions permitted by Accounting Standards Codification ("ASC") Topic 740 - Income Taxes and clarifying existing guidance to facilitate consistent application. ASU 2019-12 is effective for fiscal years and interim periods beginning after December 15, 2020. The Company has incurred net losses since its inception and maintains a full valuation allowance on the net deferred tax assets. As such, the Company does not expect the adoption of this standard to have a material impact on the financial condition, results of operations and cash flows, or financial statement disclosures.

In August 2018, the FASB issued "ASU 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract." The objective of the standard is to align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. We adopted this standard on January 1, 2020 on a prospective basis. The adoption of this ASU did not have a material impact on the Company's financial condition, results of operations, cash flows, and financial statement disclosures.

**3. Merger of Neoleukin Therapeutics, Inc. and Aquinox Pharmaceuticals, Inc.**

On August 8, 2019, Aquinox Pharmaceuticals, Inc. ("Aquinox") and Neoleukin Therapeutics, Inc. ("Former Neoleukin") completed a transaction pursuant to the Agreement and Plan of Merger dated August 5, 2019. Former Neoleukin became a wholly owned subsidiary of Aquinox and Aquinox subsequently changed its name to Neoleukin Therapeutics, Inc. All of the outstanding shares of common stock of the Former Neoleukin were exchanged for 4,589,771 shares of common stock of the Company and 101,927 shares of non-voting convertible preferred stock of the Company.

The total consideration paid was \$51.6 million and consists of:

**(in thousands)**

Fair value of 4,589,771 shares of Aquinox common stock	\$	15,054
Fair value of 101,927 shares of Aquinox convertible preferred stock		33,432
Cash consideration for fractional shares		5
Transaction costs		3,087
<b>Total consideration</b>	<b>\$</b>	<b>51,578</b>

The fair value of the Aquinox securities issued to stockholders of Former Neoleukin was based on the closing stock price on August 7, 2019, the last day of trading prior to the completion of the transaction.

The transaction was accounted for as an asset acquisition as Former Neoleukin did not meet the definition of a business under Accounting Standard Codification Topic 805, Business Combinations (“ASC 805”) as substantially all of the value was in the In Process Research & Development (“IPR&D”) asset. The estimated fair value of the IPR&D asset was expensed as the Company determined that the asset has no alternative future use in accordance with ASC 730 “Research and Development”.

The following table summarizes the assets acquired and liabilities assumed:

**(in thousands)**

<b>Assets acquired:</b>		
Cash and cash equivalents	\$	3,282
Receivables, prepayments and deposits		560
Property and equipment, net		1,034
In process research and development asset		47,716
Intangible asset		659
<b>Total assets acquired</b>		<b>53,251</b>
<b>Liabilities assumed:</b>		
Accounts payable and other liabilities		1,472
Financing lease liability		201
<b>Total liabilities assumed</b>		<b>1,673</b>
<b>Total consideration</b>	<b>\$</b>	<b>51,578</b>

**4. Cash, cash equivalents and restricted cash**

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

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

<b>(in thousands)</b>	<b>September 30, 2020</b>	<b>December 31, 2019</b>
Cash and cash equivalents	\$ 201,150	\$ 143,093
Restricted cash	878	—
<b>Total cash, cash equivalents, and restricted cash</b>	<b>\$ 202,028</b>	<b>\$ 143,093</b>

## 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 a lease agreement for approximately 33,300 square feet of office space in Seattle, Washington, for the Company's future principal executive offices, a laboratory for research and development and related uses. In January 2020, the Company issued an irrevocable letter of credit in the amount of \$0.5 million for the security deposit in accordance with the terms of the lease. The lease commenced on January 15, 2020 and rent obligations are scheduled to commence on December 1, 2020. The Company will also be responsible for the payment of additional rent to cover the Company's share of the annual operating and tax expenses and utilities costs for the building. The lease expires on December 1, 2028, with the option to extend the lease for two five-year terms. The lease provides for a tenant improvement allowance of \$8.0 million, which is included in the base rent, and an optional additional tenant improvement allowance with a maximum amount of \$1.5 million, which will result, if elected, in additional rent expense recognized over the term of the lease. In September 2020, the Company elected to utilize this additional tenant improvement allowance. This resulted in a remeasurement of the lease liability due to an increase in lease payments over the term of the lease. The Company recorded an increase to the lease liability and related right-of-use asset of \$1.0 million. As of September 30, 2020, there was a tenant improvement allowance receivable of \$4.2 million recorded in other current assets related to reimbursable build-out costs incurred by the Company, of which \$3.9 million were unpaid and recorded in accounts payable and accrued liabilities in the condensed consolidated balance sheet. In November 2020, the Company executed an amendment to this lease that extends the scheduled rent commencement date to February 1, 2021 and the base term expiration to February 1, 2029. The amendment will not have an impact on total fixed lease payments over the base term. In addition, the amendment did not impact the associated operating lease liability or right-of-use asset as of September 30, 2020, as the event did not exist at, and arose subsequent to, September 30, 2020.

The Company has a lease agreement for approximately 6,272 square feet of office space in Seattle, Washington, for the Company's principal executive offices, a laboratory for research and development and related uses. In June 2020, the Company executed an amendment to this lease pursuant to which the Company has the option to terminate the lease, without penalty, at any point subsequent to November 1, 2020 with 45 days advance written notice. The Company determined that it is not reasonably certain to not exercise this termination option after December 15, 2020.

On June 30, 2020, the Company terminated its lease agreement for 10,946 square feet of office space in Vancouver, Canada. The lease termination resulted in an extinguishment of the lease liability and the write-off of the related right-of-use asset. After incurring additional expenses included in the termination fee of \$0.5 million, the Company recognized a loss of \$0.3 million on the termination of the lease, which was recorded in general and administrative expenses in June 2020. In addition, the Company wrote-off leasehold improvements and other property and equipment associated with the lease and incurred a loss on disposal of \$0.2 million in June 2020.

As of September 30, 2020, and December 31, 2019, the Company's operating lease right-of-use assets were \$10.4 million and \$0.8 million, respectively. As of September 30, 2020, and December 31, 2019, the Company's finance lease right-of-use assets were \$0.2 million and \$0.3 million, respectively.

## 6. Equity

### *(a) Offering of common stock and pre-funded warrants*

On July 7, 2020, the Company completed an underwritten public offering of 3,262,471 shares of its common stock at a price of \$15.25 per share and pre-funded warrants to purchase 1,737,529 shares of its common stock at a price of \$15.249999 per pre-funded warrant. The pre-funded warrants can be exercised at any time after issuance for an exercise price of \$0.000001 per share. The aggregate net proceeds received by the Company from the offering, net of underwriting discounts and commissions and offering costs of approximately \$4.9 million, were \$71.3 million.

**(b) Stock-based compensation expense**

Stock-based compensation expense is classified in the condensed consolidated statement of operations as follows:

<i>(in thousands)</i>	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Research and development expenses	\$ 571	\$ 98	\$ 1,200	\$ 178
General and administrative expenses	1,117	5,053	2,193	6,839
Total stock-based compensation expense	\$ 1,688	\$ 5,151	\$ 3,393	\$ 7,017

Total unrecognized compensation cost for all stock-based compensation plans was \$23.6 million as of September 30, 2020. This cost is expected to be recognized over a weighted average remaining vesting period of 3.31 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		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Expected volatility	94.84%	90.00%	93.86%	90.00%
Expected dividends	0%	0%	0%	0%
Expected terms (years)	6.07	6.00	6.02	6.00
Risk free rate	0.34%	1.44%	0.42%	1.44%

**(c) Stock options**

A summary of the Company's stock option activity and related information for the nine months ended September 30, 2020 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, 2019	5,840,538	\$ 5.11	7.72	\$ 45,037
Options granted	2,006,000	11.52		
Options exercised	(581,270)	7.88		
Options cancelled/forfeited	(497,338)	15.65		
Outstanding at September 30, 2020	6,767,930	\$ 5.99	8.70	\$ 42,143
Exercisable as of September 30, 2020	1,840,302	\$ 5.11	7.20	\$ 13,694

During the nine months ended September 30, 2020, the Company granted stock options to purchase 1,781,000 shares of common stock to employees and 225,000 shares to non-employee directors. The stock options granted to employees have an exercise price per share ranging from \$6.44 to \$17.01. The stock options granted to non-employee directors during the nine months ended September 30, 2020 have an exercise price per share ranging from \$12.25 and \$13.58.

**(d) Restricted stock units**

A summary of the Company's restricted stock unit activity and related information for the nine months ended September 30, 2020 is as follows:

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Non-vested at December 31, 2019	72,000	\$ 3.47
Restricted stock units granted	152,000	9.26
Restricted stock units vested	(36,000)	3.47
Restricted stock units forfeited	(1,500)	3.47
Non-vested at September 30, 2020	<u>186,500</u>	<u>\$ 8.19</u>

**(e) Employee stock purchase plan**

The Company's 2020 Employee Stock Purchase Plan ("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 the Company's shares of 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. The first offering period commenced on May 16, 2020.

**7. Restructuring**

In July 2018, the Company's Board of Directors approved a restructuring plan to reduce operating costs and better align the Company's workforce with the needs of its business following the June 27, 2018 announcement that its Phase 3 Leadership 301 clinical trial evaluating once-daily, oral rosiptor for the treatment of IC/BPS failed to meet its primary endpoint. The Company has halted all further development activities with rosiptor. In 2018 and 2019, the Company incurred and paid aggregate restructuring charges of \$7.4 million related to clinical trial closing costs, contract cancellations, closing of its office in San Bruno, California, severance payments and other employee-related costs. During the second quarter of 2019, the Company revised its original estimate of aggregate restructuring charges lower by \$2.0 million based upon updated information from its vendors related to a completed project. There were no amounts accrued as of September 30, 2020 or December 31, 2019.

On November 6, 2018, the Company's Board of Directors approved an additional restructuring plan to further reduce operating costs. The Company incurred and paid aggregate restructuring charges of \$1.6 million related to severance payments and other employee-related costs. There were no amounts accrued as of September 30, 2020.

For the nine months ended September 30, 2020, the Company incurred and paid an immaterial amount of restructuring charges. For the nine months ended September 30, 2019, restructuring recoveries of \$1.9 million were recorded in research and development expenses and restructuring costs of \$0.6 million in general and administrative expenses.

## 8. Earnings (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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Outstanding stock options	6,767,930	6,203,993	6,767,930	6,203,993
Restricted stock units	186,500	72,000	186,500	72,000
Common stock to be issued upon conversion of convertible preferred stock	—	10,192,700	—	10,192,700
Shares issuable under 2020 ESPP	18,011	—	18,011	—
	<u>6,972,441</u>	<u>16,468,693</u>	<u>6,972,441</u>	<u>16,468,693</u>

## 9. 401(k) plan

In May 2020, the Company established a 401(k) plan that allows full-time employees to contribute a portion of their salary, subject to statutory limits. The Company makes matching cash contributions up to a pre-defined annual maximum contribution per employee per year. During the three and nine months ended September 30, 2020, the Company's total expense for the matching contributions was immaterial.

## 10. Sale of Aquinox Canada

On July 31, 2020, the Company sold all issued and outstanding capital stock of its Canadian subsidiary, Aquinox Pharmaceuticals (Canada) Inc. ("Aquinox Canada") to an unrelated third party for cash consideration of \$8.2 million. The Company concluded that the sale did not meet the criteria for discontinued operations reporting as it did not represent a strategic shift that had a major effect on the Company's operations and financial results. As of the date of sale, Aquinox Canada's remaining assets included intellectual property and other assets developed through past research and development activities, all of which had no book value. The transaction resulted in a net gain on sale of \$7.8 million, after deducting \$0.4 million in transaction costs, which is recorded as a reduction of operating expenses in the Company's condensed consolidated statement of operations. The sale of Aquinox Canada will trigger a significant capital loss carryforward for tax purposes. However, the deferred tax asset related to the capital loss carryforward will be subject to a full valuation allowance as the Company has determined that it is more likely than not that the benefit of the loss will not be realized.

## 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 consolidated 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, 2019.*

### 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. 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 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 document 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 document 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, including, among other things, impacts on our business due to health pandemics or other contagious outbreaks, such as the current COVID-19 pandemic. 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 are a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using de novo protein design technology. We use sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. Existing protein engineering treatments generally involve the modification of native proteins. With our proprietary platform we design completely new protein structures from the ground up, capable of demonstrating specifically desired 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 deliver greater therapeutic benefit. 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. We are initially focused on key cytokine mimetics, which we refer to as Neoleukin de novo cytokine mimetics. Neoleukin de novo cytokine mimetics can be modified to adjust affinity, thermodynamic stability, resistance to biochemical modification, pharmacokinetic characteristics, and targeting to tumor or inflamed tissues.

We commenced operations in Canada in December 2003. Aquinox Pharmaceuticals (Canada) Inc., a corporation formed under the Canada Business Corporations Act, or Aquinox Canada, was a wholly owned subsidiary of Aquinox Pharmaceuticals, Inc., a Delaware corporation formed in May 2007 (“Aquinox”). On August 8, 2019, upon the merger of Aquinox with Neoleukin Therapeutics, Inc., or Former Neoleukin, pursuant to an Agreement and Plan of Merger dated August 5, 2019, Former Neoleukin merged with a wholly owned subsidiary of Aquinox. Upon completion of the transaction, Aquinox was renamed Neoleukin Therapeutics, Inc. We sold all of the issued and outstanding capital stock of Aquinox Canada to an unrelated third party in July 2020.

## NL-201

Our lead product candidate, NL-201, is an IL-2/IL-15 immunotherapy designed to eliminate binding to the alpha subunit of the IL-2 receptor (also known as CD25) while maintaining high-affinity binding to the beta and gamma subunits. The protein portion of NL-201 was subsequently modified via site-specific covalent conjugation to a poly(ethylene glycol), or PEG, molecule with the goal of extending its blood half-life. In samples of isolated human immune cells, NL-201 was shown to be a more selective stimulator of CD8<sup>+</sup> T cells and NK, or natural killer, cells versus regulatory T cells, as compared with IL-2. NL-201 significantly increases the ratio of CD8<sup>+</sup> T cells to regulatory T cells within the tumor microenvironment and demonstrates significant tumor growth inhibition across multiple preclinical murine tumor models. When compared to the checkpoint inhibitors PD-1 and PD-L1 in the syngeneic CT26 colon cancer model, NL-201 treatment produced greater tumor growth inhibition. We have since completed multi-dose, non-GLP and GLP toxicology studies of NL-201 in rats and non-human primates. This included completion of GLP in-life dosing with no unexpected toxicities observed. In addition, NL-201 induced a detectable immunogenic response in only 4 of 26 non-human primates after repeated weekly doses. When present, anti-drug antibodies, or ADAs, appear to be of low or intermediate titer and did not appreciably alter lymphocyte proliferation compared to that of ADA-negative animals. These results suggest that ADAs did not significantly impact the activity of NL-201. Furthermore, ADA-positive non-human primates did not experience differences in adverse effects or tolerability compared to ADA-negative animals. NL-201 is intended to be used as either a single-agent or in combination with complementary therapeutic modalities, including checkpoint inhibitors. In addition, we believe NL-201 holds promise in combination with allogenic cell therapy to expand and maintain populations of transplanted CAR-T and NK cells.

For our initial clinical development plan, we expect to administer NL-201 as monotherapy by intravenous injection in patients with a variety of relapsed and refractory solid tumors. Dosage and escalation schedules will be determined by evaluation of safety, tolerability, pharmacokinetics, and pharmacodynamic measures to achieve the optimal regimen for outpatient administration. Multiple schedules may be tested during Phase 1. Subsequently, we expect that expansion cohorts will be enrolled using tumor-specific inclusion/exclusion criteria to evaluate both safety and antitumor activity in more uniform patient populations. If the clinical data are considered promising, additional trials will be initiated, which may include combination regimens and trials with registrational intent.

We remain focused on our efforts to submit an Investigational New Drug, or IND, Application for our lead immunotherapy therapeutic candidate, NL-201, during the fourth quarter of 2020. At this time, we do not expect a delay to the submission of our IND due to COVID-19 but acknowledge the potential exists for this timing to be impacted. In addition, we have submitted a Clinical Trial Notification, or CTN, application for NL-201 in Australia.

### **Other Research Programs**

Beyond our initial focus on NL-201, our research team is working on further applying *de novo* protein design principles to develop therapeutics to address significant unmet medical needs, including but not limited to therapeutic areas such as immuno-oncology, inflammation, and autoimmunity. Our research is powered by the Neoleukin platform, our computational framework for developing highly selective, hyper-stable *de novo* immunomodulatory proteins. In addition to NL-201, we are developing targeted and conditionally active IL-2/IL-15 mimetics, as well as cytokine mimetic programs for other oncology targets. Our research team is also actively applying the Neoleukin platform to generate *de novo* receptor agonist and antagonist candidates against multiple targets of interest for inflammatory and autoimmune indications. As we validate additional candidates, they will enter our preclinical pipeline.

Due to the COVID-19 public health emergency, we have been investigating the application of our *de novo* protein technology to prevent or treat SARS-CoV2 infection. In November 2020, we announced the publication of our scientific work in the journal *Science* detailing the creation of CTC-445.2d, or NL-CVX1, a *de novo* protein decoy that is specifically designed to block infection of SARS-CoV-2, the virus causing the ongoing COVID-19 pandemic. Our findings demonstrated that NL-CVX1 blocks infection of human cells *in vitro*, even when a high viral burden is used. Furthermore, intranasal administration of NL-CVX1 protected Syrian hamsters from a lethal dose of SARS-CoV-2. We are currently evaluating the possibility of advancing this molecule to clinical trials in humans.



## 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 or delay our pursuit of potential in-licenses or acquisitions.

Based upon our current operating plan, we believe our cash-on-hand will be sufficient to fund operations into 2023.

## COVID-19 Impact

The COVID-19 pandemic has spread across the globe and continues to impact worldwide economic activity. During this unprecedented time, protecting the health and well-being of our employees and community is a top priority. In addition, we are focused on maintaining continuity of our research, development and business activities while balancing potential impacts from the COVID-19 pandemic.

In March 2020, we transitioned to a work from home policy for our employees and discontinued all work-related travel. Business-critical research and development work has continued, adhering to guidelines to ensure employee safety. We continually assess our work policies and monitor guidance from the state and the U.S. Centers for Disease Control and Prevention, or the CDC, in order to determine any changes to current work practices.

## Results of Operations

### Operating Loss

The following table summarizes our operating loss for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Research and development	\$ 6,216	\$ 1,420	\$ 4,796	\$ 16,557	\$ (471)	\$ 17,028
Acquired in-process research and development	—	47,716	(47,716)	—	47,716	(47,716)
General and administrative	3,860	10,380	(6,520)	12,359	15,358	(2,999)
Gain on sale of Aquinox Canada	(7,826)	—	(7,826)	(7,826)	—	(7,826)
	<u>\$ 2,250</u>	<u>\$ 59,516</u>	<u>\$ (57,266)</u>	<u>\$ 21,090</u>	<u>\$ 62,603</u>	<u>\$ (41,513)</u>

### Research and Development Expenses

Research and development expenses consists primarily of testing services, manufacturing costs, personnel related costs (including stock-based compensation and travel expenses), facility-related costs and lab supplies.

For the three and nine months ended September 30, 2020, research and development expenses were \$6.2 million and \$16.6 million, respectively, compared to \$1.4 million and \$(0.5) million for the three and nine months ended September 30, 2019, respectively. The credits in the nine months ended September 30, 2019 were a result of reductions to accrued research and development expenses following confirmation by vendors that final costs were less than contracted. The increase in research and development expenses during the three and nine months ended September 30, 2020 was due to increased expenses incurred from IND-enabling activities related to our lead product candidate, NL-201, and in connection with the advancement of other Neoleukin technologies compared to lower research and development costs during the three and nine months ended September 30, 2019 as a result of the suspension of all research and development activities with rosiptor in June 2018.

### **Acquired in-process research and development**

The acquired in-process research and development expense arose from the merger between Aquinox and Former Neoleukin in 2019 and was expensed immediately as management determined that the asset has no alternative future use in accordance with ASC 730.

### **General and Administrative Expenses**

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

For the three and nine months ended September 30, 2020, general and administrative expenses were \$3.9 million and \$12.4 million, respectively, compared to \$10.4 million and \$15.4 million for the three and nine months ended September 30, 2019, respectively. The higher general and administrative expenses during the three and nine months ended September 30, 2019 as compared to the three and nine months ended September 30, 2020 were primarily due to severance costs and the recognition of stock-based compensation expense for certain options that vested as a result of the merger between Aquinox and Former Neoleukin in the three months ended September 30, 2019. The general and administrative expenses for the three and nine months ended September 30, 2020 reflect an increase in personnel related costs, facility-related costs, and professional service fees in the three and nine months ended 2020.

### **Gain on sale of Aquinox Canada**

The gain relates to the sale of Aquinox Canada during the three months ended September 30, 2020. The gain of \$7.8 million recognized is the total consideration of \$8.2 million, less transaction costs of \$0.4 million.

### **Other income, net**

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Interest income	\$ 7	\$ 392	\$ (385)	\$ 487	\$ 1,278	\$ (791)
Foreign exchange gains/(losses)	(2)	1	(3)	9	(6)	15
Other expenses	(4)	(9)	5	(43)	(10)	(33)
Total other income, net	<u>\$ 1</u>	<u>\$ 384</u>	<u>\$ (383)</u>	<u>\$ 453</u>	<u>\$ 1,262</u>	<u>\$ (809)</u>

Interest income during the three and nine months ended September 30, 2020 decreased compared to the same period in 2019 due to a decrease in interest rates partially offset by higher cash and investment balances for the three and nine months ended September 30, 2020.

## Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Our operating activities used \$15.3 million and \$10.8 million of cash flows during the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of \$320.2 million, working capital of \$196.7 million and cash and cash equivalents of \$201.2 million. On July 7, 2020, we completed an underwritten public offering of our common stock and pre-funded warrants resulting in aggregate net proceeds, net of underwriting discounts and commissions and offering costs of approximately \$4.9 million, totaling \$71.3 million.

### Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	\$ (15,346)	\$ (10,758)
Investing activities	(1,566)	94
Financing activities	75,847	33
Effect of exchange rate changes on cash, cash equivalents and restricted cash	—	9
Net change in cash, cash equivalents and restricted cash	<u>\$ 58,935</u>	<u>\$ (10,622)</u>

#### *Net cash used in operating activities*

Net cash used in operating activities for the nine months ended September 30, 2020 increased compared to the nine months ended September 30, 2019 due to an increase in operating expenses resulting primarily from expenses incurred in developing our lead product candidate, NL-201, and partially offset by cash received from the sale of Aquinox Canada, as compared to a reduction in costs in the nine months ended September 30, 2019 due to the restructuring in the second half of 2018 and the halting of all development activities relating to rosiptor.

#### *Net cash provided by (used in) investing activities*

For the nine months ended September 30, 2020, cash used in investing activities consisted primarily of laboratory and computer equipment acquisitions. For the nine months ended September 30, 2019, cash provided by investing activities was the result of cash received in the merger between Aquinox and Former Neoleukin.

#### *Net cash provided by financing activities*

For the nine months ended September 30, 2020, net cash provided by financing activities consisted primarily of the proceeds received in our offering of common stock and pre-funded warrants of \$71.3 million, net of underwriting discounts and commissions and offering costs. For the nine months ended September 30, 2019, cash provided by financing activities was the result of proceeds from stock option exercises.

## 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 September 30, 2020, we had approximately \$201.2 million in cash and cash equivalents. Based on our current business plans, we believe that our existing cash and cash equivalents will be sufficient to fund our planned operations into 2023. 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 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 potential delays in our preclinical studies, our development programs and our planned clinical trials due to the effects of the COVID-19 pandemic;
- 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.

## Contractual Obligations and Commitments

Our future minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC. There have been no material changes from the contractual commitments previously discussed in that Annual Report on Form 10-K.

## Critical Accounting Policies and Significant Judgments and Estimates

The preparation of these consolidated 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 consolidated 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, 2019. There have been no material changes to our significant accounting policies during the three and nine months ended September 30, 2020.

### Recent Accounting Pronouncements

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

### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

Management believes there have been no material changes to our quantitative and qualitative disclosures about market risks during the nine months ended September 30, 2020, compared to those discussed in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC.

### Interest rate risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. As of September 30, 2020, we had cash equivalent holdings in U.S. government money market funds of \$108.3 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of these investments, we have estimated the effect on our investment portfolio of a hypothetical increase in interest rates by one percent (100 basis points) to have an immaterial impact in the fair value of our investment portfolio as of September 30, 2020.

## Item 4. Controls and Procedures

*Evaluation of disclosure controls and procedures.* Under the supervision and with the participation of our principal executive officer and 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 officer and 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 Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

*Changes in internal control over financial reporting.* We have completed the transition of accounting and financial reporting operations from our Vancouver, British Columbia office to our new headquarters in Seattle, Washington. We believe we have taken the necessary steps to monitor and maintain appropriate internal control over financial reporting during the three and nine months ended September 30, 2020 and will evaluate the operating effectiveness of related controls during subsequent periods. There were no other changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**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.

**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 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.
- 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, 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.
- Our business is heavily dependent on the success of our Neoleukin platform and of our most advanced product candidate, NL-201. Existing and future preclinical studies and clinical trials of these 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 future clinical trials or those of any future collaborators may reveal significant adverse events not seen in our 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 expect to rely on third parties to conduct certain of our preclinical studies or 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 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.

- The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our preclinical development activities and planned clinical trials.
- If we are not able to obtain, maintain, and enforce patent protection for our product candidates, our Neoleukin platform technology, or other proprietary technologies we may develop, development and commercialization of our product candidates may be adversely affected.

## Item 1A. 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 consolidated 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 seriously harmed. 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 Our Financial Position and Capital Needs

***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 development of biopharmaceutical product candidates is capital-intensive. If our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand or create our development, regulatory, manufacturing, marketing, and sales capabilities. We have used substantial funds to develop our technology and product candidates and will require significant funds to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to manufacture and market products, if any, which are approved for commercial sale. In addition, we expect to continue incurring costs associated with operating as a public company.

Preclinical studies and clinical trials for our product candidates will require substantial funds to complete. As of September 30, 2020, we had approximately \$201.2 million in cash and cash equivalents. We expect to incur substantial expenditures in the foreseeable future as we seek to advance NL-201 and any future product candidates through preclinical and clinical development, the regulatory approval process and, if approved, commercial launch activities. Based on our current operating plan, we believe that our available cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into 2023. 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 what we expect and we may need to seek additional funds sooner than planned. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the timing, cost and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into collaborations and/or research and development agreements;
- the timing and amount of milestone and other payments we may receive or make under our collaboration agreements;
- 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 submissions and timing of regulatory approvals;

- the potential delays in our preclinical studies, our development programs and our planned clinical trials due to the effects of the COVID-19 pandemic;
- the cost of commercialization activities if our product candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. 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, before our product candidates are clinically tested, approved for commercialization and successfully marketed.

We will be required to seek additional funding in the future and currently intend to do so through additional 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. Our future debt financings, if available, 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 our rights to 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. 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, and all of our product candidates are in preclinical development. We continue to incur significant expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in every reporting period since our inception in 2003. For the nine-month period ended September 30, 2020, we reported a net loss of \$20.6 million. For the years ended December 31, 2019 and 2018, we reported a net loss of \$69.4 million and \$31.6 million, respectively. As of September 30, 2020, we had an accumulated deficit since inception of \$320.2 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we seek 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 any of our future product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fails 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.

***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.***

Our operations to date have been primarily limited to organizing and staffing our company, acquiring product and technology rights, discovering and developing novel de novo proteins, undertaking preclinical studies, and, prior to the merger, developing small molecule drug candidates and conducting clinical trials of rosiptor. We have not yet obtained regulatory approval for any product candidate. 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 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 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 currently anticipate. Even if we can complete the development and regulatory process for any future product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we can generate revenues from the sale of any 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 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 ongoing activities, we believe that our existing cash and cash equivalents will be sufficient to fund our operating requirements for at least the next 12 months. However, circumstances may cause us to consume capital more rapidly than we anticipate. We will likely require additional capital for the further development and potential commercialization of future product candidates and may also need to raise additional funds sooner to pursue a more accelerated development of future product candidates.

If we need 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:

- significantly delay, scale back or discontinue clinical trials related to the development or commercialization of any of our future product candidates or cease operations altogether;
- 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; or
- relinquish, or license on unfavorable terms, our rights to any future product candidates that we otherwise would seek to develop or commercialize ourselves.

If we need to conduct additional fundraising activities and we do not raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from pursuing 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 additional product candidates for development;
- if we in-license or acquire product candidates from third parties, the cost of in-licensing or acquisition;
- the initiation, progress, timing, costs and results of clinical trials for any future product candidates;
- the clinical development plans we establish for any future product candidates;
- 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 COVID-19 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

***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.***

We are in the early stages of our development efforts. We have no products on the market and all of our product candidates, including NL-201, are still in the preclinical or 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. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. We currently expect to submit an Investigational New Drug application, or IND, with respect to NL-201 by the end of 2020. However, it is possible that the FDA may deny our IND or require additional testing before allowing clinical testing in humans. Alternatively, we may obtain data while preparing for an IND that causes us to delay or even abandon clinical testing of NL-201. Additionally, we have a portfolio of targets and programs that are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development. If we do not receive regulatory approvals for clinical testing and commercialization of our 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 delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- preclinical study results may show 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, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologicals similar to our product candidates;
- our third-party manufacturers' inability 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 clinical trials;
- delays in enrolling patients in our clinical trials;
- high drop-out rates of our clinical trial patients;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials;
- greater than anticipated costs of our 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.

We or our future partners' 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 our clinical trials for NL-201 will be with patients who have received one or more prior treatments. Subsequently, for those of our products that prove to be sufficiently beneficial, if any, we would expect to seek 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.

***Our business is heavily dependent on the success of our Neoleukin platform and of our most advanced product candidate, NL-201. Existing and future preclinical studies and clinical trials of these 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. We have invested a significant portion of our efforts and financial resources in the development of our proprietary system of advanced computational algorithms and methods for the design of functional *de novo* proteins, which we refer to as our Neoleukin platform, with an initial focus on key cytokine mimetics, which we refer to as Neoleukin *de novo* cytokine mimetics. Our lead product candidate, NL-201, is a Neoleukin *de novo* protein derived from our Neoleukin platform. However, NL-201 and our other product candidates are still in the preclinical or earlier stage. 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 our lead product candidates. Our product candidates may not be successful in clinical trials or receive regulatory approval. Even if they are successful in clinical trials, regulatory authorities may not complete their review in a timely manner, or additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. 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. 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 plan to seek regulatory approval to commercialize our product candidates 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 platform, NL-201, and our other 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;
- 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.

***Our future clinical trials or those of any future collaborators may reveal significant adverse events not seen in our 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 clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, we may be required to 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 the FDA, EMA or other applicable regulatory authorities. We, the FDA, EMA or other applicable regulatory authorities, or an IRB 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. We designed NL-201 to mimic the therapeutic activity of the cytokine interleukin-

2, or IL-2, and interleukin-15, or IL-15, while limiting the toxicity caused by the preferential binding of native IL-2 and native IL-15 to cells that co-express the alpha subunit, known as CD25. However, it is possible NL-201 will demonstrate significant adverse events similar to, or in addition to, those associated with IL-2 and IL-15, such as vascular leak syndrome, hypotension, impaired kidney and liver function, and mental status changes. Therapies involving cytokines have been known to cause side effects such as neurotoxicity and cytokine release syndrome.

Further, de novo proteins are a new class of therapeutics that have not been previously tested in humans. De novo proteins can be substantially different from all known proteins and as a result, it is unknown to what extent, if any, these de novo proteins will produce immunologic reactions in patients. Immunologic reactions could substantially limit the effectiveness of the treatment, the duration of treatment, or represent safety risks.

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.

***Our approach to the discovery and development of our therapeutic treatments is based on novel de novo protein design technology that are unproven and may not result in marketable products.***

The success of our business depends primarily upon our ability to discover, develop, and commercialize a pipeline of product candidates using our Neoleukin platform. Unlike traditional protein-based therapeutics that modify native proteins, our Neoleukin platform designs new proteins from the ground up. Our platform uses advanced computational algorithms and methods to design functional de novo proteins that are hyper-stable, modifiable, and are designed to optimize desired intermolecular interactions and eliminate undesirable interactions. While we believe this approach will enable us to develop product candidates that may offer unique therapeutic benefits, the scientific basis of our efforts to develop product candidates using our Neoleukin platform is ongoing and may not result in viable product candidates.

While we have had favorable preclinical study results related to precursors to NL-201, we have not yet submitted an IND related to NL-201 or any other product candidate from our Neoleukin platform. Our approach may be unsuccessful in moving NL-201 from preclinical studies into clinical development, discovering additional product candidates, and any product candidates that we are currently developing may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing or make the product candidates 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 programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

To date, we have not tested any of our product candidates in any clinical trials. We may ultimately discover that our Neoleukin platform and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. Our product candidates may also be unable to remain stable in the human body for the period of time required for the drug to reach the target tissue, or they may trigger immune responses that inhibit the activity of the product candidate or that cause adverse side effects in humans. We may spend substantial funds attempting to mitigate these properties and may never succeed in doing so. In addition, product candidates based on our Neoleukin platform may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Our Neoleukin platform and any product candidates resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective, or harmful ways.

The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied product candidates. Because the FDA has no prior experience with de novo proteins as therapeutics, we anticipate that this may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. We or any future partners may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If the products resulting from our Neoleukin platform and research programs prove to be ineffective, unsafe, or commercially unviable, our Neoleukin Platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations, and prospects.

***Preclinical and clinical development involve a lengthy and expensive process, with an uncertain outcome, and results of earlier 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 our current product candidates or any future product candidates.***

All of our product candidates are in preclinical or earlier development and their risk of failure is high. 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 its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the success of later-stage clinical trials. 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. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing, and we have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. 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. 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 future clinical trials will ultimately be successful or support clinical development of our current or any of our future product candidates.

We intend to advance NL-201, our lead development candidate from our Neoleukin platform, toward IND submission by the end of 2020. Commencement of our future clinical trials is subject to finalizing the trial design and submitting an IND or similar submission to the FDA, EMA, or comparable foreign regulatory authorities. Even after we submit our IND or comparable submissions in other jurisdictions, the FDA, EMA, or comparable foreign regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us 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, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.***

We or any collaborators may experience delays in initiating or completing clinical trials or may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize NL-201 or 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, or IRBs, 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, produce negative or inconclusive results, and we may decide, or regulators may 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;
- 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 or lack of adequate funding to continue the clinical trial. 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 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 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.

Our inability to enroll a sufficient number of patients for our clinical trials 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.

***Interim and preliminary or topline 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 that could result in material changes in the final data.***

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete 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. 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. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim or preliminary or topline data and final data could significantly harm our reputation and business prospects.

***Failure to obtain regulatory approval in international jurisdictions would prevent any future product candidates from being marketed outside the United States.***

In order to market and sell our products in the European Union and other jurisdictions, we must obtain separate 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 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. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. 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. 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 in the European Union or another jurisdiction, 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. 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 policies 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 to include covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, increased the minimum rebate due for innovator drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation and regulation also revised the definition of AMP for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices. Furthermore, the Affordable Care Act imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial provisions affecting compliance were enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Certain provisions of the Affordable Care Act have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the

Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. The Affordable Care Act has also been subject to judicial challenge. In December 2018, a federal district court judge, in a challenge brought by a number of state attorneys general, found the Affordable Care Act unconstitutional in its entirety. Pending appeals, which could take some time, the Affordable Care Act is still operational in all respects. Congress may consider other legislation to repeal or replace elements of the Affordable Care Act. Because of the continued uncertainty about the implementation of Affordable Care Act, including the potential for further legal challenges or repeal of Affordable Care Act, we cannot quantify or predict with any certainty the likely impact of the Affordable Care Act or its repeal on our business, prospects, financial condition or results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President 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 2029 unless additional Congressional action is taken. 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 been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Furthermore, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent 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 and 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 Canada and require us to develop and implement costly compliance programs.***

As we expand our operations outside of the United States and Canada, 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, and Canadian laws applicable to the foreign operations of Canadian businesses and individuals, such as the Corruption of Foreign Public Officials Act, or CFPOA. 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 us 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 DOJ. 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 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.

The CFPOA prohibits Canadian businesses and individuals from giving or offering to give a benefit of any kind to a foreign public official, or any other person for the benefit of the foreign public official, where the ultimate purpose is to obtain or retain a business advantage. Furthermore, a company may be found liable for violations by not only its employees, but also by its third-party agents. Any failure to comply with the CFPOA, as well as applicable laws and regulations in foreign jurisdictions, could result in substantial penalties or restrictions on our ability to conduct business in certain foreign jurisdictions, which may have a material adverse impact on us and our share price.

***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 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. While we do not currently have any product candidates in clinical development, if we were able to identify and establish product candidates and advance them through clinical development, in order to market any products that may ultimately be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, 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.

***We may not be successful in our efforts to use our Neoleukin platform 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 based on our Neoleukin platform, which may fail to identify other 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 focus our research and development efforts on our lead product candidate, NL-201, with initial indications including renal cell carcinoma and melanoma. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Due to the ongoing COVID-19 public health emergency, we are also utilizing a portion of our research and computational bandwidth to investigate the potential application of our de novo protein technology toward COVID-19. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future 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.

Our lead product candidate, NL-201, is under development for the treatment of advanced solid tumors, including melanoma and renal cell carcinoma. If approved, it would face competition from approved advanced melanoma and renal cell carcinoma treatments, including multiple checkpoint inhibitors, tyrosine kinase inhibitors, VEGF inhibitors, recombinant human IL-2, and several chemotherapy drugs or combinations. Further, we are aware of several IL-2 or IL-15 agonists in various stages of clinical and preclinical development. Nektar Therapeutics, Inc. has a modified IL-2 molecule in Phase III clinical trials. ImmunityBio (formerly Altor BioScience Corporation) has a modified IL-15 molecule in Phase II clinical trials. Alkermes plc, Novartis International AG, Sanofi (formerly Synthorx), Cue Biopharma, Inc., Philogen S.p.A. and Roche AG have disclosed Phase I and/or II clinical trials involving modified IL-2 or IL-15 molecules, and we are aware of IL-2 or IL-15 programs in preclinical studies at Medicenna Therapeutics Corp, Pivotal BioSciences Inc., BioNTech SE, Xencor Inc. and Ascendis Pharma A/S. Furthermore, several large pharmaceutical companies have disclosed preclinical investments in this field, including AstraZeneca plc, Bristol-Myers Squibb, Roche AG, and Celgene Corporation.

Many of these 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.

***We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.***

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 BPCIA. There is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. 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.

### **Risks Related to Our Reliance on Third Parties**

***We expect to rely on third parties to conduct certain of our preclinical studies or 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 intend to rely in the future 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. Because we intend to rely on these third parties and will not have the ability to conduct all preclinical studies or clinical trials independently, we will have less control over the timing, quality, and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs, and consultants 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 preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials 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 legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical 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 and clinical trials to be conducted in accordance with Good Clinical Practices, 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. 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 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 currently rely, and expect to continue to 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. There can be no assurance that our preclinical and clinical development product supplies will not be limited, available at acceptable prices. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

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 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 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, in December 2019 the outbreak of COVID-19 originated in Wuhan, China, has since spread across the globe. To date, this outbreak has resulted in extended shutdowns of businesses in the United States, Canada and many other countries and has had ripple effects to businesses around the world. Global health concerns, such as COVID-19, could also result in adverse effects to our manufacturing operations. 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. Even if our collaborators 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 filing 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**

#### ***The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our preclinical development activities and planned clinical trials.***

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States. As a result of the COVID-19 pandemic, or similar pandemics, we may experience disruptions that could severely impact our business, manufacturing, preclinical development activities, preclinical studies and planned clinical trials, including:

- delays or disruptions in preclinical development activities, including non-clinical experiments and investigational new drug application-enabling good laboratory practice standard toxicology studies due to unforeseen circumstances in supply chain;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact timelines for regulatory submission, trial initiation and regulatory approval;
- interruption or delays in our CROs and collaborators meeting expected deadlines or complying with regulatory requirements related to preclinical development activities, preclinical studies and planned clinical trials;
- interruptions of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays or difficulties in any planned clinical site initiation, including difficulties in obtaining IRB approvals, recruiting clinical site investigators and clinical site staff;
- delays or difficulties in enrolling patients in clinical trials;
- increased rates of patients withdrawing from any planned clinical trials following enrollment as a result of contracting COVID-19 or being forced to quarantine;

- diversion of healthcare resources away from the conduct of our preclinical development activities, preclinical studies and planned clinical trials, including the diversion of hospitals serving as any potential clinical trial sites and hospital staff supporting the conduct of our planned clinical trials;
- interruption of planned key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and planned clinical study endpoints;
- limitations on employee or collaborator resources that would otherwise be focused on the conduct of our preclinical development activities, preclinical studies and planned clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions; and
- reduced ability to engage with the medical and investor communities due to the cancellation of conferences scheduled throughout the year.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct preclinical development activities, preclinical studies and planned clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our common stock and other biopharmaceutical companies, as well as the broader equity and debt markets, have been highly volatile as a result of the COVID-19 pandemic and the resulting impact on economic activity. As a result, we may face difficulties raising capital when needed, and any such sales may be on unfavorable terms to us. Further, to the extent we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted.

The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, manufacturing, preclinical development activities, preclinical studies and planned clinical trials and will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of COVID-19, the duration of the outbreak, the potential for a second outbreak after it is contained, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

***We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.***

We have approximately 65 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers, and other organizations. Our ability to manage our operations and 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.***

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 our research and development programs and have a material and adverse effect on our business, financial condition, results of operations, and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our product candidates and technologies related to our Neoleukin Platform, and the specialized nature of the regulatory approval process. 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.

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 and 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 or providing 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 impose criminal and civil penalties, including through civil whistleblower or qui tam actions, among other things, prohibits 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;
- 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 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) 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 and 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 of up to \$10 million, which may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we begin clinical trials 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 business and operations would suffer in the event of computer system failures or security breaches.***

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 security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed.

***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, medical epidemics such as the corona virus outbreak 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. 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.

***Our ability to use our U.S. net operating losses to offset future taxable income will be subject to certain limitations.***

As of December 31, 2019, we had U.S. net operating losses, or NOLs, of \$25.5 million, for which we have recorded a full valuation allowance. These NOLs and tax credit carryforwards expire in various years beginning in 2028, if not utilized. Utilization of the NOLs will be subject to significant annual limitations due to historical ownership changes pursuant to Sections 382 of the Internal Revenue Code, or the Code. If we experience further changes to our stock ownership in the future, some of which changes are outside our control, the tax benefits related to the NOLs may be further limited 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.

***Recent tax reform legislation could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law new tax legislation, the Tax Cuts and Jobs Act, that significantly changes the Code. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Any federal net operating losses created in 2018 and thereafter will be carried forward indefinitely pursuant to the Tax Cuts and Jobs Act. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. The impact of this Tax Cuts and Jobs Act on holders of our common stock is also uncertain and could be adverse. We urge investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

***Risks Related to Intellectual Property***

***If we are not able to obtain, maintain, and enforce patent protection for our product candidates, our Neoleukin platform technology, or other proprietary technologies we may develop, 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, we have an exclusive license to develop and commercialize products covered by patent applications with claims covering the composition of matter of key molecule families as well as methods of using the computational algorithms that form the basis of the Neoleukin platform. However, we may not be able to apply for patents on certain aspects of our product candidates 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. Future patents we 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 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 potential licensors fail to maintain the patents and patent applications covering our future 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.***

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. 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.

***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 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.
- 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 may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

### **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 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, including market volatility and economic uncertainty related to the COVID-19 pandemic.

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.

***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.

***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.

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.

***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 Securities Exchange Act of 1934, as amended, or 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.

***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 consolidated 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 registration statements covering the sale of up to \$250.0 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.

***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, 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 Equity Incentive Plan may have an adverse effect 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 of directors 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 of directors, 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 of directors or by such person or persons requested by a majority of the board of directors 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 of directors, 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 restated certificate of incorporation and amended and restated 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 restated certificate of incorporation, to the fullest extent permitted by law, will provide 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 restated certificate of incorporation, or our restated 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, 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 restated 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 our restated certificate of incorporation or amended and restated 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.

***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**

Not applicable.

**Item 6. Exhibits**

<b>Number</b>	<b>Description</b>
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a).</a>
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a).</a>
32.1#	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350.</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

# 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: November 9, 2020

/s/ Jonathan G. Drachman

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Jonathan G. Drachman  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 9, 2020

/s/ Robert Ho

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Robert Ho  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

## CERTIFICATIONS

I, Jonathan G. Drachman, 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: November 9, 2020

/s/ Jonathan G. Drachman

Jonathan G. Drachman  
*President and Chief Executive Officer*

## CERTIFICATIONS

I, Robert Ho, 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: November 9, 2020

/s/ Robert Ho

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Robert Ho

*Chief Financial Officer*



**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 September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Jonathan G. Drachman, President and Chief Executive Officer of the Company, and Robert Ho, Chief Financial Officer of the Company, each hereby certifies, 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 the 9<sup>th</sup> day of November 2020.

/s/ Jonathan G. Drachman

Jonathan G. Drachman

*President and Chief Executive Officer*

/s/ Robert Ho

Robert Ho

*Chief 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.