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DELTA REPORT

10-Q

NGNE - NEOLEUKIN THERAPEUTICS, I

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	5585
CHANGES	38
DELETIONS	2395
ADDITIONS	3152

REFINITIV

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

FORM10-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, 2023 March 31, 2024

OR

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

For the transition period from _____ to _____

Commission file number: 001-36327

Neoleukin Therapeutics, Neurogene Inc.

(Exact name of registrant as specified in its charter)

Delaware	**98-0542593**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
535 W 24th St. 5th Floor New York, NY	
(Address of principal executive offices)	**10011** (Zip Code)

188 East Blaine Street, Suite 450 (855) 508-3568

Seattle, Washington 98102

(Address of principal executive offices, including zip code)

(Registrant's telephone number, including area code): (866) 245-0312

code

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, stock, par value $0.000001 per share	**NLTX**NGNE	The Nasdaq Capital 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	☐o	Accelerated filer	☐o
Non-accelerated filer	☒x	Smaller reporting company	☒x
		Emerging growth company	☐o

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. ☐ o

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 10, 2023 May 6, 2024, there were 9,397,901 12,980,289 shares of the registrant’s common stock outstanding.

NEOLEUKIN THERAPEUTICS, INC.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 2023

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Except as otherwise indicated herein or as the context otherwise requires, references in this report to, "the Company," "we," "us," "our" and similar references refer to Neoleukin Therapeutics, Inc. (formerly Aquinox Pharmaceuticals, Inc.), a Delaware

corporation. The name “Neoleukin” is a trademark of the Company in the United States. This report also contains references to registered marks, trademarks, and trade names of other companies that are property of their respective holders.

PART I. FINANCIAL INFORMATION **Part I - Financial Information**

Item 1.Condensed Financial Statements

NEOLEUKIN THERAPEUTICS, INC. **Neurogene Inc.**
Condensed **Consolidated** **Balance Sheets**
(In Thousands, Except Share Information)
(Unaudited)

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 150,140	$ 148,210
Short-term investments	19,393	48,947
Prepaid expenses and other current assets	4,608	3,191
Total current assets	174,141	200,348
Property and equipment, net	16,475	17,174
Operating lease right-of-use assets	3,565	3,681
Finance lease right-of-use assets	87	98
Restricted cash	339	508
Other non-current assets	743	764
Total assets	$ 195,350	$ 222,573
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,522	$ 2,596
Accrued expenses and other current liabilities	6,824	17,495
Operating lease liabilities, current	2,670	2,559
Finance lease liabilities, current	43	42
Lease contingent value rights liability, current	430	281
Intellectual property contingent value rights liability	329	—
Total current liabilities	11,818	22,973
Operating lease liabilities, non-current	11,642	12,302
Finance lease liabilities, non-current	53	65

Lease contingent value rights liability, non-current	857	1,006
Other liabilities	203	203
Total liabilities	24,573	36,549
Stockholders' equity:		
Preferred stock, $0.000001 par value; 50,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 0 shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.000001 par value; 450,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 12,860,995 and 12,823,665 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	374,852	373,178
Accumulated deficit	(204,075)	(187,154)
Total stockholders' equity	170,777	186,024
Total liabilities and stockholders' equity	$ 195,350	$ 222,573

	September 30, 2023	*December 31, 2022*
Assets		
Current assets		
Cash and cash equivalents	*$ 25,226*	*$ 37,887*
Short-term investments	*53,281*	*58,497*
Other current assets	*1,386*	*2,750*
Total current assets	*79,893*	*99,134*
Property and equipment, net	*484*	*6,163*
Operating lease right-of-use assets	*8,685*	*9,715*
Other non-current assets	*524*	*936*
Total assets	*$ 89,586*	*$ 115,948*
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	*$ 3,658*	*$ 9,547*
Operating lease liabilities	*1,550*	*1,375*
Finance lease liabilities	*4*	*140*
Total current liabilities	*5,212*	*11,062*
Non-current operating lease liabilities	*9,134*	*10,322*
Non-current finance lease liabilities	*5*	*233*
Total liabilities	*14,351*	*21,617*
Stockholders' equity		
Common stock - $0.000001 par value - authorized, 20,000,000 as of September 30, 2023 and December 31, 2022; issued and outstanding, 8,805,284 as of September 30, 2023 and 8,529,668 as of December 31, 2022	—	—
Preferred stock - $0.000001 par value - authorized, 5,000,000 as of September 30, 2023 and December 31, 2022; issued and outstanding, 0 as of September 30, 2023 and December 31, 2022	—	—

Additional paid-in capital	*547,105*	*545,407*
Accumulated other comprehensive income (loss)	*—*	*(21)*
Accumulated deficit	*(471,870)*	*(451,055)*
Total stockholders' equity	*75,235*	*94,331*
Total liabilities and stockholders' equity	*$ 89,586*	*$ 115,948*

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

NEOLEUKIN THERAPEUTICS, INC. Neurogene Inc.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(In Thousands, Except Share Information)
(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development expenses	$ 13,541	$ 10,283
General and administrative expenses	5,238	2,752
Total operating expenses	18,779	13,035
Loss from operations	(18,779)	(13,035)
Other income (expense):		
Interest income	2,320	777
Interest expense	(3)	(2)
Other income	143	-
Other expense	(602)	(3)
Net loss	$ (16,921)	$ (12,263)
Per share information: (1)		
Net loss per share, basic and diluted	$ (1.00)	$ (28.28)
Weighted-average shares of common stock outstanding, basic and diluted	16,903,735	433,623

(In thousands of U.S. dollars, except (1) For the three months ended March 31, 2023, net loss per share information is presented for the Company's then outstanding Class A common stock. For the three months ended March 31, 2024, net loss per share information is presented for the Company's common stock. See Note 1, *Reverse Merger and share amounts) Pre-Closing Financing* and Note 3, *Net Loss Per Share Attributable to Common Stockholders*, for additional information.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**

Operating expenses				
Research and development	$ 617	$ 9,471	$ 7,880	$ 31,128
General and administrative	4,952	4,138	12,470	13,718
Impairment of property and equipment	—	—	3,418	—
Total operating expenses	5,569	13,609	23,768	44,846
Loss from operations	(5,569)	(13,609)	(23,768)	(44,846)
Interest income	1,043	559	2,968	766
Other income (loss), net	—	(22)	(15)	(32)
Net loss	$ (4,526)	$ (13,072)	$ (20,815)	$ (44,112)
Comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	13	(20)	21	(92)
Comprehensive loss	$ (4,513)	$ (13,092)	$ (20,794)	$ (44,204)
Net loss per share – basic and diluted	$ (0.41)	$ (1.18)	$ (1.86)	$ (3.99)
Basic and diluted weighted average common shares outstanding	11,101,440	11,050,207	11,218,710	11,039,964

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

NEOLEUKIN THERAPEUTICS, INC. Neurogene Inc.
Condensed Consolidated Statements of Cash Flows Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In Thousands, Except Share Information)
(Unaudited)
(In thousands of U.S. dollars)

	Nine Months Ended September 30,	
	2023	**2022**
Operating activities		
Net loss	$ (20,815)	$ (44,112)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,694	6,789
Depreciation and amortization	483	1,193
Impairment of property and equipment	3,418	—
Impairment of operating lease right-of-use asset	146	—
Amortization of operating lease right-of-use assets	884	776

Amortization and accretion of premiums/discounts on available-for-sale securities	(1,880)	(105)
Loss (gain) on sale of property and equipment	(47)	108
Changes in operating assets and liabilities:		
Other current assets and other non-current assets	1,384	(287)
Accounts payable and accrued liabilities	(5,605)	1,823
Operating lease liabilities	(1,013)	(859)
Net cash used in operating activities	(21,351)	(34,674)
Investing activities		
Purchases of property and equipment	(551)	(1,006)
Proceeds from sale of property and equipment	2,115	—
Purchases of available-for-sale securities	(91,883)	(81,595)
Proceeds from maturities of available-for-sale securities	99,000	15,000
Net cash provided by (used in) investing activities	8,681	(67,601)
Financing activities		
Proceeds from exercise of stock options	—	134
Payment on finance lease obligations	(365)	(54)
Proceeds from the issuance of common stock under Employee Stock Purchase Plan	4	63
Net cash provided by (used in) financing activities	(361)	143
Net change in cash, cash equivalents, and restricted cash during the period	(13,031)	(102,132)
Cash, cash equivalents, and restricted cash, beginning of period	38,765	143,345
Cash, cash equivalents, and restricted cash, end of period	$ 25,734	$ 41,213
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment unpaid at period-end	$ —	$ 28

	Convertible Preferred Stock						Stockholders' Equity										
	Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Preferred Stock		Class A Common Stock		Class B Common Stock		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid- In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance- December 31, 2023	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	12,823,665	$ —	$ 373,178	$ (187,154)	$ 186,024
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,045	—	1,045

Common stock issued upon exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	37,330	—	629	—	629
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(16,921)	(16,921)
Balance- March 31, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	12,860,995	$ —	$ 374,852	$ (204,075)	$ 170,777

	Convertible Preferred Stock						Stockholders' Deficit										
	Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Preferred Stock		Class A Common Stock		Class B Common Stock		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid- In Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance- December 31, 2022	18,604,653	$34,414	13,291,208	$28,675	74,405,719	$181,277	—	$ —	428,334	$ —	—	$ —	—	$ —	$ 5,098	$ (150,837)	$ (145,739)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	293	—	293
Class A common stock issued upon exercise of stock options	—	—	—	—	—	—	—	—	13,532	—	—	—	—	—	112	—	112
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(12,263)	(12,263)
Balance- March 31, 2023	18,604,653	$34,414	13,291,208	$28,675	74,405,719	$181,277	—	$ —	441,866	$ —	—	$ —	—	$ —	$ 5,503	$ (163,100)	$ (157,597)

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

NEOLEUKIN THERAPEUTICS, INC. Neurogene Inc.
Condensed Consolidated Statements of Stockholders' Equity Cash Flows
(In Thousands)
(Unaudited)

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

	Three Months Ended March 31,	
	2024	2023
Operating activities		
Net loss	$ (16,921)	$ (12,263)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,045	293
Depreciation and amortization of property and equipment	814	812
Asset impairment	91	—
Non-cash operating lease expense	176	160
Amortization of finance lease right-of-use assets	11	6
Amortization and accretion of premiums/discounts on held-to-maturity investments	(446)	—
Intellectual property contingent value rights liability	329	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(1,417)	(780)
Other assets	21	—
Accounts payable	135	825
Accrued expenses and other current liabilities	(4,879)	(2,444)
Operating lease liabilities	(609)	(164)
Net cash used in operating activities	(21,650)	(13,555)
Investing activities		
Purchases of property and equipment	(65)	(29)
Proceeds from maturities of held-to-maturity investments	30,000	—
Net cash provided by (used in) investing activities	29,935	(29)
Financing activities		
Offering costs in connection with pre-closing financing	(4,287)	—
Transaction costs related to reverse merger	(2,855)	—
Proceeds from the issuance of common stock upon exercise of options	629	112
Principal payments on finance leases	(11)	(5)
Net cash (used in) provided by financing activities	(6,524)	107
Net increase (decrease) in cash, cash equivalents and restricted cash	1,761	(13,477)
Cash, cash equivalents and restricted cash at beginning of period	148,718	82,021
Cash, cash equivalents and restricted cash at end of period	$ 150,479	$ 68,544
Supplemental disclosure of non-cash investing and financing activities:		
Additions to operating lease right of use assets from new operating lease liabilities	$ 60	$ —
Property and equipment included in accounts payable and accrued expenses	$ 141	$ —
Supplemental cash flow information:		
Cash paid for interest	$ 3	$ 2

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income (Loss)	Deficit	Equity
Balances, December 31, 2022	8,529,668	$ —	$ 545,407	$ (21)	$ (451,055)	$ 94,331
Shares issued upon vesting of restricted stock units	34,000	—	—	—	—	—
Unrealized gain on available-for-sale securities	—	—	—	39	—	39
Stock-based compensation	—	—	1,191	—	—	1,191
Net loss	—	—	—	—	(14,204)	(14,204)
Balances, March 31, 2023	8,563,668	$ —	$ 546,598	$ 18	$ (465,259)	$ 81,357
Shares issued upon the exercise of pre-funded warrants	236,000	—	—	—	—	—
Issuance of shares under Employee Stock Purchase Plan	2,616	—	4	—	—	4
Shares issued upon vesting of restricted stock units	2,000	—	—	—	—	—
Stock-based compensation	—	—	331	—	—	331
Unrealized loss on available-for-sale securities	—	—	—	(31)	—	(31)
Net loss	—	—	—	—	(2,085)	(2,085)
Balances, June 30, 2023	8,804,284	$ —	$ 546,933	$ (13)	$ (467,344)	$ 79,576
Shares issued upon vesting of restricted stock units	1,000	—	—	—	—	—
Stock-based compensation	—	—	172	—	—	172
Unrealized gain on available-for-sale securities	—	—	—	13	—	13
Net loss	—	—	—	—	(4,526)	(4,526)
Balances, September 30, 2023	8,805,284	$ —	$ 547,105	$ —	$ (471,870)	$ 75,235

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

NEOLEUKIN THERAPEUTICS, INC.

Condensed Statements of Stockholders' Equity

(Unaudited)

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income (loss)	Deficit	Equity
Balances, December 31, 2021	8,491,494	$ —	$ 536,362	$ —	$ (393,498)	$ 142,864
Shares issued upon exercises of stock options	7,300	—	134	—	—	134
Stock-based compensation	—	—	2,446	—	—	2,446
Net loss	—	—	—	—	(15,351)	(15,351)
Balances, March 31, 2022	8,498,794	$ —	$ 538,942	$ —	$ (408,849)	$ 130,093
Issuance of shares under Employee Stock Purchase Plan	15,176	—	63	—	—	63
Shares issued upon vesting of restricted stock units	2,000	—	—	—	—	—
Stock-based compensation	—	—	2,312	—	—	2,312
Unrealized loss on available-for-sale securities	—	—	—	(72)	—	(72)
Net loss	—	—	—	—	(15,688)	(15,688)
Balances, June 30, 2022	8,515,970	$ —	$ 541,317	$ (72)	$ (424,537)	$ 116,708
Shares issued upon vesting of restricted stock units	2,950	—	—	—	—	—
Stock-based compensation	—	—	2,031	—	—	2,031
Unrealized loss on available-for-sale securities	—	—	—	(20)	—	(20)
Net loss	—	—	—	—	(13,072)	(13,072)
Balances, September 30, 2022	8,518,920	$ —	$ 543,348	$ (92)	$ (437,609)	$ 105,647

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

NEOLEUKIN THERAPEUTICS, NEUROGENE INC.
Notes to the Condensed Financial Statements NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(Unaudited)

1. Nature Organization and Description of operations Business

Neoleukin Neurogene Inc. (formerly known as Neoleukin Therapeutics, Inc.) (the "Company" or "Neurogene") is a clinical-stage biotechnology company that is a result of the reverse merger discussed below. The operating entity of Neurogene Inc. is the wholly owned subsidiary incorporated in the state of Nevada and also named Neurogene Inc. ("Neoleukin" or "the Company" Neurogene OpCo") has historically been . Neurogene OpCo was incorporated as a biopharmaceutical limited liability company creating next generation immunotherapies for cancer,

inflammation, in Delaware on January 26, 2018 and autoimmunity using *de novo* protein design technology. Based converted into a Delaware corporation on decisions made by July 3, 2018, and then merged with a wholly owned subsidiary of the Company's Board parent company and re-domiciled to Nevada on December 18, 2023 in connection with the reverse merger described below. Both Neurogene and Neurogene OpCo have a principal place of Directors business in November 2022 and March 2023, New York, NY. Neurogene was formed to harness the Company has restructured operations power of gene therapy, combined with its EXACT gene regulation technology, to significantly reduce its workforce, discontinue development of NL-201, a *de novo* protein that was turn today's complex devastating neurological diseases into treatable conditions. The Company's first clinical-stage program to utilize the EXACT technology is NGN-401, which is in an ongoing Phase 1 1/2 clinical trial for the treatment of cancer, and suspended Rett syndrome. In addition to NGN-401, Neurogene is also pursuing a conventional gene therapy program in an ongoing Phase 1/2 clinical trial of NGN-101 for the treatment of CLN5 Batten disease. Since beginning operations, the Company has devoted substantially all its efforts to research and development, activities in order to conserve capital recruiting management and focus on other strategic alternatives for the Company.technical staff, administration, and raising capital.

Reverse Merger and Pre-Closing Financing

On July 17, 2023 July 18, 2023, Neoleukin Project North Merger Sub, Therapeutics, Inc., a Delaware corporation and a wholly owned subsidiary of Neoleukin ("Merger Sub"), and Neurogene Inc., a privately held Delaware corporation ("Neurogene"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which, among other matters, with its wholly owned subsidiary ("Merger Sub") and subject Neurogene OpCo. Pursuant to the satisfaction or waiver terms of the conditions set forth in the Merger Agreement, upon closing on December 18, 2023 (the "Closing"), Merger Sub will merge merged with and into Neurogene OpCo, with Neurogene OpCo continuing as a wholly owned subsidiary of Neoleukin the Company and the surviving corporation of the merger (referred to herein as the "reverse merger").

At the time of Closing (or immediately prior to, where indicated), the following also occurred:

- The Company changed its name from "Neoleukin Therapeutics, Inc." to "Neurogene Inc." and is referred to herein as the "Company." Unless the context otherwise requires, references to "Neoleukin Therapeutics, Inc." or "Neoleukin" refer to the Company prior to Closing.
- Immediately prior to Closing, Neoleukin effected a 1-for-4 reverse stock split (the "Merger" "Reverse Stock Split"). The Merger is intended Unless noted otherwise, all references herein to qualify for federal income tax purposes as a tax-free reorganization under share and per share amounts reflect the provisions of Section 368(a) Reverse Stock Split.
- All of the Internal Revenue Code then outstanding shares of 1986, Neurogene OpCo Class A common stock were converted into 3,240,888 shares of the Company's common stock, based on an exchange ratio of approximately 0.0756 (the "Exchange Ratio").
- All of the then outstanding shares of Neurogene OpCo preferred stock were converted into 7,231,747 shares of the Company's common stock and 1,825,635 pre-funded warrants, based on the Exchange Ratio.
- Each then outstanding Neurogene OpCo stock option was exchanged for an equivalent stock option of the Company, adjusted to reflect the Exchange Ratio as amended necessary.
- Each then outstanding Neurogene OpCo pre-funded warrant to purchase shares of Neurogene OpCo common stock was converted into a pre-funded warrant to purchase shares of the Company's common stock, adjusted to reflect the Exchange Ratio as necessary. Refer to the discussion below for further detail on Neurogene OpCo pre-funded warrants.

Concurrently with the execution and delivery of the Merger Agreement, and in order to provide Neurogene OpCo with additional capital for its development programs, Neurogene OpCo entered into a subscription agreement (the "IRC" "Subscription Agreement") with certain investors. Pursuant to the terms of the Subscription Agreement, immediately prior to the Closing, Neurogene OpCo issued and sold to the investors: (i) 2,792,206 shares of Neurogene OpCo common stock and (ii) 1,811,739 pre-funded warrants, exercisable for 1,811,739 shares of Neurogene OpCo common stock, at a purchase price of approximately $20.63 per share or $20.63 per warrant, for an aggregate purchase price of approximately $95.0 million (the "Pre-Closing Financing").

2. Risks and Uncertainties

The Merger Agreement Company is subject to customary closing conditions, including approval of certain matters by stockholders of each of Neoleukin and Neurogene, and is anticipated risks common to close companies in the fourth quarter biotechnology industry, including, but not limited to, successful development of 2023, assuming satisfaction or waiver technology, obtaining additional funding, protection of all proprietary technology, compliance with government regulations, risks of failure of pre-clinical studies, clinical studies and clinical trials, the conditions need to obtain marketing approval for its drug candidates and its consumer products, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the Merger. Upon closing the Merger, ability to transition from pilot scale manufacturing to large scale production.

Liquidity and Financial Condition

Since its inception, the Company has funded its operations primarily with proceeds from the sales of equity securities and has incurred significant recurring losses, including net losses of $16.9 million and $12.3 million for the three months ended March 31, 2024 and 2023, respectively. In addition, the Company used cash in operations of $21.7 million and $13.6 million for the three months ended March 31, 2024 and 2023, respectively, and had an accumulated deficit of $204.1 million as of March 31, 2024. Management expects to incur costs related substantial and increasing losses in future periods as the Company advances its products through its clinical and regulatory process and will rely on outside capital to payments fund its operations for post-employment separation benefits, retention bonuses, the foreseeable future. The Company has not generated positive cash flows from operations, and to third party service providers which there are not recorded no assurances that the Company will be successful in obtaining an adequate level of financing for the development and commercialization of its product candidates.

As of March 31, 2024, the Company had cash, cash equivalents and investments of approximately $169.5 million. On December 18, 2023, the Company closed the reverse merger and the Pre-Closing Financing. The Company expects its available cash and cash equivalents on hand as of the issuance date of these financial statements. statements

If will be sufficient to fund its obligations as they become due for at least one year beyond the Merger is completed, Neoleukin will change its name issuance date of these financial statements. As a result of the reverse merger with Neoleukin Therapeutics, the Company assumed an ATM or “at-the-market” Equity Offering Sales Agreement with BofA Securities, Inc., as agent (“BofA”), pursuant to Neurogene Inc. which the Company was able to offer and sell, from time to time through BofA, shares of the Company’s common stock, having an aggregate offering price of up to $40.0 million. The Registration Statement on Form S-3 that was prepared for the ATM expired on December 21, 2023, and in March 2024, the Company formally terminated the ATM.

In the event the Company is unable to secure additional outside capital, management will be required to seek other alternatives which may include, among others, a delay or termination of Neurogene would be expected to become clinical trials or the management development of its product candidates, temporary or permanent curtailment of the surviving corporation. Company’s operations, a sale of assets, or other alternatives with strategic or financial partners.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. 3. Summary of significant accounting policies Significant Accounting Policies

(a) Basis of presentation Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and pursuant to the rules and regulations of the United States Securities and Exchange Commission (“SEC”) for interim financial information. Accordingly, these financial statements do not include all of the information and footnotes required by U.S. GAAP for complete financial statements and should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023, filed with the Securities and Exchange Commission SEC on March 20, 2023 March 18, 2024.

In management’s opinion, the unaudited condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) necessary to present fairly the financial position of the Company as of September 30, 2023 March 31, 2024, and results of operations and cash flows for all periods presented. The interim results presented are not necessarily indicative of results that can be expected for the full year ending December 31, 2023 December 31, 2024.

On September 25, 2023, as approved by the Company's stockholders on June 8, 2023, the Company effected a one-for-five reverse stock split of the authorized and outstanding common stock of the Company. As previously disclosed, the Company's stockholders approved a proposal to authorize the Company's Board of Directors to implement, at the Company's Board of Directors' discretion, a reverse stock split at a ratio not less than one-for-two and not greater than one-for-five, with the exact ratio to be set within that range at the discretion of the Company's Board of Directors. The Company's Board of Directors approved the reverse stock split at a ratio of one-for-five on August 30, 2023. No fractional shares were issued in connection with the reverse stock split. Stockholders who were otherwise entitled to receive fractional shares received a cash payment in lieu of such fractional shares. All share information in these condensed financial statements has been adjusted for this reverse stock split.

(b) Use of estimates and assumptionsEstimates

The preparation of the financial statements in conformity accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant In preparing these financial statements, management used significant estimates in the following areas, requiring estimates include among others: recoverability of the Company's net deferred tax assets and related valuation allowance, useful lives and recognition recoverability of stock-based compensation, property and equipment, determining the incremental borrowing rate utilized in the measurement of operating for calculating lease liabilities and related right-of-use assets and finance lease liabilities, amortization/depreciation and impairment of property and equipment, and pre-clinical, assets, clinical trial accruals, accrual estimates for all contingent value rights ("CVRs"), the value attributed to employee stock options and other accruals. stock-based awards, and valuation of common stock. On an ongoing basis, the Company reviews its estimates to ensure that they appropriately reflect changes in the business or as new information becomes available. Actual results could may differ from these estimates.

Segment Information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company operates as a single operating segment and has one reportable segment. The Company's operations and its assets are held in the United States.

Cash and Cash Equivalents

The Company considers all highly-liquid investments purchased with original maturities of 90 days or less at time of purchase to be cash equivalents. Cash and cash equivalents include cash held in banks and are stated at fair value.

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

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 150,140	$ 148,210
Restricted cash	339	508
Total cash, cash equivalents and restricted cash	$ 150,479	$ 148,718

Cash equivalents consist of money market funds in which the carrying value equals the fair value. Restricted cash includes $0.3 million in cash deposits the Company maintains with its bank as collateral for the irrevocable letters of credits related to its lease obligations.

Concentrations of Credit Risk

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company's cash and cash equivalent accounts, at times, may exceed federally insured limits. As of March 31, 2024, the Company had $149.9 million in excess of the federally insured limits. The Company places its cash in financial institutions that management believes to be of high credit quality.

Exit and Disposal Costs

In connection with the reverse merger and through early fiscal 2025, the Company has incurred and expects to incur costs to wind-down Neoleukin's Phase 1 trial of NL-201. This trial has ceased further development, and the Company has no plans to continue developing Neoleukin's de novo protein technology. As a result, the trial's activities do not provide the Company any future economic benefit. In accordance with ASC 420 Exit or Disposal Costs, the Company accrued the remaining costs to be incurred in the trial. The liability was classified as accrued expenses and other current liabilities in the condensed consolidated balance sheet.

A summary of the accrued liabilities activity recorded in connection with the wind-down Neoleukin's Phase 1 trial of NL-201 for the three months ended March 31, 2024 is as follows (in thousands):

	Balance at December 31, 2023	Liability Adjustment	Amounts Paid	Balance at March 31, 2024
Trial wind-down costs:				
Phase 1 NL-201 Trial	$ 1,962	$ (3)	$ (319)	$ 1,640

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements filed with the Company's Annual Report on Form 10-K for the year ended December 31, 2023. Since the date of those estimates. financial statements, there have been no changes to the Company's significant accounting policies.

Net Loss Per Share Attributable to Common Stockholders

For the prior year period in which the Company had multiple classes of stock participating in earnings, the Company used the two-class method in calculating net loss per share. The two-class method requires income available to ordinary shareholders for the period to be allocated between ordinary shares and participating securities based upon their respective rights. The Company considered its convertible preferred stock to be participating securities as holders would be entitled to participate in dividends and earnings of the Company. As the holders of the convertible preferred stock have no obligation to fund losses, the two-class method is not applicable during periods with a net loss.

Basic net loss per share of Class A and Class B common stock was computed by dividing net loss attributable to the Company by the weighted-average number of shares of Class A and Class B common stock outstanding during the period. In periods of losses, diluted net loss per share was computed on the same basis as basic net loss per share as the inclusion of any other potential shares outstanding would be anti-dilutive.

Following the Company's reverse merger in December 2023, the Company only has one class of common stock remaining, referred to throughout as "common stock." Basic net loss per share of common stock is computed by dividing net income attributable to the Company by the weighted-average number of shares of common stock outstanding during the period. In periods of losses, diluted net loss per share is computed on the same basis as basic net loss per share as the inclusion of any other potential shares outstanding would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share amounts):

	Three Months Ended March 31,		
	2024	2023	
	Common stock	Class A	Class B
Numerator:			
Net loss	$ (16,921)	$ (12,263)	$ —
Denominator:			
Weighted-average shares outstanding in computing net loss per share, basic and diluted	16,903,735	433,623	—
Net loss per share, basic and diluted	$ (1.00)	$ (28.28)	$ —

(c) The following potentially dilutive securities have been excluded from the diluted per share calculations as they would be anti-dilutive:

	Three Months Ended March 31,	
	2024	2023
Series A-1 convertible preferred stock (1)	—	18,604,653
Series A-2 convertible preferred stock (1)	—	13,291,208
Series B convertible preferred stock (1)	—	74,405,719
Stock options	1,475,458	618,881
Total	1,475,458	106,920,461

(1) The convertible preferred stock does not reflect the application of the 0.0756 Exchange Ratio.

Recently Issued Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on its condensed financial statements or disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280). The amendments in this update expand segment disclosure requirements, including new segment disclosure requirements for entities with a single reportable segment among other disclosure requirements. This update is effective for the Company in the consolidated financial statements for the year ending December 31, 2024, and interim periods beginning after January 1, 2025. The Company is analyzing the impact of this standard on its disclosures in the condensed consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Improvements to Income Tax Disclosures, which requires consistent categories and greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. This standard will be effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the impact of this standard on the Company’s condensed consolidated financial statements and related disclosures but does not expect the adoption of ASU 2023-09 to be material.

4. Investments

The following table summarizes the Company's investment securities as of March 31, 2024 (in thousands):

	March 31, 2024			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Cash equivalents:				
Money market funds	$ 145,225	$ —	$ —	$ 145,225
Short-term investments:				
U.S. treasury notes	19,393	—	(1)	19,392
Total	$ 164,618	$ —	$ (1)	$ 164,617

	December 31, 2023			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Cash equivalents:				
Money market funds	$ 144,358	$ —	$ —	$ 144,358
Short-term investments:				
U.S. treasury notes	48,947	16	—	48,963
Total	$ 193,305	$ 16	$ —	$ 193,321

All of the Company's investments mature within the next 12 months.

5. Fair Value of Financial Instruments

As of March 31, 2024 and December 31, 2023, financial assets measured at fair value on a recurring basis are categorized in the table below based upon the lowest level of significant input to the valuations (in thousands):

	March 31, 2024		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	$ 145,225	$ —	$ —
U.S. treasury notes	19,393	—	—
Total	$ 164,618	$ —	$ —

	December 31, 2023		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	$ 144,358	$ —	$ —
U.S. treasury notes	48,947	—	—
Total	$ 193,305	$ —	$ —

Money market funds are cash equivalents and are included in cash and cash equivalents in the condensed consolidated balance sheet as of March 31, 2024 and December 31, 2023.

6. Prepaid expenses and other current assets

Prepaid expenses and other assets consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Refunds and other receivables	$ 589	$ 600
Prepaid expenses	2,765	1,496
Other current assets	1,254	1,095
Total prepaid and other current assets	$ 4,608	$ 3,191

7. Property and Equipment, Net

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

Property

	March 31, 2024	December 31, 2023
Lab equipment	$ 3,115	$ 3,144
Manufacturing equipment	6,262	6,142
Office Equipment	19	19
Leasehold improvements	15,374	15,376
Software	268	268
Construction in progress	229	234
Total property and equipment, cost	25,267	25,183
Less accumulated depreciation	(8,792)	(8,009)
Property and equipment, net	$ 16,475	$ 17,174

Depreciation and equipment are recorded at cost amortization expense for the three months ended March 31, 2024 and are amortized using the straight-line basis over a range of three to seven years. 2023 was approximately $0.8 million and $0.8 million, respectively.

The Company reviews the carrying value of Management has reviewed its property and equipment for impairment whenever events and circumstances indicate that the carrying value of an asset may might not be recoverable from recoverable. During the estimated future cash flows expected three months ended March 31, 2024, the Company recorded impairment losses on idle equipment of $0.1 million, which was charged to result from its use and eventual disposition. In cases where undiscounted expected future cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of assets. The factors considered by management in performing this assessment include current operating results, trends and prospects, the manner in which the property is used, and the effects of obsolescence, demand, competition, and other economic factors. Based on management's assessment, as a result of the corporate restructuring announced in March 2023, including the decision to suspend all research and development activities, there were indicators of impairment of certain property and equipment. In March 2023, the Company recorded $3.4 million in impairment charges. There were no additional indicators of impairment of property and equipment as of September 30, 2023 and none as of December 31, 2022.

(d) Leases

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

The Company includes options to extend the lease in its lease liability and right-of-use asset when it is reasonably certain that it will exercise that option. None of the Company's options to extend the rental term of any of its existing leases were considered reasonably certain as of September 30, 2023.

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

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

(e) Fair value of financial instruments

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

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

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

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

(in thousands)	September 30, 2023			
	Total	**Level 1**	**Level 2**	**Level 3**

Financial assets				
Money market funds	$ 24,711	$ 24,711	$ —	$ —
U.S. treasury securities	53,281	53,281	—	—
Total financial assets	$ 77,992	$ 77,992	$ —	$ —

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

(f) Investments

The Company's short-term investments consist entirely of investments in U.S. treasury securities. These investments are classified as available-for-sale debt securities and are therefore reported at fair value in the condensed balance sheets. Unrealized gains and losses are included in accumulated other comprehensive income (loss). There were no realized gains or losses on investments consolidated statement of operations. Fair value for the three and nine months ended September 30, 2023 and 2022.

The Company assesses investments for impairment at each reporting period. An investment is considered impaired when the amortized cost basis exceeds the fair value. When this is the case, the Company assesses whether the impairment is credit-related or noncredit-related based on various factors. When an impairment, or idle assets was determined by a portion of an impairment, is considered credit-related, an allowance for credit losses is recorded. For the nine months ended September 30, 2023, the Company recognized no year-to-date credit losses and no allowance for credit losses is recorded as of September 30, 2023. The aggregate fair value of investments with unrealized losses as of September 30, 2023 is $22.8 million.

(g) Net loss per share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding quoted purchase price for the period, without consideration assets.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Compensation, bonuses and related benefits	$ 1,109	$ 3,496
Research and development	4,728	4,895
Accrued severance, bonus, and retention (1)	68	2,476
Accrued offering costs in connection with pre-closing financing	—	3,334
Accrued transaction costs related to reverse merger	—	2,557
Other	919	737
Total accrued expenses and other current liabilities	$ 6,824	$ 17,495

(1) Includes accrued severance, bonus, and retention payments for common stock equivalents. Common stock equivalents are included in the calculation of diluted earnings per share only in periods of net income current and are excluded in the calculation of diluted net loss per share in periods of net loss as their inclusion would be anti-dilutive. Outstanding pre-funded warrants as of September 30, 2023 and September 30, 2022 was 2,296,602 and 2,532,602, respectively. They are considered outstanding as of their issuance date and are included in basic and diluted net loss per share because they are fully vested and exercisable for nominal cash consideration. former Neoleukin employees.

(h) Accounting for stock-based compensation

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

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

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

(i) Restructuring charges

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

(j) Recently issued and recently adopted accounting standards

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

3. Cash, cash equivalents, and restricted cash

The Company considers all highly liquid investments with an original contractual maturity or a remaining maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist of money market funds and U.S. treasury securities as of September 30, 2023 and December 31, 2022.

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

(in thousands)	**September 30, 2023**	**December 31, 2022**
Cash and cash equivalents	$ 25,226	$ 37,887
Restricted cash	508	878
Total cash, cash equivalents, and restricted cash	$ 25,734	$ 38,765

Restricted cash, included in other non-current assets in the condensed balance sheets, includes $0.5 million in cash deposits the Company maintains with its bank as collateral for the irrevocable letter of credit related to its lease obligations.

4. Investments **9. Commitments and Contingencies**

Operating and Finance Leases

Supplemental lease expense related to leases for the three months ended March 31, 2024 and 2023 was as follows (in thousands):

	Three Months Ended March 31,	
	2024	**2023**
Operating lease cost	$ 524	$ 259
Finance lease cost		
Amortization of finance leases	11	6
Interest on finance lease liabilities	3	2
Variable lease cost	331	54
Short-term lease cost	23	23
Total lease cost	$ 892	$ 344

The Company's investments consist following table summarizes the maturity of the following:

	September 30, 2023			
(in thousands)	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash equivalents:				
Money market funds	$ 24,711	$ —	$ —	$ 24,711
Short-term investments:				
U.S. treasury securities - due within 1 year	53,281	3	(3)	53,281
Total	$ 77,992	$ 3	$ (3)	$ 77,992

	December 31, 2022			
(in thousands)	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Cash equivalents:				
Money market funds	$ 33,767	$ —	$ —	$ 33,767

U.S. treasury securities - due within 3 months	3,473	—	—	3,473
Short-term investments:				
U.S. treasury securities - due within 1 year	58,518	6	(27)	58,497
Total	$ 95,758	$ 6	$ (27)	$ 95,737

5. Leases

The Company enters into Company's operating and finance lease arrangements for its facilities as well as certain equipment, classified either as liabilities on an undiscounted cash flow basis and a reconciliation to the operating or and finance leases.

The Company has an operating lease agreement, as amended by the execution of two subsequent amendments, for approximately 33,300 square feet of office space in Seattle, Washington for liabilities recognized on the Company's principal executive offices, a laboratory for research and development, and related uses. The lease commenced on January 15, 2020 and expires on February 1, 2029, with the option to extend the lease for two five-year terms. The lease provides for a tenant improvement allowance condensed consolidated balance sheet as of up to $9.5 million, which has been fully utilized. March 31, 2024 (in thousands):

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

Maturity of operating lease liabilities	
2024 (remaining)	$ 2,923
2025	3,987
2026	3,695
2027	3,239
2028	3,294
2029	616
Total lease payments	$ 17,754
Less: interest	(3,442)
Total operating lease liabilities	$ 14,312

Maturity of finance lease liabilities	
2024 (remaining)	$ 38
2025	50
2026	15
2027	6
Total lease payments	$ 109
Less: interest	(13)
Total finance lease liabilities	$ 96

In September 2023, Supplemental balance sheet information related to leases as of March 31, 2024 was as follows (in thousands):

Leases		
Operating right-of-use assets	$	3,565
Operating lease liabilities, current		2,670
Operating lease liabilities, non-current		11,642
Total operating lease liabilities	$	14,312
Finance right-of-use assets	$	87
Finance lease liabilities, current		43
Finance lease liabilities, non-current		53
Total finance lease liabilities	$	96

Other information		
Cash paid for amounts included in measurement of operating lease liabilities (in thousands)	$	1,306
Cash paid for amounts included in measurement of finance lease liabilities (in thousands)	$	13
Weighted-average remaining lease term - operating leases (in years)		4.64
Weighted-average remaining lease term - finance lease (in years)		2.30
Weighted-average discount rate - operating leases		9.72 %
Weighted-average discount rate - finance lease		11.49 %

Lease CVR

As of March 31, 2024, $1.3 million was recorded on the Company initiated Company's condensed consolidated balance sheet as a term sheet lease CVR liability consisting of lease commitments that were probable and estimable at the Closing. The commitments relate to Neoleukin's sublease agreement, effective October 31, 2023, for a new sublease one of its properties with an unrelated third party for the Eastlake Lease expected to begin in November 2023. As a result, the Company considered the sublease terms to be an indicator of impairment and tested the recoverability of this office and laboratory space using entity-specific undiscounted cash flows. Based on these undiscounted cash flows, the Company concluded the undiscounted future cash flows expected to result from the sublease of its operating lease right-of-use asset was less than the carrying value. Therefore, the Company measured the long-lived asset impairment as the amount by which the carrying value remainder of the asset group exceeds its fair value and recorded an impairment charge lease term.

The following table summarizes the maturity of $0.1 million which is included in general and administrative expenses in the condensed statement Company's lease CVR as of operations and comprehensive income (loss). March 31, 2024 (in thousands):

Maturity of Lease CVR		
2024 (remaining)	$	281
2025		598

2026	408
Total lease CVR payments	$ 1,287

Intellectual Property CVR

In October 2023, April 2024, the Company entered into an a licensing and intellectual property assignment agreement to sublease the Eastlake Lease to with an unrelated third party. Pursuant party to develop and commercialize legacy Neoleukin assets (the "Third Party Licensing Agreement"). The third party will make a one-time upfront payment of approximately $0.75 million to Neurogene less any unused portion of the $50,000 advance previously paid to Neurogene and the third party will reimburse Neurogene $10,000 for patent expenses paid by Neurogene. On April 29, 2024, the Company received the upfront payment of approximately $0.75 million under the Third Party Licensing Agreement. The Third Party Licensing Agreement contains development, regulatory and commercialization milestones totaling up to approximately $11.0 million, as well as royalty payments.

Under the CVR Agreement, each CVR holder is eligible to receive 100% of the net proceeds, if any, derived from any consideration paid as a result of the sale of Neoleukin's pre-merger legacy assets pursuant any agreements entered into before the Closing, and 80% of net proceeds, if any, derived from any consideration paid as a result of the sale of Neoleukin's pre-merger legacy assets pursuant any agreements entered into within one year after the Closing (the "Intellectual Property CVR"). Since the Third Party Licensing Agreement was entered into within one year after the Closing, the CVR holders are eligible to receive 80% of the net proceeds derived from the Third Party Licensing Agreement. Contingent consideration liabilities related to the terms CVR Agreement will only be recorded if the liabilities are probable and estimable as of the sublease, balance sheet date.

The Company has accrued approximately $0.6 million (80% of the upfront payment) as a contingent consideration liability related to the Intellectual Property CVR as the upfront payment was deemed probable and estimable as of March 31, 2024. However, as of March 31, 2024, the development and sales milestones were not deemed probable under the Third Party Licensing Agreement. As of March 31, 2024, the liability in the condensed consolidated balance sheet was $0.3 million, as it was reduced by approximately $0.3 million due to eligible expenses incurred by the Company is entitled to receive approximately $1.6 million in lease payments. that offset the liability.

All other payments under the Contingent Value Rights Agreement, dated as of December 18, 2023, by and between the Company and the Rights Agent (the "CVR Agreement") were not considered probable and estimable as of March 31, 2024 and therefore no additional contingent consideration liability has been recorded.

The term Company will evaluate the probable and estimable range of outcomes under the CVR Agreement at each reporting period until the end of the sublease will be from November 1, 2023 through September 30, 2026. CVR term and adjust the amounts accrued for as necessary.

Employment Agreements

The Company has employment and consulting agreements with key personnel providing for compensation and severance in certain circumstances, as defined in the respective employment agreements.

Other Research and Development Arrangements

As of September 30, 2023, and December 31, 2022 March 31, 2024, the Company had standing agreements with consultants, contractors or service providers that generally be terminated by the Company with 30 to 60 days written notice, unless otherwise indicated.

Litigation and Legal Proceedings

The Company is subject to litigation and other claims that arise in the ordinary course of business. While the ultimate result of outstanding legal matters cannot presently be determined, the Company does not expect that the ultimate disposition will have a material effect on its results of financial condition, results of operations or cash flows. However, legal matters are inherently unpredictable and subject to significant

uncertainties, some of which are beyond the Company's operating lease right-of-use assets were $8.7 million control. As such, there can be no assurance that the final outcome of any particular legal matter will not have a material adverse effect on the Company's financial condition results of operations or cash flows.

10. Licenses

License Agreement with The University of Edinburgh

In December 2020, the University Court of the University of Edinburgh (the "University of Edinburgh") and $9.7 million, Neurogene entered into the Master Collaboration Agreement ("MCA"). Under the MCA, Neurogene and the University of Edinburgh agreed to collaborate on certain research and development projects ("Projects") and Neurogene agreed to provide funding for such Projects for a 40-month initial term, which term was extended in November 2023 for an additional 33 months and may be further extended by mutual agreement. In exchange for such funding, the University of Edinburgh granted Neurogene the option to exclusively license any intellectual property arising from such Projects. If Neurogene exercises an exclusive option for a particular Project, Neurogene will enter into a separate exclusive license agreement on its own terms with the University of Edinburgh. Under the MCA, Neurogene is obligated to pay semi-annual installment payments relating to funding of costs for personnel and lab consumables for the 40-month period. Either party may terminate the MCA for convenience upon 90 days' notice. If Neurogene terminates the MCA, it would be responsible for all non-cancellable costs and commitments related to any particular Project and any and all funding costs for any person working on such Project.

In March 2022, Neurogene exercised its option through the collaboration under the MCA and entered into a License Agreement (the "March 2022 Edinburgh License Agreement") with University of Edinburgh, pursuant to which Neurogene licensed certain patents and know-how related to the EXACT technology and optimized *MECP2* cassettes on an exclusive basis. Under the March 2022 Edinburgh License Agreement, Neurogene obtained an exclusive, worldwide license to the licensed patents to develop, manufacture, supply, sell, and commercialize any products that utilize the licensed patents (the "Licensed Products") in exchange for low single-digit percentage royalties on future commercial net sales of the Licensed Products. Royalties are payable on a Licensed Product-by-Licensed Product and country-by-country basis until the latest of the expiration of the last licensed patent covering such Licensed Product in the country where the Licensed Product is sold, or, if no licensed patent exists or has expired in such country, then ten years from first commercial sale of such Licensed Product in such country. In connection with the license, Neurogene is also obligated to pay the University of Edinburgh up to $5.3 million in regulatory-related milestones and up to $25.0 million in sales-related milestones based on annual net sales of Licensed Products in excess of defined thresholds.

The expense recorded by the Company related to the MCA was $0.4 million and $0.3 million for the three months ended March 31, 2024 and 2023, respectively. As

License Agreement with Virovek

In September 2020, Neurogene entered into a Non-Exclusive License Agreement with Virovek, Inc., pursuant to which Neurogene has a license to use certain patents and know-how on a non-exclusive basis related to Neurogene's baculovirus ("baculo") process in exchange for low single-digit percentage royalties on future commercial net sales of September 30, 2023 each product using the baculo process, development milestone payments of up to $0.2 million in the aggregate, and a nonrefundable annual license fee. During the three months ended March 31, 2023, the Company's finance lease right-of-use assets, included within property Company recorded a milestone expense of $0.1 million for the Rett Syndrome Investigational New Drug filing.

License Agreement with Sigma-Aldrich Co

In January 2023, Neurogene entered into a Non-Exclusive License Agreement with Sigma-Aldrich Co. LLC, pursuant to which Neurogene has a license to certain patents and equipment know-how on a non-exclusive basis related to certain cell lines used in Neurogene's baculo process in exchange for a small annual fee on a product-by-product basis, payable once the condensed balance sheets, first product candidate enters the clinic. In addition, on a product-by-product basis, Neurogene is obligated to pay up to $2.5 million in the aggregate for development-

related milestones. During the three months ended March 31, 2024 and 2023, the Company recorded a license expense of $0.06 million and $0, respectively.

No expenses were immaterial. As of December 31, 2022, recorded related to other in-process license agreements during the Company's finance lease right-of-use assets were $0.5 million. three months ended March 31, 2024 and 2023. None will be due under these agreements unless and until certain development milestones are reached.

6. 11. Stockholders' Equity (Deficit)

(a) Common stock and pre-funded warrants

On August 30, 2023 As of March 31, 2024, the Company's Board of Directors approved the reverse stock split at a ratio of one-for-five of the Company's authorized and outstanding shares of common stock, which became effective on September 25, 2023. All share information in these condensed financial statements has been adjusted for this reverse stock split.

The Company is authorized to issue 20,000,000 450,000,000 shares of common stock with a par value of $0.000001 as of September 30, 2023 and December 31, 2022. As of September 30, 2023 and December 31, 2022, the total number of shares of common stock issued and outstanding was 8,805,284 and 8,529,668, respectively. per share.

As of September 30, 2023, the

The Company had has pre-funded warrants outstanding to purchase an aggregate of 2,296,602 4,063,361 shares of common stock. stock as of March 31, 2024. The pre-funded warrants are exercisable at any time for an exercise price of $0.000005, $0.000001, except that the terms of the pre-funded warrants provide that such warrants cannot be exercised by the holders if, after giving effect thereto, the holders would beneficially own more than 9.99% of the outstanding common stock, (the "Exercise Cap"), subject to certain exceptions. However, any holder may increase or decrease the Exercise Cap such percentage to any other percentage (not in excess of 19.99%) upon at least 61 days' prior notice from the holder to the Company. On July 18, 2023, the Company received notice from the holders of all of its outstanding pre-funded warrants to increase the Exercise Cap up to 19.99%, effective 61 days from the date of such notice. The holders of the pre-funded warrants will not have the right to vote the shares underlying the pre-funded warrants on any matter except to the extent required by Delaware law. These warrants were classified as equity.

During the second quarter of 2023, 236,000 The Company had reserved shares of common stock were issued upon for future issuance as follows:

	March 31, 2024	December 31, 2023
Unvested restricted stock units	482,384	–
Options outstanding	1,475,458	823,833
Shares available for future grant under the 2023 Equity Incentive Plan	1,526,632	2,237,722
Total common stock reserved	3,484,474	3,061,555

12. Stock-Based Compensation

The Company measures stock-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the exercise of pre-funded warrants. Proceeds vesting period of the exercise to the Company were immaterial.

On October 5, 2023 592,650 shares of common stock were issued upon the exercises of pre-funded warrants. Proceeds of the exercises to the Company were immaterial.

On November 4, 2021, the Company entered into an ATM or “at-the-market” Equity Offering Sales Agreement (the “Sales Agreement”) with BofA Securities, Inc., as agent (“BofA”), pursuant to which the Company may offer and sell, from time to time through BofA, shares of the Company’s common stock, having an aggregate offering price of up to $40.0 million. The offer and sale of the shares will be made pursuant to a shelf registration statement on Form S-3 and the related prospectus filed on December 11, 2020, and declared effective by the SEC on December 21, 2020, as supplemented by a prospectus supplement dated November 4, 2021. awards. The Company has no obligation to sell any such shares under the Sales Agreement. Through September 30, 2023, no sales of common stock have been made pursuant to the Sales Agreement. As of March 20, 2023, the Company is subject to limitations on the amount of funds the Company can raise by selling shares of our common stock using our Form S-3, including sales under this ATM facility, to one-third of the aggregate market value of the shares of our common stock held by non-affiliates, or public float, due to the so-called "baby shelf" requirements set forth recorded stock-based compensation expense in the SEC general instructions of Form S-3. These restrictions will remain following expense categories in place until such time as our public float exceeds $75 million.

(b) Stock-based compensation expense

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development expenses	$ —	$ 973	$ 252	$ 3,288
General and administrative expenses	172	1,058	1,442	3,501
Total stock-based compensation expense	$ 172	$ 2,031	$ 1,694	$ 6,789

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 564	$ 174
General and administrative	481	119
Total expense	$ 1,045	$ 293

Total unrecognized compensation expense for all stock-based compensation plans was $1.0 million as of September 30, 2023. This expense is expected to be recognized over a weighted average remaining vesting period of 1.92 years. In accordance with the terms of the Merger Agreement, all stock options with an exercise price per share of less than $18.90 will vest immediately upon the closing of the Merger.

The fair values following table summarizes the option activity:

	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (years)
Outstanding at December 31, 2023	823,833	$ 31.43	5.89
Granted	741,652	$ 34.59	
Exercised	(37,330)	$ 16.89	
Expired/Forfeited	(52,697)	$ 72.62	
Outstanding at March 31, 2024	1,475,458	$ 31.03	7.77
Exercisable at March 31, 2024	530,779	$ 30.95	5.15

As of stock March 31, 2024, the aggregate intrinsic value of outstanding options granted are estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Expected volatility	—	84.18 %	86.77 %	83.80 %
Expected dividends	—	0 %	0 %	0 %
Expected terms (years)	—	6.08	5.60	6.04
Risk free rate	—	2.83 %	3.67 %	2.63 %

There were no stock and exercisable options granted during was approximately $32.2 million and $15.1 million, respectively. The aggregate intrinsic value of options exercised was approximately $0.7 million for the three months ended September 30, 2023 March 31, 2024.

(c) Stock options

A summary of the Company's stock option activity and related information for the nine months ended September 30, 2023 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at December 31, 2022	1,702,833	$ 24.47	8.32	$ —
Options granted	52,100	$ 3.52		
Options exercised	—	$ —		
Options cancelled/forfeited	(859,867)	$ 27.06		
Outstanding at September 30, 2023	895,066	$ 19.70	4.03	$ 4
Exercisable as of September 30, 2023	738,616	$ 21.90	3.04	$ —

There were no exercises of options during the nine months ended September 30, 2023. During the nine months ended September 30, 2022, 7,300 shares of common stock were issued upon exercise of options with an aggregate intrinsic value of $0.1 million. The weighted-average grant date fair value of options granted during was $25.97 and $12.99 per share for the nine three months ended September 30, 2023 March 31, 2024 and September 30, 2022 2023, respectively. The Company recorded stock-based compensation related to stock options of approximately $1.0 million and $0.3 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, the total unrecognized compensation expense related to unvested stock option awards was $2.54 and $4.80 per share, respectively. approximately $18.7 million, which the Company expects to recognize over a weighted-average period of 3.43 years.

The fair value of each option was estimated on the grant date using the weighted average assumptions in the table below:

	Three Months Ended March 31,	
	2024	2023
Expected volatility	86.39%-87.64%	82.96%-83.70%
Risk-free interest rate	3.97%-4.32%	3.45%-4.46%
Expected life (in years)	5.77-6.08	3.58-6.08
Expected dividend yield	—	—
Fair value of common stock (1)	$	18.39

(d) (1)Restricted Prior to the reverse merger, the Company periodically estimated the fair value of the Company's common stock units considering, among other things, valuations of its common stock prepared by management with the assistance of a third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Following the reverse merger, the fair value of the Company's common stock is based on the closing stock price on the date of grant as reported on the Nasdaq Global Market.

A summary of the Company's RSU activity and related information for the nine three months ended September 30, 2023 March 31, 2024 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2022	75,700	$ 21.09
Restricted stock units granted	—	$ —
Restricted stock units vested	(37,000)	$ 21.95
Restricted stock units forfeited	(32,950)	$ 20.59
Non-vested at September 30, 2023	5,750	$ 18.45

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	—	$ —
Restricted stock units granted	482,384	$ 36.06
Unvested at March 31, 2024	482,384	$ 36.06

(e) Employee stock purchase plan

The Company's 2020 ESPP was adopted by 252,124 of these RSUs were granted with vesting in two equal tranches based on certain performance conditions ("PSUs"). Each PSU entitles the Company's Board holder to receive one share of Directors in March 2020 and approved

by the Company's stockholders in May 2020. A total of 151,987 shares of Company's common stock have been reserved for issuance under when the 2020 ESPP.

Subject PSU vests. During the three months ended March 31, 2024, the related performance conditions were not met and are not currently considered probable to share and dollar limits vest. As such, no expense is recognized as described in the plan, the 2020 ESPP allows eligible employees to contribute, through payroll deductions, up to 15% of their earnings for the purchase of shares of the Company's common stock at the lower of 85% of the closing price of the Company's common stock on the first trading day of the offering period or 85% of the closing price of the Company's common stock on the last trading day of the offering period. There are two six-month offering periods during each fiscal year, ending on May 15 and November 15.

Under the terms of the Merger Agreement, the 2020 ESPP will be suspended and no new offering period will commence under the 2020 ESPP prior to the closing of the Merger. If any current offering period is still in effect upon the closing of the Merger, the last day of the offering period will be accelerated to a date before the closing of the Merger as determined by the Company's Board of Directors (or relevant committee thereof) in its discretion.

As of September 30, 2023 and December 31, 2022, employee contributions included in accounts payable and accrued liabilities in the accompanying condensed balance sheet were immaterial.

7. Net loss per share March 31, 2024.

The Company excluded recorded stock-based compensation expense related to RSUs of approximately $0.1 million for 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,	
	2023	2022	2023	2022
Outstanding stock options	895,066	1,883,179	895,066	1,883,179
Restricted stock units	5,750	90,850	5,750	90,850
Shares issuable under 2020 ESPP	1,492	12,384	1,492	12,384
	902,308	1,986,413	902,308	1,986,413

three months ended March 31, 2024. As of March 31, 2024, there was approximately $8.2 million of unrecognized compensation cost related to unvested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 2.95 years.

8. Restructurings and impairment charges 13. Subsequent Events

November workforce reduction

On November 14, 2022, From April 1, 2024 until the financial statements were issued, the Company announced a corporate restructuring as a result of the strategic decision granted 14,415 options to discontinue further development of NL-201. In conjunction with this decision, the Company's Board of Directors approved a restructuring plan that included a reduction of approximately 40% of the Company's workforce (the "November 2022 Reduction").

14 employees, 15,887 options were exercised and 103,407 pre-funded warrants were exercised.

In connection with the November 2022 Reduction, the Company incurred aggregate restructuring charges consisting of severance payments, benefits, and other employee related costs of $1.7 million, of which $1.4 million was recognized during the fourth quarter of 2022. The remaining

$0.3 million was incurred during the nine months ended September 30, 2023, all of which is included in research and development expenses in the statement of operations and comprehensive income (loss). The Company expects to pay all remaining restructuring charges associated with the November 2022 Reduction by the end of the fourth quarter of 2023.

March workforce reduction

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

In connection with the March 2023 Restructuring Plan, the Company incurred additional aggregate restructuring charges consisting of severance payments, benefits, and other employee related costs of $1.8 million, all of which was incurred during the nine months ended September 30, 2023. Of the $1.8 million of restructuring charges incurred during the nine months ended September 30, 2023, $0.6 million is included in general and administrative expenses and $1.2 million is included in research and development expenses in the condensed statement of operations and comprehensive income (loss). The Company expects to pay all remaining restructuring charges associated with the March 2023 Restructuring Plan by the end of the first quarter of 2024.

A summary of the accrued liabilities activity recorded in connection with the November 2022 Reduction and March 2023 Restructuring Plan for the nine months ended September 30, 2023 is as follows (in thousands):

	Accrued at December 31, 2022	Charges	Amounts Paid	Accrued at September 30, 2023
Employee severance, benefits, and related costs				
November 2022 Reduction	$ 1,041	$ 327	$ (1,249)	$ 119
March 2023 Restructuring Plan	$ —	$ 1,782	$ (1,443)	$ 339
Total	$ 1,041	$ 2,109	$ (2,692)	$ 458

Impairment charges

As a result of the March 2023 Restructuring Plan, the Company determined that sufficient indicators existed to trigger the performance of an interim long-lived asset impairment analysis as of March 31, 2023. In the first quarter of 2023, the Company tested the recoverability of its asset groups for property and equipment using entity-specific undiscounted cash flows. Based on these undiscounted cash flows, the Company concluded the undiscounted future cash flows expected to result from the eventual disposition of its long-lived assets were less than the carrying value of the asset groups. Therefore, the Company measured the long-lived asset impairment as the amount by which the carrying value of the asset group exceeds its fair value and recorded an impairment charge of $3.4 million. The fair value of the asset group reflect the Company's best estimate of what hypothetical market participants would use to determine a transaction price for the asset group which represents a Level 3 fair value measurement. In the second quarter of 2023, the Company sold property and equipment previously assessed for impairment with a carrying value of $1.8 million, for a $0.2 million gain on sale, net. Of this total gain, $0.3 million of gain on sale is included in research and development expenses and a $0.1 million loss on sale included in general and administrative expenses in the condensed statement of operations and comprehensive income (loss).

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

NEUROGENE 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 thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023.

Forward-Looking Statements

The following Some of the information contained in this discussion of and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our financial condition plans and results of operations contains strategy for our business, include forward-looking statements within that involve risks, uncertainties, and assumptions. As a result of many factors, including those factors set forth in the meaning section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of Section 27A this report entitled "Risk Factors." You should carefully read the "Cautionary Note About Forward-Looking Statements" and "Risk Factors" sections of the Securities Act of 1933, as amended, and Section 21E Annual Report on Form 10-K to gain an understanding of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). important factors that could cause actual results to differ materially from the results described below.

Forward-looking statements are based inherently uncertain and you should not place undue reliance on our management's beliefs and assumptions and on information currently available to our management. All these statements, other than which speak only as of the date that they were made. These cautionary statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events, including the timing and outcome of our exploration of potential strategic alternatives, or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning should be considered in connection with any discussion of future operating written or financial performance. These statements are only predictions. All oral forward-looking statements included that we may issue in the future. Except as required by law, we do not undertake any obligation to revise or update publicly any forward-looking statements after completion of the filing of this quarterly report Quarterly Report on Form 10-Q are based on information available 10-Q to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this quarterly report on Form 10-Q may turn out to be wrong. Actual reflect later events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make circumstances or by known to reflect the occurrence of unanticipated events, or unknown risks, uncertainties otherwise.

In this section, references to "we," "our," "us," and other factors. In evaluating these statements, you should specifically consider various factors, including "the Company" refer to post-merger Neurogene Inc. and our wholly owned subsidiary incorporated in the risks outlined under the caption "Risk Factors" set forth in Item 1A state 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. Nevada, also named Neurogene Inc. ("Neurogene OpCo"), unless otherwise indicated.

Overview

We have historically been Despite recent scientific advances in genetics, most neurological diseases, particularly those with devastating consequences to patients, are left untreated. Conventional gene therapy is an attractive potential treatment approach for only a biopharmaceutical company focused on creating next generation immunotherapies for cancer, inflammation, and autoimmunity using *de novo* protein design technology. We developed sophisticated computational methods limited number of monogenic diseases due to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. Based on decisions made the challenges caused by the Company's Board complex biology of Directors in November 2022 neurological diseases and March 2023, by inherent variable transgene uptake and expression. We are a clinical-stage biotechnology company committed to overcoming these limitations and turning today's complex devastating neurological diseases into treatable conditions. By harnessing our proprietary transgene regulation technology, EXACT™ (Expression Attenuation via Construct Tuning), we are building a robust and differentiated product portfolio of genetic medicines for rare neurological diseases with high unmet need not otherwise addressable by conventional gene therapy. Our EXACT approach leverages key scientific breakthroughs, including gene transfer technology, microRNA-based genetic circuits, and adeno-associated virus delivery, and is designed to deliver therapeutic levels of transgene to key areas of the Company has restructured operations brain that underlie neurological disease pathology.

Our first clinical-stage program to significantly reduce its workforce, discontinue utilize the EXACT platform is NGN-401, which is under development of NL-201, a *de novo* protein that was in Phase 1 clinical trial for the treatment of cancer, Rett syndrome, a disease with a patient population that has a significant unmet need, and suspended all that ultimately progresses to substantial neurological and physical impairment and premature death. In January 2023, we received clearance from the FDA for our IND application for a Phase 1/2 clinical trial of NGN-401 for the treatment of pediatric female patients. The Phase 1/2 clinical trial is an open-label, multi-center clinical trial that will assess the safety, tolerability, and efficacy of two doses of NGN-401 delivered using a one-time intracerebroventricular procedure, which we believe is the most suitable route of administration to achieve optimal biodistribution in key regions of the brain. In January 2024, we announced that the clearance by the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency of the clinical trial application for NGN-401, allowing us to expand enrollment of the Phase 1/2 clinical trial in the UK. Consistent with our clinical development strategy, in February 2024, we amended the protocol to expand the low dose Cohort 1 to add three additional patients for a total of eight patients and remove staggered dosing, as well as adding a second high dose cohort of eight patients. This approach provides us the flexibility to evaluate two doses concurrently, both of which we expect to be efficacious based on preclinical data, with higher doses demonstrating greater biodistribution preclinically. We also believe that including two concurrent dose cohorts in this clinical trial will result in a more robust dataset that we will be able to use to inform a future registrational trial design. NGN-401 was manufactured at our manufacturing facility and clinical-grade product is being used for dosing in the Phase 1/2 clinical trial that is currently enrolling participants. We have now also received acknowledgement from the Australian Therapeutic Goods Administration and approval from the Human Research Ethics Committee to conduct the Phase 1/2 clinical trial for NGN-401, providing clearance for the trial in a third region.

In March 2024, we announced the dosing of the third patient in the Phase 1/2 clinical trial in Cohort 1. In May 2024, we presented data from the Phase 1/2 clinical trial at the ASGCT 27th Annual Meeting which demonstrated a favorable safety profile in the first three pediatric patients dosed in Cohort 1 (starting in 3Q:23 through 1Q:24), including one with a mild variant predicted to result in residual MeCP2 expression, with no signs or symptoms indicative of overexpression-related toxicity reported in any patient. In addition, no treatment-emergent or procedure-related serious
adverse events were observed.

The baseline demographics of the first three patients who received NGN-401 in Cohort 1 (1E15 vector genomes) include:

	Patient 1	**Patient 2**	**Patient 3**
Age at Dosing	7 years old	4 years old	6 years old
Race	Asian	White	White
***MECP2* mutation**	Mild	Severe	Severe
Time post-NGN-401 administration	~9 months	~6 months	~3 months

We expect preliminary clinical data from the first cohort of patients in this study in the fourth quarter of 2024 and an updated dataset from an expanded number of patients in the second half of 2025.

We believe that our EXACT platform has broad applicability in complex neurological diseases not otherwise easily addressable by conventional gene therapy. In addition to our Rett syndrome program, we have multiple programs in the discovery stage. We anticipate advancing one program into clinical development in 2025.

In addition to NGN-401, we are also pursuing a conventional gene therapy program in an ongoing Phase 1/2 clinical trial of NGN-101 for the treatment of CLN5 Batten disease. This patient population has a significant unmet need, and experiences extensive neurological and physical impairment leading to blindness, loss of motor function and early mortality. Our Phase 1/2 clinical trial of NGN-101 is the first trial to assess the treatment of both neurodegenerative and ocular disease manifestations of Batten disease. A third-party manufacturer produced product for the NGN-101 program to initiate the Phase 1/2 clinical trial. Dosing for this program commenced in the second quarter of 2022. We have completed

enrollment in the first two dosing cohorts and are currently enrolling a higher dosing cohort and expect interim clinical data in the second half of 2024. To enable a go/no-go decision to advance the program into a registration study, we are planning to request a clinical/regulatory strategy meeting with the FDA in the second half of 2024. The focus of this meeting will be to align with the FDA on the expected clinical requirements to support a streamlined registration pathway, which will be necessary to move this program forward into a pivotal clinical trial. Given the rarity of the disease, FDA alignment on a streamlined registrational pathway will be critical for continued investment in the program.

We also established a fully operational current good manufacturing practices ("cGMP") facility in Houston, Texas used to manufacture current and future product for research, toxicology and clinical studies. We believe that our in-house manufacturing capabilities better enable control of product quality and development activities in order to conserve capital timelines, strategic pipeline and focus on other strategic alternatives for financial flexibility, and clinical-to-commercial continuity.

Completion of the Company. Reverse Merger and Pre-Closing Financing

Merger Agreement

On July 17, 2023 December 18, 2023, we entered into an completed our business combination with with our wholly owned subsidiary incorporated in the state of Nevada, Neurogene Inc. ("Neurogene OpCo") (the "Closing") in accordance with the terms of the Agreement and Plan of Merger, dated as of July 17, 2023 (the "Merger Agreement") with , by and among the Company, Project North Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Neoleukin the Company ("Merger Sub"), and Neurogene Inc., a Delaware corporation ("Neurogene"), OpCo, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, including the approval of certain matters by the stockholders of each of Neoleukin and Neurogene, Merger Sub will merge merged with and into Neurogene OpCo, with Neurogene continuing OpCo surviving as a wholly owned subsidiary of our the Company (the "Reverse Merger"). In connection with the completion of the Reverse Merger, the Company changed its name from "Neoleukin Therapeutics, Inc." ("Neoleukin") to "Neurogene Inc.," and the surviving corporation business conducted by the Company became primarily the business conducted by Neurogene OpCo. Immediately prior to Closing, the Company effected a 1-for-4 reverse stock split (the "Reverse Stock Split"). Unless noted otherwise, all references in this Quarterly Report on Form 10-Q to share and per share amounts reflect the Reverse Stock Split.

Concurrently with the execution and delivery of the merger Merger Agreement, and in order to provide Neurogene OpCo with additional capital for its development programs, Neurogene OpCo entered into a subscription agreement (the "Merger" "Subscription Agreement").

Subject with certain investors named therein (the "Investors"), pursuant to which, subject to the terms and conditions of the Merger Subscription Agreement, at the closing of the Merger: (a) each then-outstanding share of Neurogene capital stock (including shares of Neurogene common stock, shares of Neurogene preferred stock, and shares of Neurogene common stock issued in a concurrent financing transaction) will be converted into the right to receive a number of shares of our common stock or pre-funded warrants entitling the holder thereof to purchase shares of our common stock, as elected by the Neurogene stockholder and calculated in accordance with the Merger Agreement; (b) each then-outstanding pre-funded warrant to purchase shares of Neurogene common stock issued by Neurogene shall be converted into and become exchangeable for a pre-funded warrant entitling the holder thereof to purchase shares of our common stock, subject to adjustment as set forth in the Merger Agreement; (c) each then-outstanding option to purchase Neurogene common stock will be assumed by us, subject to adjustment as

set forth in the Merger Agreement; and (d) each then-outstanding Neurogene restricted stock unit will be assumed by us, subject to adjustment as set forth in the Merger Agreement. Under the terms of the Merger Agreement, prior to the closing of the Merger, our Board of Directors (the "Board") will take actions to (i) accelerate the vesting of each then-outstanding option to purchase our common stock with an exercise price below $18.90 per share, after giving effect to the one-for-five reverse stock split effected September 25, 2023, that is held by a current employee, director or consultant of us as of immediately prior to the closing effective time of the Reverse Merger, or who ceases to be a current employee, director or consultant of us as of immediately prior to Neurogene OpCo issued and sold, and the closing of the Merger, subject to the terms and conditions set forth in the Merger Agreement, (ii) accelerate the vesting of any of our unvested, time-based restricted stock units and (iii) deliver to the holders of such restricted stock units a number of Investors purchased, 2,792,206 shares of our common stock equal to the number of vested and unsettled shares underlying such restricted stock units, in each case, in accordance with the terms of the Merger Agreement.

Under the terms of the Merger Agreement, upon the closing of the Merger, on a pro forma basis and based upon the number of shares of our common stock expected to be issued in the Merger, pre-Merger Neurogene stockholders will own approximately 84% of the combined company and our pre-Merger stockholders will own approximately 16% of the combined company, in each case, on an as-converted basis to reflect the exercise of any pre-funded warrants, subject to change based on our net cash at closing of the Merger.

Concurrently with the execution of the Merger Agreement, we entered into support agreements with certain of our stockholders (the "Supporting Stockholders"). As of the date of this filing, Supporting Stockholders own an aggregate of approximately 31% of our common stock, pursuant to which such Supporting Stockholders have agreed, among other things, to cast votes for all shares held or controlled by such Supporting Stockholders in favor of certain matters related to the Merger and against any alternative acquisition proposals.

Additionally, in connection with the execution of the Merger Agreement, we entered into a letter agreement with Baker Bros. Advisors LP ("BBA"), pursuant to which the parties agreed to provide BBA with certain rights to (i) nominate one person for election as a director of the Company, provided that BBA owns at least 12.5% of our then-outstanding voting OpCo common stock and (ii) enter into 1,811,739 pre-funded warrants, exercisable for 1,811,739 shares of Neurogene OpCo common stock, at a Registration Rights Agreement with any BBA entity who may be deemed purchase price of approximately $20.63 per share or $20.63 per warrant, for an "affiliate" aggregate purchase price of the Company (collectively, the "Baker Entities" approximately $95.0 million (the "Pre-Closing Financing").

Reverse Stock Split

On September 25, 2023, as approved by the Company's stockholders on June 8, 2023, the Company effected a one-for-five reverse stock split Background

We were founded in 2018, and have devoted substantially all of the authorized and outstanding common stock of the Company. As previously disclosed, the Company's stockholders approved a proposal our resources to authorize the Company's Board of Directors to implement, at the Company's Board of Directors' discretion, a reverse stock split at a ratio not less than one-for-two and not greater than one-for-five, with the exact ratio to be set within that range at the discretion of the Company's Board of Directors. The Company's Board of Directors approved the reverse stock split at a ratio of one-for-five on August 30, 2023. No fractional shares were issued in connection with the reverse stock split. Stockholders who were otherwise entitled to receive fractional shares received a cash payment in lieu of such fractional shares.

Corporate Restructurings

In November 2022, we announced a corporate restructuring as a result of the strategic decision to discontinue development of NL-201 and turn our focus to the next generation of *de novo* cytokine mimetics that further widen the therapeutic window. In March 2023, we announced a further corporate restructuring to significantly reduce our workforce and suspend our conducting research and development activities (including with respect to the NGN-401 and NGN-101 programs) and undertaking preclinical studies, establishing our manufacturing facility, conducting clinical trials and the manufacturing of product used in order to conserve our clinical trials and preclinical studies, business planning, developing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and focus on other strategic alternatives providing general and administrative support for the Company.

17 these activities.

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

Finances

Assuming the completion of the Merger, we will need to raise substantial additional capital to support the continuing operations and pursue the growth strategy of the combined company. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance have funded our operations through primarily with outside capital (e.g., proceeds from the sale of preferred stock and common stock) and have raised aggregate net proceeds of $332.4 million from these private placements. However, we have incurred significant recurring losses, including a net loss of $16.9 million and $12.3 million for the three months ended March 31, 2024 and 2023, respectively. In addition, as of March 31, 2024, we had an accumulated deficit of $204.1 million and cash, cash equivalents and short term investments totaling $169.5 million. In order to continue our operations, we must achieve profitable operations and/or obtain additional equity or debt financings, or other financing. Until we achieve profitability, management plans to fund our operations and capital sources, which may include collaborations expenditures with other companies or other strategic transactions. cash on hand and the sale and issuance of securities. There are can be no assurances assurance that we will be successful in obtaining an adequate level raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to consider actions such as reducing the scope of financing our operations and planned capital expenditures or selling certain assets, including intellectual property assets.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors, including the timing, scope and results of our research and development activities. Management expects that our expenses and capital requirements will increase substantially in connection with our ongoing activities as we:

- advance the NGN-401 and when needed NGN-101 programs through clinical development, including in any additional indications;
- advance discovery programs from preclinical development into and through clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish sales, marketing and distribution infrastructure to commercialize any approved product candidates;
- establish a commercialization infrastructure and scale up internal and external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval

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- expand clinical, scientific, management and administrative teams;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know-how;
- implement operational, financial and management systems; and
- incur additional legal, accounting and other expenses related to operating as a public company.

We do not have any products approved for commercial sale and have not generated any commercial revenue from product sales. Our ability to generate product revenue sufficient to achieve and maintain profitability will depend upon the successful development and eventual commercialization of one or more of our product candidates, which we expect, if it ever occurs, will take many years. We expect to spend a significant amount in development and marketing costs prior to such time. We will therefore require substantial additional capital to develop our product candidates and support our continuing operations. We may never succeed in achieving regulatory and marketing approval for our product candidates. We may obtain unexpected results from our preclinical and clinical trials. We may elect to discontinue, delay, or modify preclinical and clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. Accordingly, until such time that we can generate a sufficient amount of revenue from product sales or other sources, if ever, management expects to finance our operations through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants.

However, we may be unable to raise additional capital from these sources on favorable terms, acceptable to us or at all. Any Our failure to raise obtain sufficient capital as and on acceptable terms when needed could have a negative material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Our management cannot provide assurance that we will ever generate positive cash flow from operating activities. See "*Liquidity and Capital Resources*."

In December 2020, we entered into the Master Research Collaboration ("MCA") with the University Court of the University of Edinburgh (the "University of Edinburgh") to support our pipeline development and expansion, and to accelerate scientific innovation to continue to improve upon conventional gene therapy. In November 2023, the collaboration agreement was amended and extended through December 2026. The University of Edinburgh has a vibrant community of over 500 neuroscience researchers and is widely recognized as a preeminent center for neuroscience research, especially in areas of neurodegeneration and in neurodevelopmental disorders, such as Rett syndrome. For example, researchers currently in neuroscience centers at the University of Edinburgh conducted the seminal preclinical work for Rett syndrome, including discovery of the MeCP2 protein, its function as a transcriptional repressor, developing the first and most widely adopted animal model of Rett syndrome, demonstrating for the first time the reversibility of phenotypes in any neurodevelopmental disorder as well as the first ever preclinical gene therapy efforts in Rett syndrome. Under the terms of the agreement, we have the option to in-license product candidates from Dr. Stuart Cobb's laboratory, where he has a dual appointment as a Professor in Translational Neuroscience at the Patrick Wild Centre and the Centre for Discovery Brain Sciences and serves as our Chief Scientific Officer. Dr. Cobb may be entitled to receive in the future a percentage of certain license-related payments from Neurogene to the University of Edinburgh in accordance with the University of Edinburgh's standard policies for professor inventors.

Impact of Global Economic Events

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including high inflation, changes in interest rates, changes in foreign currency exchange rates, recent bank failures, proposed or adopted federal U.S. legislation seeking to limit the provision of services in our sector by certain non-U.S. entities, geopolitical factors, including the ongoing conflicts between Russia and Ukraine and Israel and the surrounding areas and the responses thereto, and supply chain disruptions. While management is closely monitoring the impact of the current macroeconomic conditions on all aspects of our business, including the impacts on our participants in our Phase 1/2 clinical trials, employees, suppliers, vendors and business partners, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside our control and could exist for an extended period of time. Management will continue to evaluate the nature and extent of the potential impacts to our business, results of operations, liquidity and capital resources. For additional information, see the section entitled "Risk Factors."

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred, including:

- expenses incurred to conduct the necessary discovery-stage laboratory work, preclinical studies and clinical trials required to obtain regulatory approval;
- acquired licenses and intellectual property that are accounted for as asset acquisitions and have no alternative future use;

- personnel expenses, including salaries, benefits and stock-based compensation expense for our employees engaged in research and development functions;
- costs of funding research performed by third parties, including pursuant to agreements with clinical research organizations ("CROs") that conduct our clinical trials, as well as investigative sites, consultants and CROs that conduct our preclinical and nonclinical studies;
- expenses incurred under agreements with our third-party contract development and manufacturing organizations ("CDMOs"), as well as internal manufacturing scale-up expenses, including the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- fees paid to consultants who assist with research and development activities;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

Before a product receives regulatory approval, we record upfront and milestone payments to third parties under licensing arrangements as expense, provided that there is no alternative future use of the rights in other research and developments projects.

Non-refundable prepayments for research and development costs that are paid in advance of performance are capitalized as a prepaid expense and amortized over the service period as the services are provided. Costs for certain development activities, such as outside research programs funded by us, are recognized based on an evaluation of the progress to completion of specific tasks with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial condition statements as prepaid or accrued research and development expense as applicable.

We track outsourced development costs and other external research and development costs to specific product candidates on a program-by-program basis, including fees paid to CROs, CDMOs and research laboratories in connection with our preclinical development, process development, and clinical development activities. We also incur personnel and other operating expenses for research and development programs, which are presented in aggregate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct clinical trials, including later-stage clinical trials for current and future product candidates, and prepare regulatory filings for our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees and consultants in executive, finance and accounting, legal, operations support, information technology and human resource functions. General and administrative expenses also include corporate facility costs not otherwise included in research and development expense, including rent, utilities, depreciation and maintenance, as well as legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We expect that our general and administrative expense will increase in the future to support our continued research and development activities, potential commercialization efforts and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, legal support and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the SEC, insurance and investor relations costs. If any of our current or future product candidates obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team, as well as an expanded regulatory and compliance function.

Interest Income

Interest income consists primarily of interest earned on our ability to pursue our business plans and strategies. If we are unable to secure adequate additional funding, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more product candidates, reduce our early stage research projects, reduce the size of our team, or delay our pursuit of potential in-licenses or acquisitions. If we are not able to complete the Merger, we would expect our Board of Directors to consider exploring other strategic alternatives, which may include a sale, merger, divestiture of assets, licensing or winding down and dissolution.

Based on our current business plans, even if we are not able to complete the Merger, we believe that our existing cash, cash equivalents and short-term investments short term investments. We expect our interest income to fluctuate depending on interest rates and the amount of cash that is invested.

Income Taxes

We assess our income tax positions and record tax benefits based upon management's evaluation of the facts, circumstances, and information available at the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sufficient sustained, we record the amount of tax benefit with a greater than 50 percent likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions for which it is not more likely than not that a tax benefit will be sustained, no tax benefit is recognized in the financial statements.

Since inception, we have not recorded any income tax benefits for net operating losses ("NOLs") or for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our NOLs and tax credits will not be realized. Accordingly, we have established a valuation allowance against such deferred tax assets for all periods since inception.

As of December 31, 2023, we had federal and state NOL carryforwards in the amount of $277.9 million and $35.1 million, respectively, which may be available to fund our planned operations through at least 12 months following the filing date offset future taxable income. The state NOL carryforwards will begin to expire in 2038, unless previously utilized. Most federal NOL carryforwards were generated subsequent to January 1, 2018, and therefore are able to be carried forward indefinitely. As of this Form 10-Q. December 31, 2023, we also had federal research tax credit and federal orphan drug tax credit carryforwards of $7.5 million and $2.2 million, respectively, which may be used to offset future tax liabilities. These tax and orphan drug credit carryforwards begin to expire in 2039 and 2042, respectively, unless previously utilized.

Results of Operations

Operating Comparison of the Three Months Ended March 31, 2024 and 2023

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

	Three Months Ended March 31,		
	2024	**2023**	**Change**
Operating expenses:			
Research and development expenses	$ 13,541	$ 10,283	$ 3,258
General and administrative expenses	5,238	2,752	2,486
Total operating expenses	18,779	13,035	5,744
Loss from operations	(18,779)	(13,035)	(5,744)

Other income (expense):			
Interest income	2,320	777	1,543
Interest expense	(3)	(2)	(1)
Other income	143	-	143
Other expense	(602)	(3)	(599)
Net loss	$ (16,921)	$ (12,263)	$ (4,658)

Research and Development Expenses

The following table summarizes our operating research and development expenses for the three and nine months ended September 30, 2023 and 2022: periods indicated (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(in thousands)	**2023**	**2022**	**$**	**%**	**2023**	**2022**	**$**	**%**
Research and development	$ 617	$ 9,471	$ (8,854)	(93)%	$ 7,880	$ 31,128	$ (23,248)	(75)%
General and administrative	4,952	4,138	814	20 %	12,470	13,718	(1,248)	(9)%
Impairment on property and equipment	—	—	—	— %	3,418	—	3,418	100 %
Total operating expenses	$ 5,569	$ 13,609	$ (8,040)	(59)%	$ 23,768	$ 44,846	$ (21,078)	(47)%

	Three Months Ended March 31,		
	2024	**2023**	**Change**
Program specific expenses:			
Rett syndrome	$ 2,019	$ 786	$ 1,233
Batten disease	1,190	1,246	(56)
Early Discovery	1,466	392	1,074
Discontinued Programs	(39)	109	(148)
Unallocated internal expenses:			
Personnel-related	4,718	3,869	849
Share-based compensation	564	174	390
Manufacturing	2,805	2,811	(6)
Other	818	896	(78)
Total research and development expenses	$ 13,541	$ 10,283	$ 3,258

Research and Development Expenses

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

For the three months ended September 30, 2023, research and development expenses were $0.6 million, compared to $9.5 million $13.5 million for the three months ended September 30, 2022. The decrease in research and development expenses during March 31, 2024, as compared to $10.3 million for the three months ended September 30, 2023 is March 31, 2023.

Expenses related to the Rett syndrome program increased primarily due to lower personnel a $1.3 million increase in clinical trial costs NL-201 for the Phase 1/2 clinical trial of NGN-401, offset by a $0.1 million decline in preclinical costs. The decrease in expenses related to the Batten disease program was primarily driven by a $0.1 million decrease in clinical trial costs for the Phase 1/2 clinical trial of NGN-101. The increase in expenses related to the Early Discovery program was primarily driven by a $0.9 million increase in preclinical costs lab supplies and $0.1 million increase in chemistry, manufacturing and control costs.

In 2021, we re-prioritized our pipeline and discontinued certain programs that were in the preclinical and IND-enabling phase of development and shifted focus to developing programs such as NGN-401 for the treatment of Rett syndrome with our EXACT technology. The decline in expenses and consulting fees as related to Discontinued Programs in the first quarter of 2024 was primarily driven by a result of the decision to discontinue development of NL-201 reduction in November 2022 and the decision to suspend research and development activities and focus on strategic alternatives in March study closeout costs. Expenses for Discontinued Programs were substantially complete by year end 2023.

For the nine months ended September 30, 2023, research The increase in unallocated internal expenses was driven primarily by higher salaries, benefits, and development expenses were $7.9 million, compared share-based compensation costs due to $31.1 million for the nine months ended September 30, 2022. The decrease an increase in research and development expenses during the nine months ended September 30, 2023 is primarily due to lower personnel costs, NL-201 clinical costs, preclinical costs, lab supplies expenses, and consulting fees as a result of the decision to discontinue development of NL-201 in November 2022 and the decision to suspend research and development activities and focus on strategic alternatives in March 2023. Additionally, the decrease is due in part to all facility expense being captured in general and administrative expenses beginning in the second quarter of 2023 after the decision to suspend research and development activities in March 2023. headcount.

General and Administrative Expenses

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

For the three months ended September 30, 2023, general and administrative expenses were $5.0 million, compared to $4.1 million $5.2 million for the three months ended September 30, 2022 March 31, 2024, as compared to $2.8 million for the three months ended March 31, 2023. The increase was primarily attributable to: (i) increases in legal, audit, and other professional and consulting fees of approximately $0.9 million resulting from the transition from a private company into a public company, (ii) increases in rent of approximately $0.5 million as the Company assumed the Eastlake Lease (as defined below) and the Blaine Lease (as defined below) after the Reverse Merger closed, (iii) increases in compensation costs and stock-based compensation of approximately $0.8 million associated with increased headcount in general and administrative expenses during functions and a higher stock price as compared to prior year and (iv) increases in insurance and information technology costs of approximately $0.3 million. This was partially offset by the recovery of approximately $0.2 million related to a business email compromise attack by a third party in the prior year.

Interest Income

Interest income increased by $1.5 million for the three months ended September 30, 2023 March 31, 2024 as compared to the three months ended March 31, 2023. The increase was primarily due to increases a significant increase in legal expenses the amount of Neurogene's cash balances and professional services fees associated with a moderate rise in interest rates.

Other Income

Other income increased by $0.1 million for the proposed Merger, as well as an impairment charge on our Eastlake Lease operating lease right-of-use asset, triggered by a new sublease expected to begin in November 2023. The increase was partially offset by a decrease in personnel-related costs.

For the nine three months ended September 30, 2023, general and administrative expenses were $12.5 million, March 31, 2024 as compared to $13.7 million for the nine three months ended September 30, 2022 March 31, 2023. The decrease in general and administrative expenses during the nine months ended September 30, 2023 increase was primarily due to decreases in personnel-related costs, consulting fees, and other general and administrative costs as a result of the decision to discontinue development of NL-201 in November 2022 and the decision to suspend research and development activities and focus on strategic alternatives in March 2023. The decrease was partially offset by increases in legal expenses and professional services fees sublease income associated with the proposed Merger, as well as by increases in facility lease expenses due to all such expense being captured in general and administrative expenses beginning in the second quarter of 2023 Eastlake Lease assumed after the decision to suspend research and development activities in March 2023. Reverse Merger closed.

Impairment on Property and Equipment

In connection with the March 2023 Restructuring Plan, we determined that sufficient indicators existed to trigger the performance of an interim long-lived asset impairment analysis as of March 31, 2023. We recorded an impairment charge on our property and equipment of $3.4 million for the nine months ended September 30, 2023. No impairment charges were recorded during the three and nine months ended September 30, 2022.

Workforce Reductions

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

In connection with the November 2022 Reduction, we incurred aggregate restructuring charges consisting of severance payments, benefits, and other employee related costs of $1.7 million, of which $1.4 million was recognized during the fourth quarter of 2022. The remaining $0.3 million was incurred during the nine months ended September 30, 2023, all of which is included in research and development expenses in the statement of operations and comprehensive income (loss). We expect to pay all remaining restructuring charges associated with the November 2022 Reduction by the end of the fourth quarter of 2023.

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

In connection with the March 2023 Restructuring Plan, we incurred additional aggregate restructuring charges consisting of severance payments, benefits, and other employee related costs of $1.8 million, all of which was incurred during the nine months ended September 30, 2023. Of the $1.8 million of restructuring charges incurred during the nine months ended September 30, 2023, $0.6 million is included in general and administrative expenses and $1.2 million is included in research and development expenses in the condensed statement of operations and comprehensive income (loss). We expect to pay all remaining restructuring charges associated with the March 2023 Restructuring Plan by the end of the first quarter of 2024. Other Expenses

Interest Income

Interest income during Other Expenses increased by $0.6 million for the three months ended September 30, 2023 was $1.0 million March 31, 2024 as compared to $0.6 million during the three months ended September 30, 2022. Interest income during the nine months ended September 30, 2023 was $3.0 million as compared to $0.8 million during the nine months ended September 30, 2022 March 31, 2023. The increase during the three and nine months ended September 30, 2023 is was primarily due to broad increases the accrual of a contingent consideration liability related to the Intellectual Property CVR (as defined in Note 9, *Commitments and Contingencies*, in the interest rate environment resulting notes to the financial statements included in higher interest earned Part I, Item 1 of this Quarterly Report on our money market fund Form 10-Q) in connection with the licensing and U.S. treasury security investments. intellectual property assignment agreement with a third party to develop and commercialize legacy Neoleukin assets (the “Third Party Licensing Agreement”).

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred net significant operating losses and negative cash flows from our operations. Our operating activities used $21.4 million and $34.7 million of cash flows during the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $471.9 million, working capital of $74.7 million, and cash, cash equivalents, and short-term investments of $78.5 million.

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

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**
Net cash (used in) provided by:		
Operating activities	$ (21,351)	$ (34,674)
Investing activities	8,681	(67,601)
Financing activities	(361)	143
Net change in cash, cash equivalents, and restricted cash	$ (13,031)	$ (102,132)

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2023 and September 30, 2022 consisted of net loss for the period adjusted for non-cash items and changes in components of operating assets and liabilities. For the nine months ended September 30, 2023, a net loss of $20.8 million was adjusted for non-cash items including impairment on property and equipment of $3.4 million, stock-based compensation expense of $1.7 million, accretion of premiums on available-for-sale securities (net of amortization of discounts) of $1.9 million and a net decrease of $5.2 million due to changes in operating assets and liabilities. For the nine months ended September 30, 2022, a net loss of $44.1 million was adjusted for non-cash items including stock-based compensation expense of $6.8 million, depreciation and amortization expense of $1.2 million and a net decrease of $0.7 million due to changes in operating assets and liabilities.

Net cash used in investing activities

For the nine months ended September 30, 2023, cash provided by investing activities consisted primarily of proceeds from the maturities of our available-for-sale securities of $99.0 million and from the sale of property and equipment of $2.1 million, partially offset by purchases of available-

for-sale securities of $91.9 million. For the nine months ended September 30, 2022, cash used in investing activities consisted primarily of purchases of available-for-sale securities of $81.6 million and laboratory equipment of $1.0 million, partially offset by proceeds from the maturities of our available-for-sale securities of $15.0 million.

Net cash provided by financing activities

For the nine months ended September 30, 2023 net cash used in financing activities consisted of payments on our finance lease obligations. For the nine months ended September 30, 2022, net cash provided by financing activities consisted primarily of proceeds from stock option exercises and purchases of common stock under our 2020 Employee Stock Purchase Plan.

Operating and Capital Expenditure Requirements

We have not generated product revenue or achieved profitability since our inception and we expect to continue to incur net significant expenses and operating losses for the foreseeable future. future as we advance the clinical development of our product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing for our product candidates to support commercialization and providing general and administrative support for our operations, including the costs associated with operating as a public company. As of September 30, 2023, a result, we had approximately $78.5 million in cash, cash equivalents, and short-term investments. Based on will need additional capital to fund our current business plans, operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. We believe that our existing cash, cash equivalents, and short-term investments capital resources will be sufficient to fund our operating requirements operations through at least 12 months following the filing date of this Form 10-Q. However, our future capital requirements and See 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:

- our ability to complete the Merger;
- the number and characteristics of any future product candidates we develop or may acquire;
- the scope, progress, results, and costs of researching and developing our product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates;
- the cost of manufacturing our future product candidates and any products that may achieve regulatory approval;
- the cost of commercialization activities if any product candidates or future product candidates are approved for sale, including marketing, sales and distribution costs;

- the timing, receipt and amount of sales of, or royalties on, future approved products, if any;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;

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

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

As of March 31, 2024, we had cash, cash equivalents and short term investments totaling $169.5 million. Since inception and through the issuance of these financial statements, we have funded our operations primarily through private placements of convertible preferred stock and common stock for net proceeds of $332.4 million.

Future Capital Requirements

In order to complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that management believes will be necessary to commercialize product candidates, if approved, we will require substantial additional capital. Accordingly, until such time as we can generate a sufficient amount of revenue from product sales or other sources, if ever, management expects to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that we raise additional capital through equity financings or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our own common stock, make certain investments or engage in merger, consolidation, licensing, or asset sale transactions. If we raise capital through collaborations, partnerships, and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional capital from these sources on favorable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from macroeconomic conditions, geopolitical instability, government regulation and otherwise. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including by requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Management cannot provide assurance that we will ever generate positive cash flow from operating activities.

In order to continue our operations, we must achieve profitable operations and/or obtain additional equity or debt financing. Until we achieve profitability, management plans to fund our operations and capital expenditures with cash on hand and the sale and issuance of securities. We may not be successful in raising additional capital and such capital, if available, may not be on terms that are acceptable to us.

We have incurred, and expect to continue to incur, additional costs associated with operating as a public company. In addition, we anticipate that we will need substantial additional funding in connection with our continuing operations. Management bases its projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than management expects.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, timing, progress, results, and costs of researching and developing genetic medicines, and conducting larger and later-stage clinical trials;
- the scope, timing, progress, results, and costs of researching and developing other product candidates that we may pursue;
- the costs, timing, and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- Our ability to establish, maintain, and derive value from collaborations, partnerships or other marketing, distribution, licensing, or other strategic arrangements with third parties on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional capital to meet the capital requirements associated with such operating plans.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2024	**2023**
Net cash used in operating activities	$ (21,650)	$ (13,555)
Net cash provided by (used in) investing activities	29,935	(29)
Net cash (used in) provided by financing activities	(6,524)	107
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 1,761	$ (13,477)

Cash Flows from Operating Activities

For the three months ended March 31, 2024, we used $21.7 million of cash in operating activities. Cash used in operating activities reflected our net loss of $16.9 million, a $6.7 million net decrease in our operating assets and liabilities and noncash charges of $2.0 million, which consisted primarily of $1.0 million in stock-based compensation and $0.8 million in depreciation. The primary use of cash was to fund our operations related to the development of our product candidates, costs associated with the Reverse Merger and the Pre-Closing Financing, and related severance and retention payments to former Neoleukin employees.

For the three months ended March 31, 2023, we used $13.6 million of cash in operating activities. Cash used in operating activities reflected our net loss of $12.3 million, a $2.6 million net decrease in our operating assets and liabilities, offset by noncash charges of $1.3 million, which consisted primarily of $0.8 million in depreciation and $0.3 million in stock-based compensation. The primary use of cash was to fund our operations related to the development of our product candidates.

Cash Flows from Investing Activities

For the three months ended March 31, 2024, net cash flows provided by investing activities consisted of proceeds from the maturities of investments of $30.0 million partially offset by purchases of property and equipment of $0.07 million.

For the three months ended March 31, 2023, net cash flows used in investing activities consisted of purchases of property and equipment of $0.03 million.

Cash Flows from Financing Activities

For the three months ended March 31, 2024, net cash flows used in financing activities consisted of $4.3 million in offering costs paid in connection with the Pre-Closing Financing and $2.9 million in transaction costs related to the Reverse Merger, partially offset by proceeds of $0.6 million from the exercise of stock options.

For the three months ended March 31, 2023, net cash flows provided by financing activities consisted of proceeds of $0.1 million from the exercise of stock options.

Contractual Obligations and Commitments

Lease Obligations

New York Headquarters Lease

We sub-lease approximately 6,000 square feet of office space for our corporate headquarters in New York, New York, with a term expiring in June 2026.

Houston Lease

We lease 42,342 square feet for a manufacturing facility in Houston, Texas. The lease expires in August 2029. We have the option to renew the lease term for two additional five-year terms. The renewal periods were not included in the lease term for purposes of determining the lease liability or right-of-use asset.

Blaine Lease in Seattle

We lease approximately 33,300 square feet of office space in Seattle, Washington that was previously used by Neoleukin for offices, a laboratory for research and development, and related uses (the “Blaine Lease”). The lease expires on February 1, 2029, with the option to extend the lease for two five-year terms. The renewal periods were not included in the lease term for purposes of determining the lease liability.

Eastlake Lease in Seattle

We lease approximately 6,272 square feet of office space in Seattle, Washington, that was previously used by Neoleukin for additional office and laboratory space for research and development and related uses (the “Eastlake Lease”). We also assumed the existing agreement to sublease the Eastlake Lease to an unrelated third party (“Eastlake Sublease”). Pursuant to the terms of the Eastlake Sublease, we are entitled to receive a total of approximately $1.6 million in lease payments. The term of the sublease is through September 30, 2026.

Lease CVR

Each contingent value right ("CVR") distributed pursuant to the CVR Agreement, dated December 18, 2023, by and between the Company and the Rights Agent (the "CVR Agreement") contains the contractual right to receive certain net savings, if any, realized by June 30, 2029 in connection with certain legacy lease obligations related to our business prior to the Reverse Merger (the "Lease CVR"). In accordance with the terms of the Lease CVR within the CVR Agreement, we accrued approximately $1.3 million as a contingent consideration liability on our condensed consolidated balance sheet. The commitment relates to Neoleukin's sublease agreement, effective October 31, 2023, for one of its properties with an unrelated third party for the remainder of the lease term. For more information on the Lease CVR, see Note 9, *Commitments and Contingencies—Lease CVR*, in the notes to the financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Intellectual Property CVR

In accordance with the terms of the Intellectual Property CVR within the CVR Agreement, we accrued approximately $0.6 million as a contingent consideration liability on our condensed consolidated balance sheet. The commitment relates to the Third Party Licensing Agreement. The liability in the condensed consolidated financial statements was $0.3 million, as it was reduced by approximately $0.3 million due to eligible expenses incurred that offset the liability. For more information on the Intellectual Property CVR, see Note 9, *Commitments and Contingencies—Intellectual Property CVR*, in the notes to the financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

The following table summarizes our contractual obligations and commitments as of March 31, 2024 (in thousands):

Maturity of operating lease liabilities		
2024 (remaining)	$	2,923
2025		3,987
2026		3,695
2027		3,239
2028		3,294
2029		616
Total lease payments	$	17,754

Maturity of finance lease liabilities		
2024 (remaining)	$	38
2025		50
2026		15
2027		6
Total lease payments	$	109

Maturity of Lease CVR		
2024	$	281
2025		598
2026		408
Total Lease CVR payments	$	1,287

Research and Development and Manufacturing Agreements

We enter into agreements with certain vendors for the provision of goods and services, which includes manufacturing services with contract development and manufacturing organizations and development and clinical trial services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not presented separately.

License and Collaboration Agreements

License Agreement with The University of Edinburgh

In December 2020, we entered into the MCA with University of Edinburgh. Under the MCA, Neurogene and the University of Edinburgh agreed to collaborate on certain research and development projects ("Projects"), and we agreed to provide funding for such Projects for a 40-month initial term, which term was extended in November 2023 for an additional 33 months and may be further extended by mutual agreement. In exchange for such funding, the University of Edinburgh granted us the option to exclusively license any intellectual property arising from such Projects. Under the MCA, we are obligated to pay semi-annual installment payments relating to funding of costs for personnel and lab consumables for the 40-month period. Either party may terminate the MCA for convenience upon 90 days' notice. If we terminate the MCA, we would be responsible for all non-cancellable costs and commitments related to any particular Project and any and all funding costs for any person working on such Project.

In March 2022, we exercised our option through the collaboration under the MCA, and entered into a License Agreement (the "March 2022 Edinburgh License Agreement") with University of Edinburgh, pursuant to which we licensed certain patents and know-how related to the EXACT technology and optimized *MECP2* cassettes on an exclusive basis. Under the March 2022 Edinburgh License Agreement, we obtained an exclusive, worldwide license to the licensed patents to develop, manufacture, supply, sell, and commercialize any products that utilize the licensed patents (the "Licensed Products") in exchange for low single-digit percentage royalties on future commercial net sales of the Licensed Products. Royalties are payable on a Licensed Product-by-Licensed Product and country-by-country basis until the later of the expiration of the last licensed patent covering such Licensed Product in the country where the Licensed Product is sold, or, if no licensed patent exists or has expired in such country, then ten years from first commercial sale of such Licensed Product in such country (the "Royalty Term"). The term of the March 2022 Edinburgh License Agreement continues until the end of the Royalty Term and the expiration of all of the payment obligation thereunder. We may terminate the March 2022 Edinburgh License Agreement for convenience upon 90 days' notice. In connection with the license, we are also obligated to pay the University of Edinburgh up to $5.3 million in regulatory-related milestones and up to $25.0 million in sales-related milestones based on annual net sales of Licensed Products in excess of defined thresholds.

License Agreement with Virovek

In September 2020, we entered into a Non-Exclusive License Agreement with Virovek, Inc., pursuant to which we have a license to use certain patents and know-how on a non-exclusive basis related to our baculovirus process in exchange for low single-digit percentage royalties on future commercial net sales of each product using the baculovirus process, development milestone payments of up to $0.2 million in the aggregate, and a nonrefundable annual license fee. This agreement continues until the later of (a) the expiration of the last to expire patent right that covers the manufacture, use, offer for sale, sale, importation, export or supply of any licensed product, (b) ten years after the first commercial sale of any licensed product, or (c) the expiration of all regulatory or market exclusivities. We may terminate this agreement for convenience upon 60 days' notice.

License Agreement with Sigma-Aldrich Co

In January 2023, we entered into a Non-Exclusive License Agreement with Sigma-Aldrich Co. LLC, pursuant to which we have a license to certain patents and know-how on a non-exclusive basis related to certain cell lines used in our baculovirus process in exchange for a small annual fee on a product-by-product basis, payable once the first product candidate enters the clinic. In addition, on a product-by-product basis, we are obligated to pay up to $2.5 million in the aggregate for development-related milestones. This agreement remains in force for as long as we continue to possess and use the licensed technology. We may terminate this agreement for convenience upon 60 days' notice.

Off-Balance Sheet Arrangements

We currently do not have, and did not have during the periods presented, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of theseOur financial statements are prepared in accordance with U.S. GAAP GAAP. The preparation of the financial statements and related disclosures requires us management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience, known trends and events and various other factors that we believe to be management believes are 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 Management evaluates estimates and assumptions on a periodic basis. Our actual results may differ from these estimates under different assumptions or conditions. estimates. A summary of our significant accounting policies is presented in Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023. There have been no material changes to our significant accounting policies during the three and nine months ended September 30, 2023March 31, 2024.

Recent Accounting Pronouncements

See Note 2(j), 3, *Recently issued and recently adopted accounting standards Issued Accounting Standards* in the Notes notes to Condensed Financial Statements the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

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

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

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

Changes in internal control over financial reporting. There have not been any changes in our internal control over financial reporting during the quarter ended September 30, 2023 March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. II - Other Information

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K before making an investment decision. The occurrence of any of the following risks could materially and adversely affect our business, financial condition, reputation, or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment. It is not possible to predict or identify all such risks; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

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:

- The completion of the Merger is subject to conditions, some or all of which may not be satisfied or completed on a timely basis, if at all. Failure to complete the Merger could have material adverse effects on the Company.
- We have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale, and our results may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future may not be successful. If we are able vary from quarter to complete any such transaction, it may not result in additional value to stockholders and may present additional challenges. We may also elect to pursue a dissolution and liquidation of the Company instead of a strategic transaction, which may impact the timing and amount of payments to our stockholders. quarter.

- We will require substantial additional capital to finance our operations which may not be available in the future. If we are unable to us raise such capital when needed, or on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable forced to complete the delay, reduce or eliminate clinical trials, product development and potential programs or future commercialization of our product candidates.
- If we fail to maintain the requirements for continued listing on Nasdaq, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted. efforts.
- We have incurred significant losses in every quarter since our inception, and anticipate that we will continue expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future.
- We have a limited operating history as a company developing therapies using *de novo* protein design technology, which may make it difficult no products for you to evaluate the success of our business to date and to assess our future viability.
- We currently sale, have no source of not generated any product revenue and may never generate product revenue or become profitable.
- Our product candidates NGN-401, NGN-101 and our other programs are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of, or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Preclinical studies We are substantially dependent on the success of our most advanced product candidates, NGN-401 and NGN-101, and our ongoing and anticipated clinical trials of our product such 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. successful.
- Future clinical trials Delays in developing our manufacturing capabilities or failure to achieve operating efficiencies from such capabilities may require us to devote additional preclinical studies may reveal significant adverse events not seen in our earlier preclinical studies resources and management time to manufacturing operations and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of delay 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. timelines.
- We have a number of academic collaborations, and currently rely on and expect to continue to rely on third parties to conduct our collaboration with the University Court of the University of Edinburgh (the “University of Edinburgh”) for certain aspects of our preclinical studies research and clinical trials. If those third development programs, including working in collaboration to discover and preclinically develop our lead product candidate for Rett syndrome and our near-term future pipeline. Failure or delay of the University of Edinburgh or any other collaborator to fulfil all or part of its obligations under our agreement, a breakdown in collaboration between the parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines, a complete or terminate partial loss of the relationship our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations, and prospects.
- We rely on and expect to continue to rely on third-party manufacturers and suppliers to supply components of our product candidates. The loss of our third-party manufacturers or suppliers, or our or their failure to comply with applicable regulatory requirements or to

supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect harm our business.

- Unfavorable global economic conditions or other geopolitical developments could adversely affect In order to successfully implement our business, financial condition, stock price, plans and results strategies, we will need to grow the size of operations. our organization and we may experience difficulties in managing this growth.

- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, maintain, and enforce patent protection and other intellectual property rights or if there are delays in obtaining, required regulatory approvals for our product candidates, our Neoleukin design process technology, we will not be able to commercialize, or other proprietary technologies we may develop, the development and commercialization of our will be delayed in commercializing, such product candidates, may be adversely affected.

Risk Factors

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

Risks Related to the Pending Transaction with Neurogene

The completion of the Merger is subject to conditions, some or all of which may not be satisfied or completed on a timely basis, if at all. Failure to complete the Merger could have material adverse effects on the Company.

On July 17, 2023, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Project North Merger Sub, our wholly owned subsidiary ("Merger Sub"), and Neurogene, Inc. ("Neurogene"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Neurogene will merge with and into Merger Sub, with Neurogene continuing as our wholly owned subsidiary and the surviving corporation of the merger (the "Merger"). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the IRC. The Merger Agreement is subject to customary closing conditions and is anticipated to close in the fourth quarter of 2023, assuming satisfaction or waiver of all of the conditions of the Merger.

We cannot predict whether and when the conditions to the Merger will be satisfied, including but not limited to the requirement that our stockholders approve the issuance of adequate shares to complete the Merger and effect a change of control pursuant to certain approval requirements of the Nasdaq Capital Market as well as approval of one or both of certain proposals to be submitted to our stockholders to effect a reverse split of our outstanding stock and to increase the number of authorized shares of our common stock to allow for the issuance of an adequate number of shares to complete the Merger. If one or more of these conditions are not satisfied, and as a result, we do not complete the Merger, we would remain liable for significant transaction costs, and the focus of our management would have been diverted from seeking other potential strategic opportunities, in each case without realizing any benefits of the Merger. Certain costs associated with the Merger have already been incurred or may be payable even if the Merger is not consummated. Finally, any disruptions to our business resulting from the announcement and pendency of the Merger, including any adverse changes in our relationships with our partners, suppliers and employees, could continue or accelerate in the event that we fail to consummate the Merger.

In addition, the Merger Agreement generally requires us to operate in the ordinary course of business consistent with past practice, pending consummation of the Merger, and restricts us from taking certain actions with respect to our business and financial affairs without Neurogene's consent. Such restrictions will be in place until either the Merger is consummated or the Merger Agreement is terminated. These restrictions

could restrict our ability to or prevent us from, pursuing attractive business opportunities (if any) that arise prior to the consummation of the Merger. For these and other reasons, the pendency of the Merger could adversely affect our business, operating results and financial condition.

The price of our common stock may also fluctuate significantly based on announcements by Neurogene, other third parties, or us regarding the Merger or based on market perceptions of the likelihood of the satisfaction of the conditions to the consummation of the Merger. Such announcements may lead to perceptions in the market that the Merger may not be completed, which could cause our share price to fluctuate or decline.

If we do not consummate the Merger, the price of our common stock may decline significantly from the current market price, which may reflect a market assumption that the Merger generate revenue will be consummated. Any of these events could have a material adverse effect on our business, operating results and financial condition and could cause a decline in the price of our common stock.

The Merger will involve substantial costs and will require substantial management resources. materially impaired.

- In connection with the consummation of the Merger, management and financial resources have been diverted and w• ill continue to be diverted towards the completion of the Merger. We expect to incur substantial costs and expenses relating to, as well as the direction of management resources towards, the Merger. Such costs, fees and expenses include fees and expenses payable to financial advisors, other professional fees and expenses, fees and costs relating to regulatory filings and filing with the SEC and notices and other transaction-related costs, fees and expenses. Further, if the Merger Agreement is terminated by us under specified circumstances, we will be required to pay Neurogene a termination fee of $3.0 million and/or reimburse Neurogene's expenses up to a maximum of $1.0 million. If the Merger is not completed, we will have incurred substantial expenses and expended substantial management resources for which we will have received little or no benefit if the closing of the Merger does not occur.

Stockholder litigation could prevent or delay the consummation of the Merger or otherwise negatively impact our business, operating results and financial condition.

We may incur additional costs in connection with the defense or settlement of any stockholder litigation in connection with the Merger. These lawsuits or other future litigation may adversely affect our ability to complete the Merger. We could incur significant costs in connection with any such litigation, including costs associated with the indemnification of our directors and officers.

Furthermore, one of the conditions to the consummation of the Merger is the absence of any governmental order or law preventing the consummation of the Merger or making the consummation of the Merger illegal. Consequently, if a plaintiff were to secure injunctive or other relief prohibiting, delaying or otherwise adversely affecting our ability to complete the consummation of the Merger, then such injunctive or other relief may prevent the Merger from becoming effective within the expected time frame or at all.

The exchange ratio will not change or otherwise be adjusted based on the market price of our common stock as the exchange ratio depends on our net cash at the closing and not the market price of our common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.

At the effective time of the Merger, as set forth in the Merger Agreement, outstanding shares of Neurogene's capital stock will be converted into shares of our common stock or pre-funded warrants to purchase our common stock, and outstanding pre-funded warrants to purchase Neurogene capital stock will be converted into pre-funded warrants to purchase shares of our common stock. Applying the exchange ratio, the former Neurogene stockholders and warrant holders immediately before the Merger, including securities purchased in the financing that is expected to close immediately before the effective time of the Merger, are expected to own approximately 84% of the combined company and our stockholders and holders of Neoleukin pre-funded warrants immediately before the Merger are expected to own approximately 16% of the combined company, subject to certain assumptions, including the amount of net cash held by us at closing. In the event our net cash is lower than our current projections, the exchange ratio will be adjusted such that the number of shares issued to Neurogene's pre-closing stockholders and warrant holders will be increased, and our stockholders and warrant holders will own a smaller percentage of the combined company

following the Merger. Our net cash may be impacted based on the amount of time required to complete the preconditions to the Merger, fluctuations in our expenses between now and closing, and unexpected expenses, among other factors. Any changes in the market price of our stock before the completion of the Merger will not affect the number of shares Neurogene stockholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the Merger, the market price of our common stock increases from the market price on the date of the Merger Agreement, then Neurogene stockholders could receive Merger consideration with substantially more value for their ownership in Neurogene than the parties had negotiated when they established the exchange ratio. Similarly, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, then Neurogene stockholders could receive merger consideration with substantially lower value. While the Merger Agreement can be terminated in the event our net cash falls below $60.0 million, the Merger Agreement does not include a price-based termination right. Moreover, in the event our net cash is below $66.0 million, the exchange ratio will be adjusted such that the number of shares issued (or reserved for issuance in the case of the pre-funded warrants) to Neurogene's pre-Merger stockholders will be increased and our stockholders and warrant holders will own a smaller percentage of the combined company following the Merger.

There is no assurance that we will be able to recognize substantial value for the legacy assets of Neoleukin or avoid future costs under our lease obligations which may result in no additional value received under the Contingent Value Rights Agreement for legacy Neoleukin stockholders.

At the effective time of the Merger, each stockholder or holder of pre-funded warrants of Neoleukin immediately prior to the Merger will receive a contingent value right ("CVR"), giving such holders the right to receive a proportionate share of, among other things, any amounts that the Company may receive in payment from third parties through June 30, 2029 in connection with the disposition of the legacy assets of Neoleukin prior to or in the first year following the closing of the Merger, any amounts of future lease obligations avoided through a sublease, including that Sublease effective October 31, 2023 relating to the Eastlake Lease, assignment or termination of our existing lease obligations, in some cases net of certain costs, and any amounts that our pre-Merger stockholders may receive in connection with sales and use tax refunds from the State of Washington. There can be no assurance that we will be able to recognize any significant value through a sale or licensing of our legacy assets, recoupment of the aforementioned tax refund, or that we will be able to avoid a significant amount of our future lease obligations, in which case the holders of the CVRs may not receive any additional value in the Merger transaction for their shares or pre-funded warrants.

Some of our directors and executive officers have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.

Our directors and executive officers may have interests in the Merger that are different from, or in addition to, the interests of other of our stockholders generally. These interests with respect to our directors and executive officers may include, among others, acceleration of stock option or restricted stock unit vesting, retention bonus payments, extension of exercisability periods of previously issued stock option grants, severance payments if employment is terminated in a qualifying termination in connection with the Merger and rights to continued indemnification, expense advancement and insurance coverage. Two members of our Board will continue as directors of the combined company after the effective time, and, following the closing of the Merger, will be eligible to be compensated as non-employee directors of the combined company. In addition, certain of our directors are affiliated with investment funds which hold an interest in Neurogene and are participating in the Neurogene pre-closing financing. Further, certain current members of Neurogene’s board of directors will continue as directors of the combined company after the effective time, and, following the closing of the Merger, will be eligible to be compensated as non-employee directors of the combined company pursuant to our non-employee director compensation policy that is expected to remain in place following the effective time. Our Board was aware of and considered those interests, among other matters, in reaching their decisions to approve and adopt the Merger Agreement, approve the Merger, and recommend the approval of the Merger Agreement to our and Neurogene’s stockholders. These interests, among other factors, may have influenced the directors and executive officers of each company to support or approve the Merger.

If the Merger is not completed, our stock price may decline significantly.

The market price of our common stock is may continue to be volatile.

- If our legacy lease obligations are not subleased, assigned, terminated or otherwise addressed or the legacy assets subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology the CVR Agreement, dated December 18, 2023, by and other life science companies have historically been particularly volatile. In addition, between the market price of our common stock will likely be volatile based on whether stockholders Company and other investors believe that we can complete the Merger or otherwise raise additional capital to support our operations if the Merger is Rights Agent (the "CVR Agreement") are not consummated and another strategic transaction cannot be identified, negotiated and consummated sold, respectively, in a timely manner, if at all. The volatility of the market price of our common stock has been we may have to incur time and may be exacerbated by low trading volume. Additional factors that may cause the market price of our common stock resources to fluctuate include:
- the loss of key employees; take such actions.
- future Future sales of its common stock; shares by existing stockholders could cause our stock price to decline.
- general Our executive officers, directors and industry-specific economic conditions that may affect its research and development expenditures;
- the failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, principal stockholders have often instituted class action securities litigation against such companies.

Our stockholders will generally have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the Merger as compared to their current ownership and voting interests in the respective companies.

After the completion of the Merger, our current stockholders will generally own a smaller percentage of the combined company than their ownership of our company prior to the Merger. Immediately after the consummation of the Merger, our stockholders and warrant holders as of immediately prior to the Merger are expected to own approximately 16% of the outstanding shares of the combined company (including shares reserved for issuance under Neoleukin's exisitng pre-funded warrants); former Neurogene stockholders, including shares to be issued as well as shares reserved for issuance on exercise of the pre-funded warrants purchased in the Neurogene financing, are expected to own approximately 84% of the outstanding shares of the combined company, subject to certain assumptions, including, but not limited to, Neoleukin's net cash as of closing being at approximately $66.0 million. The Chief Executive Officer and the President of Neurogene, respectively, will serve as the Chief Executive Officer and the President of the combined company following the completion of the Merger. During the pendency of the Merger, we may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect their respective business prospects. Covenants in the Merger Agreement impede our ability to make acquisitions during the pendency of the merger, subject to specified exceptions. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during that period. Further, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, seeking, initiating control or knowingly encouraging, inducing or facilitating the communication, making, submission or announcement of any acquisition proposal or acquisition inquiry or taking any action that could reasonably be expected to lead to certain transactions involving a third party including a merger, sale of assets or other business combination, subject to specified exceptions. In addition, a termination of the

Merger Agreement by us to pursue an alternative strategic reaction would require us to pay a fee of $3.0 million plus certain fees incurred by Neurogene in pursuing a transaction with us, up to $1.0 million. An alternative transaction to the Merger could be favorable significantly influence all matters submitted to our stockholders but may not be available to us due to these restrictive covenants and termination fees.

If the Merger Agreement is terminated and the board of directors of Neurogene determines to seek another business combination, there can be no assurance that we will be able to find another third party to transact a business combination with yielding comparable or greater benefits.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit us from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances. In addition, if we terminate the Merger Agreement under specified circumstances, we could be required to pay Neurogene a termination fee of $3.0 million, plus up to $1.0 million in expense reimbursements. This termination fee may discourage third parties from submitting competing proposals to us or our respective stockholders, and may cause our Board to be less inclined to recommend a competing proposal.

The tax treatment of the CVRs is uncertain.

We intend to treat the issuance of CVRs to the persons who prior to completion of the Merger were our stockholders as a distribution of property with respect to our equity. However, the U.S. federal income tax treatment of the CVRs is uncertain. There is no legal authority directly addressing the U.S. federal income tax treatment of contingent value rights with characteristics similar to the CVRs. Therefore, it is possible that the issuance of the CVRs may be treated as a distribution of equity with respect to our stock, as an “open transaction,” or as a “debt instrument” for U.S. federal income tax purposes, and such questions are inherently factual in nature.

If we complete the Merger, the combined company will need to raise additional capital by issuing equity securities or additional debt or through licensing arrangements, which may cause significant dilution to the combined company’s stockholders or restrict the combined company’s operations.

On July 17, 2023, Neurogene entered into subscription agreements with certain investors, including existing investors of Neurogene, pursuant to which the investors agreed to purchase, in the aggregate, $95.0 million in shares of common stock and pre-funded warrants of Neurogene immediately prior to the closing of the Merger, referred to as the Neurogene pre-closing financing. The closing of the Neurogene pre-closing financing is conditioned upon the satisfaction or waiver of the conditions to the closing of the Merger as well as certain other conditions. The shares of Neurogene common stock and pre-funded warrants issued in the Neurogene pre-closing financing will result in dilution to all stockholders of the combined company (i.e., both our pre-Merger stockholders and former Neurogene stockholders).

Additional financing may not be available to the combined company when it is needed or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such financing will cause additional dilution to all stockholders of the combined company, including our pre-Merger stockholders and Neurogene’s former stockholders. It is also possible that the terms of any new equity securities may have preferences over the combined company’s common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company’s assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to the combined company.

Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger, including the conversion of Neurogene common stock issued in the Neurogene pre-closing financing.

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the

commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

The following risk factors do not take into account the proposed Merger and assume that we remain a stand-alone company except as otherwise noted.

Risks Related to Strategic Process and Potential Strategic Transaction

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

In November 2022, we made the strategic decision to wind down our clinical trial of NL-201, a *de novo* protein designed to mimic the therapeutic activity of the cytokines interleukin-2, or IL-2, and interleukin-15, or IL-15, for the potential treatment of various types of cancer. In connection with that decision, our Board of Directors, or Board, approved a reduction in our workforce designed to reduce our operating expenses to increase our cash runway.In March 2023, based on the challenging capital markets and resources required to bring our earlier stage programs forward to a point of potential viability, the Board approved a plan to significantly reduce the remainder of our workforce while we undertake a comprehensive assessment of strategic options to maximize stockholder value. These strategic options may include a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. While we have entered into a Merger Agreement as of July 17, 2023, there can be no assurance that we will be able to successfully consummate that transaction or any other strategic transaction. If we are unable to complete the proposed Merger, any additional process required to further evaluate strategic options may be very costly, time-consuming and complex and we may incur significant costs related to any such continued evaluation. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders. In addition, we may not be able to adequately limit or avoid future liabilities, including future costs relating to the lease on our headquarters, which may impair the value of any potential transaction or present additional challenges to completing a strategic transaction.

In the event we are not successful at completing the Merger, there can be no assurances that any other particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of our potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly reduce or delay any future distributions to our stockholders.

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

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

If we are successful in completing the Merger, we may be exposed to other operational and financial risks.

There can be no assurance that the Merger will be successfully completed, and the process we have undertaken to assess strategic options, the negotiation and consummation of any such transaction has required and, if the Merger is not completed, will continue to require significant time on the part of our management, and the diversion of management's attention may disrupt our orderly operation of our company.

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

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition, disposition or integration costs;

- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or incurrence of non-recurring, impairment or other charges;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

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

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

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

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

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

Litigation has arisen, and more could arise, in connection with the Merger, against Neoleukin or Neurogene which could be costly, prevent consummation of the merger, divert management's attention and otherwise materially harm Neoleukin's, Neurogene's or the

combined company's business.

A putative stockholder complaint has been filed, and additional putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against Neoleukin, Neoleukin's board of directors, Neurogene, Neurogene's board of directors and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and Neoleukin or Neurogene may not be successful in defending against any such existing or future claims. Lawsuits filed against Neoleukin, Neoleukin's board of directors, Neurogene, or Neurogene's board of directors could delay or prevent the merger, divert the attention of Neoleukin's management and employees from Neoleukin's day-to-day business and otherwise adversely affect Neoleukin's financial condition.

Risks Related to Our Limited Operating History, Financial Position and Capital Needs Requirements

We have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale, and our results may vary from quarter to quarter.

We are a clinical-stage biotechnology company with limited operating history. Since our inception in 2018, we have incurred significant operating losses and have used substantially all of our resources to conduct research and development activities, preclinical studies and Phase 1/2 clinical trials of our most advanced product candidates, establish in-house manufacturing capabilities, including analytical and process development operations to support ongoing manufacturing operations, manufacture product candidates, conduct business planning, develop and maintain our intellectual property portfolio, hire personnel, raise capital, and provide general and administrative support for these activities. We have little experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, we cannot be certain that our current and planned clinical trials will begin or be completed on time, if at all. In addition, while we are conducting a Phase 1/2 clinical trial of NGN-401 in patients with Rett syndrome and a Phase 1/2 clinical trial of NGN-101 in patients with CLN5 Batten disease, we have not yet demonstrated our ability to successfully complete clinical trials (including Phase 3 or other pivotal clinical trials), obtain regulatory or marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with an early research and development focus to a company capable of supporting larger pivotal clinical trials and eventually commercial activities, including the manufacture of commercial scale product. We may not be successful in such a transition.

We will require substantial additional capital to complete a strategic transaction and finance future our operations which may not be available in the future. If we are unable to us raise such capital when needed, or on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts.

Developing biotechnology products is a long, time-consuming, expensive and uncertain process that takes years to complete. Since our inception, we have funded our operations primarily through private financings and have incurred significant recurring losses, including a cumulative net loss from inception of $204.1 million. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to conduct a Phase 1/2 clinical trial of NGN-401 in patients with Rett syndrome and a Phase 1/2 clinical trial of NGN-101 in patients with CLN5 Batten disease, with the expectation that we will also initiate additional clinical trials in the future, and continue to research, develop and conduct preclinical studies of our other potential product candidates. In addition, if we obtain regulatory approval for any product candidate for commercial sale, including NGN-401 and NGN-101, we anticipate incurring significant commercialization expenses related to product manufacturing, marketing, sales and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our current, planned and anticipated clinical trials are highly uncertain, we cannot reasonably

estimate the actual amount of funding that will be necessary to successfully complete the development and potential commercialization of any product candidate we develop. Our future product candidates. capital requirements depend on many factors, including factors that are not within our control.

The development of biopharmaceutical product candidates is capital-intensive. As of September 30, 2023, we had approximately $78.5 million in cash, cash equivalents, and short-term investments. We have spent a significant amount of money on our operations incurred and expect to date, including research and development, preclinical and clinical studies. We will continue to incur additional costs related to associated with operating as a public company, and we do not anticipate achieving any significant revenue in the discontinued near term given the development of NL-201 and suspension stage of our research and development activities. product candidates. Accordingly, we will require substantial additional funding to continue our operations. Based on our current operating plan, we believe that our available existing cash, cash equivalents and short-term investments will should be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months following its operations into the filing date second half of this Form 10-Q. However, our current operating plan does not contemplate the resumption of research and development activities or the commencement of any clinical trials, 2026. This estimate is based on assumptions that may prove to be materially wrong, and we do not expect to be able to fully support could deplete our operations based on the assumptions of that operating plan. We announced in March 2023 that available capital resources sooner than we suspended our research and development operations to focus on reviewing strategic alternatives, and on July 17, 2023, we signed the Merger Agreement with Neurogene, which is intended to improve value for our stockholders. While we expect to have adequate capital to fund our operations through this process, our currently expect. Our future capital requirements and the period during which we expect to complete this strategic process may vary significantly from what we expect, and we may have to seek an alternate resolution to the process. In addition, even if we are successful in completing the Merger, we may still need to raise additional funds for any research and development or clinical programs we may pursue in the future. Our monthly spending levels may vary, and may also be impacted by inflationary pressures in the current economic environment. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, and because we have suspended our research and development activities while we pursue strategic alternatives, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for any product candidates that ultimately may be approved for sale. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- our ability to complete a strategic transaction such as the Merger in a timely manner and on acceptable terms; including:
  - the timing cost and progress of research, preclinical and clinical development activities;
  - the number and scope of development, preclinical and clinical programs we decide pursue to pursue;
- develop our gene therapy candidate pipeline and EXACT the terms of any collaborations and/or research and development agreements we may enter into, which may impact the cost, timing and development plans of one or more of our product candidate programs; (Expression Attenuation via Construct Timing) platform;
  - our ability to maintain secure appropriate animal models for the conduct of investigational new drug (“IND”)-enabling studies in a timely and financially feasible manner, especially large animal models, such as non-human primates (“NHPs”) needed for toxicology studies;
  - our current licenses and ability to establish new collaboration arrangements; an acceptable safety profile with IND-enabling toxicology studies to enable clinical trials;
  - successful patient enrollment in, and the initiation and completion of, larger and later-stage clinical trials;
  - the costs involved number of subjects that participate in prosecuting clinical trials and enforcing patent and other intellectual property claims; per subject trial costs;
  - the costs number and extent of manufacturing our product candidates by third parties; trials required for regulatory approval;
  - the cost of regulatory requirements, regulatory submissions and timing of regulatory approvals; countries in which the trials are conducted;
  - the length of time required to enroll eligible subjects in clinical trials;
  - the drop-out and discontinuation rate of subjects;

- potential delays additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the extent to which we encounter any serious adverse events in our preclinical studies, clinical trials;
- the timing of receipt of regulatory approvals from applicable regulatory authorities, including those required to initiate clinical trials;
- the timing, receipt and terms of any marketing approvals and post-marketing approval commitments from applicable regulatory authorities;
- the extent to which we establish collaborations, strategic partnerships, or other strategic arrangements with third parties, if any, and the performance of any such third party;
- the scale up of our clinical and regulatory capabilities, including establishing our current good manufacturing practices ("cGMP") manufacturing capabilities to support expansion of our pipeline and future registration-enabling clinical trials, and obtaining cGMP material for clinical trials or potential commercial sales;
- hiring and retaining research, clinical, regulatory, manufacturing (including quality control and quality assurance) and administrative personnel;
- our arrangements with third-party contract development programs and manufacturing organizations ("CDMOs") and contract research organizations ("CROs");
- the build-out and validation of our ongoing and planned clinical trial activities due cGMP manufacturing facility, including expansion to the effects of global events, including macroeconomic conditions and continued supply chain disruptions; commercial scale;
- the impact of inflationary pressures on salaries and wages, and costs any business interruptions to our operations or to those of goods and transportation expenses, among other things;
- the cost of commercialization activities if any future product candidates are approved for sale, including marketing, sales and distribution costs; third parties with whom we work; and
- our efforts obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

We do not have any committed external sources of funds, and adequate additional financing may not be available to enhance operational systems and hire personnel to support development of any future product candidates.

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

all. We may be required to seek the additional funding we will need to continue operating in the future funds sooner than planned through collaborations and/or licensing agreements, public or private equity offerings, or debt financings, credit collaborations and licensing arrangements or loan facilities, other sources. Such financing may dilute our stockholders or a combination of one or more of these funding sources. If the failure to obtain such financing may restrict our operating activities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our business. To the extent that we raise additional funds by issuing capital through the sale of equity or convertible debt securities, our stockholders your ownership interest will suffer dilution be diluted, and the terms of any may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder. Debt financing may adversely result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect the rights of our stockholders. In addition, as a

condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we are able to raise additional funds through future debt financings, the terms of such financings are likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. business. If we raise additional funds through licensing upfront payments or collaboration arrangements milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to our product candidates development programs, or grant licenses on terms that are not favorable to us. We also could Our ability to raise additional capital may be required adversely impacted by global macroeconomic conditions, geopolitical instability, changes in government regulations and volatility in the credit and financial markets in the United States and worldwide, over which we may have no or little control. Our failure to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish some or all of our rights to certain product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Failure to obtain raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may force us have to delay, limit reduce the scope of, suspend or terminate our eliminate clinical trials, product development and commercialization of our current programs or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations, and prospects. commercialization efforts.

We have incurred significant losses in every quarter since our inception, and anticipate that we will continue expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable.

We are a biotechnology company with a limited operating history of developing next generation immunotherapies for cancer, inflammation, and autoimmunity using *de novo* protein design technology. Investment in biotechnology product development is a highly speculative because it undertaking and entails substantial upfront capital expenditures and significant risk risks that any potential product candidate program will fail to demonstrate adequate effect efficacy or potency or an acceptable safety profile, gain regulatory approval or and become commercially viable. We do not have any no products approved by regulatory authorities for marketing or commercial sale, we have has not generated any revenue from product sales to date, all of our product candidates are in early stages of and continues to incur significant research and development and we have suspended our research and development activities for the near term while we focus on evaluating strategic alternatives. As a result, we are not profitable and have incurred losses in every reporting period since our inception as Aquinox in 2003. For the nine months ended September 30, 2023 and September 30, 2022, we reported net losses of $20.8 million and $44.1 million, respectively. As of September 30, 2023, we had an accumulated deficit since our inception as Aquinox of $471.9 million.

While we have taken measures to reduce our expenses in the near term, we continue to incur significant other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one product candidate. We may never succeed in these activities and, even if we do, we may never generate product revenue or revenues that are significant or large enough to achieve profitability. If we are unable to generate sufficient revenue through the sale of any approved products, we may be unable to continue operations including expenses relating to without additional funding.

We have incurred significant net losses in each period since we commenced operations in 2018. Our net loss was $16.9 million for the wind downthree months endedMarch 31, 2024 and our cumulative net loss from inception as of our clinical program for NL-201 and expenses related to our ongoing corporate restructuring, and are not currently moving any of our existing product candidates toward commercialization. March 31, 2024 was $204.1 million. We therefore expect to continue to have operating incur significant losses for the foreseeable future. If Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- advance our existing and future programs through preclinical and clinical development, including expansion into additional indications;
- seek to identify additional programs and additional product candidates;
- continue to develop our gene therapy product candidate pipeline and our EXACT platform;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- seek regulatory and marketing approvals for product candidates;

- seek to identify, establish and maintain additional collaborations and license agreements, including those which may enhance the biodistribution and delivery of our product candidates;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any biological products for which we may obtain marketing approval, either by ourselves or in collaboration with others;
- generate revenue from commercial sales of products for which we receive marketing approval;
- hire additional personnel, including research and development, clinical and commercial;
- add operational, financial and management information systems and personnel to support further expansion and operation as a public company;
- acquire or in-license products, intellectual property and technologies which may enhance our current technology; and
- establish commercial-scale cGMP capabilities through our own or third-party manufacturing facilities.

In addition, our expenses will increase if, among other things, we are able required by the FDA or other regulatory authorities to complete perform trials or studies in addition to, or different than, those that we currently anticipate, there are any delays in completing our clinical trials or the Merger, development of any product candidates, or there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain marketing approval for, and are successful in commercializing, one or more product candidates, we expect to resume incur substantial additional research and development activities, relating and other expenditures to Neurogene's assets develop and development plan. market additional programs and/or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our financial condition. business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our financial condition. If we are unable to bring any of our product candidates or future product candidates through full clinical trials for any reason, or if such product candidates or future product candidates do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. revenue.

If we fail to maintain the requirements for continued listing on Nasdaq, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

The continued listing standards of the Nasdaq Stock Market, or Nasdaq, require, among other things, that the minimum bid price of a listed company's stock be at or above $1.00. If the closing minimum bid price is below $1.00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with Nasdaq's listing rules and, if it does not regain compliance within the grace period, will be subject to delisting. On October 26, 2022, we received a notice from the Nasdaq Listing Qualifications Department notifying us that for 30 consecutive trading days, the bid price of our common stock had closed below the minimum $1.00 per share requirement. In accordance with Nasdaq's listing rules, we were afforded a grace period of 180 calendar days, or until April 24, 2023, to regain compliance with the bid price requirement. In April 2023, we applied for and were granted an additional 180 day compliance period, until October 20, 2023. In connection with our application for that additional grace period, we transferred our listing from the Nasdaq Global Market to the Nasdaq Capital Market effective April 27, 2023 and provided written notice to Nasdaq of our intention to cure the deficiency during this second compliance period by effecting a reverse stock split, if necessary. At our annual meeting of stockholders held on June 8, 2023, our stockholders approved a proposal to implement a reverse stock split of our common stock in a ratio that is between one-for-two shares to one-for-five shares, with the final determination on the magnitude and timing of such a reverse split to be made by our Board. On September 25, 2023, we effected a one-for-five reverse stock split as approved by our Board

of Directors and as of October 6, 2023, we regained compliance with the minimum bid price requirements of Nasdaq's listing rules as our common stock closed at a price of at least $1.00 per share for a minimum of 10 consecutive trading days.

We cannot assure you that the per share trading price of our common stock after this reverse stock split will remain above $1.00 per share. Some stockholders may view a reverse stock split negatively. In addition, the per share trading price of our common stock may decrease due to factors unrelated to a reverse stock split, including investor sentiment about the proposed merger with Neurogene as well as our future performance. Any decline in the per share trading price of the common stock may result in a greater percentage decline as an absolute number and as a percentage of our overall market capitalization as there are fewer shares of common stock outstanding following the reverse stock split. The liquidity of our common stock may also be negatively impacted by the reverse stock split because there are fewer shares of our common stock outstanding. Moreover, if the per share market price of our common stock declines following the reverse stock split, then the value of our Company, as measured by our market capitalization, will be reduced. Any reduction in our market capitalization may be magnified as a result of the smaller number of total shares of common stock outstanding following such a reverse stock split.

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

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

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

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

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

- complete development activities, including the necessary clinical trials;
- complete and submit Biologics License Applications, or BLAs, to the U.S. Food and Drug Administration, or FDA, and obtain regulatory approval for indications for which there is a commercial market;

- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop a commercial organization capable of sales, marketing, and distribution for any products for which we obtain marketing approval and intend to sell ourselves in the markets in which we choose to commercialize on our own;
- find suitable distribution partners to help us market, sell, and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- achieve market acceptance for our products, if any;
- establish, maintain, and protect our intellectual property rights; and
- attract, hire, and retain qualified personnel.

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

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

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

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

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

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

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

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

- our ability to identify or acquire additional product candidates for development;
- the initiation, progress, timing, costs, and results of clinical trials for any future product candidates;
- the estimated costs for discontinuing the development of NL-201;
- the clinical development plans we establish for any future product candidates;
- if we in-license or acquire product candidates from third parties, the cost of in-licensing or acquisition;
- the achievement of milestones and our obligation to make milestone payments under our present or any future in-licensing agreements;
- the number and characteristics of product candidates that we discover, or in-license and develop;
- the outcome, timing, and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- the cost to establish, maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection

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with licensing, preparing, filing, prosecuting, defending, and enforcing any patent claims and maintaining and enforcing other intellectual property rights;

- the effects of global macroeconomic trends, including market volatility, instability in the global banking system, supply chain disruptions, inflationary pressures, unemployment rates and impacts of a potential market recession, on our business and financial results;
- the effect of competing technological and market developments;
- the costs and timing of the implementation of commercial-scale outsourced manufacturing activities; and
- the costs and timing of establishing sales, marketing, distribution, and pharmacovigilance capabilities for any product candidates for which we may receive regulatory approval in territories where we choose to commercialize products on our own.

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

Risks Related to Discovery, Development and Commercialization

Product We face competition from entities that have developed or may develop programs for the diseases we plan to address with NGN-401 and NGN-101 or other product candidates.

The development and commercialization of biological products is highly competitive. If approved, NGN-401 and NGN-101 or other product candidates will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, NGN-401 and NGN-101 or other product candidates.

As described in "*Business—Competition*" in our Annual Report on Form 10-K, our competitors have developed, are developing or may develop programs or clinical stage products competitive with NGN-401 or NGN-101 or other earlier stage product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community for Rett syndrome and any new treatments for Rett syndrome or for CLN5 Batten disease. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy or potency, dosing and/or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective or potent, have a more attractive or less invasive dosing profile or presentation or are less expensive than any products we may develop, or if competitors develop competing products that enter the market more quickly than we are able to, if we are able to at all, and are able to gain market acceptance.

NGN-401, NGN-101 and our other programs are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize, our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Any product candidates that we have are in the early stages of development efforts. We have no products on the market and NGN-401 and NGN-101 are in the early stages of clinical development, while our other programs are in early stages of preclinical development. As a result, we have elected to discontinue development of NL-201, expect it will be many years before we have suspended development of all commercialize these product candidates and ultimately may not be successful in commercializing any of our remaining product candidates. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, our lead product candidate NGN-401 or other product candidates, which are still in drug discovery stages, including NGN-101, either alone or with third parties, and we may not cannot guarantee that we will ever obtain regulatory approval for any of our product candidates.

We have limited experience as a company in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or comparable foreign regulatory authorities. We have not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and have significantly reduced our clinical trial team in connection with the discontinuation of development of NL-201. marketing activities necessary for successful product commercialization. Before obtaining regulatory approval for the commercial distribution of any future product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety, purity and efficacy or potency in humans of such product candidates.

We or our collaborators may experience delays in initiating or completing clinical trials, and also may experience unforeseen events during, or as a result of, any current or future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize NGN-401 or NGN-101 or any other product candidates, including:

- regulators or institutional review boards ("IRBs"), the FDA or ethics committees 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 may fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the observation of an actual or suspected unexpected serious adverse reaction, serious adverse events, or adverse events of special interest could result in a partial or complete clinical hold for an unpredictable length of time, delay or halt future enrollment, require increased staggering between patient dosing, require dose reductions that could adversely affect the anticipated efficacy or potency product profile, or require a program discontinuation;
- clinical trial sites may fail to meet enrollment targets, may deviate from trial protocol, or may experience patients dropping out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy or potency, or 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 of our product candidates. Moreover, candidates may be larger than we anticipate, especially if the effect size observed in future clinical data from a Phase 1/2 clinical trial is small or is difficult to ascertain relative to natural history as a comparator, or if regulatory authorities require completion of a sham-controlled clinical trial;
- enrollment in clinical trials may be slower than we anticipate or subjects may drop out of clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our development portfolio consists 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 targets the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, independent data and programs safety monitoring boards ("DSMBs"), IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research or trials, or delay further dosing of subjects in clinical trials, for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are in earlier stages being exposed to unacceptable health risks;
- the cost of discovery and preclinical development and may never advance to clinical-stage development, and in March 2023 we suspended development clinical trials of all any of our current product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to focus conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial;
- we may be unable to manufacture sufficient quantities of our product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety, efficacy or potency concerns about our product candidates;
- we may fail to establish an appropriate safety profile for a product candidate based on evaluation of strategic alternatives clinical or preclinical data for the Company while reducing operating costs such product candidate and data emerging from other therapies in the near term. If same class as our product candidates; and
- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND or, if commenced in other jurisdictions, acceptance by the comparable foreign regulatory agency of a similar application, as well as finalizing the trial design. In the event that the FDA or applicable foreign regulatory agency requires us to complete additional preclinical studies, or we are able required to resume development, satisfy other regulatory requests prior to commencing clinical trials, the start of our clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or if other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials or impose stricter approval conditions than we

currently expect. There are able equivalent processes and risks applicable to acquire or in-license additional product candidates, but we do not receive regulatory approvals for clinical testing trial applications in other jurisdictions, including the United Kingdom ("UK"), Australia and commercialization of such product candidates, we may not be able to continue our operations. the European Union.

We may not have the financial resources to continue development of, or to modify existing collaborations or enter into new collaborations for, a product candidate if we experience any issues that cause or require us to delay or abandon preclinical or clinical trials or delay and/or prevent regulatory approval of, or our ability to commercialize, NGN-401 or NGN-101 or any other product candidates, including:

- preclinical study results showing the product candidate to be less effective than desired candidates. We or to have harmful or problematic side effects;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours;
- product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologics similar to our product candidates;
- a failure to demonstrate that the dose for the product candidate has been optimized;
- the inability of third-party manufacturers to successfully manufacture our products or to meet regulatory specifications;
- inability of any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials or commercial sales;

- delays in submitting INDs or comparable foreign applications, or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA, the European Medicines Agency, or EMA, or other applicable regulatory authorities regarding the scope or design of our future clinical trials;
- delays in enrolling patients in clinical trials for future product candidates;
- high drop-out rates of patients in our future clinical trial patients;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our future clinical trials;
- inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials;
- supply chain disruptions that may impact our ability to obtain materials for research and development, preclinical current or future clinical testing or significantly increase our costs;
- greater than anticipated costs of development, including preclinical studies and clinical trials;

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

Our collaborators' inability to complete development of, or commercialize, our NGN-401 or NGN-101 or any other 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 We currently utilize adeno-associated virus serotype 9 ("AAV9") capsid 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 delivery of these, is sometimes adequate therapeutic transgenes to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect that deliver our product candidates, will initially be targeted which may limit the safety, purity, and efficacy or potency of such product candidates.

Our current approach is to second- or third-line patients, identify, develop and that if those commercialize gene therapy product candidates prove using an AAV9 capsid for delivery of therapeutic transgenes to certain kinds of cells.

Although AAV9 has been tested in numerous clinical trials and is an approved serotype for one gene therapy product, we cannot be certain that our AAV9 product candidates will successfully advance through preclinical studies and clinical trials, or that they will not cause significant adverse events or toxicities. We also cannot be certain that we will be able to avoid triggering toxicities in our future preclinical studies or clinical trials or that our chosen routes of administration to deliver such therapies will not cause unforeseen side effects or other challenges. Although AAV9 has been shown to facilitate biodistribution and cell transduction to the central nervous system ("CNS"), the potentially limited levels of AAV9 transduction of cells in the CNS and certain retinal cells may limit the potential efficacy or potency of any of our product candidates, including NGN-401 and NGN-101.

We intend to identify and develop novel gene therapy product candidates, which makes it difficult to predict the time, cost and potential success of product candidate development.

A key part of our business strategy is to identify and develop additional product candidates. As such, our future success depends on the successful development of novel therapeutic approaches, including by utilizing our EXACT technology or other gene regulation technology. Our preclinical research and clinical trials may initially show promise in identifying potential product candidates, yet fail to yield product candidates for a number of reasons. For example, although EXACT is designed to deliver therapeutic levels of transgene while avoiding overexpression toxicity and off-target effects, there can be no assurance that any EXACT gene regulation will result in product candidates that are shown in clinical trials to be sufficiently beneficial safe, pure, and effective or potent.

To date, very few products that utilize gene transfer have been approved in those initial the United States, Europe or other markets, and no products have been approved using our EXACT technology. There have been a limited number of clinical trials we would expect to seek subsequent approval in earlier lines of therapy. Any gene transfer technologies, with only very few product candidates ever approved by the FDA or comparable foreign regulatory authorities.

As a result, it is difficult for us to predict the time and cost of product candidate development, and we develop, even if approved, cannot predict whether the application of our approach to gene therapy will result in the identification, development, and regulatory approval of any product candidates, or that other gene therapy programs will not be considered better or more attractive. There can be no assurance that any development problems we experience in the future related to our current gene therapy approaches or product candidates or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Research programs to identify new product candidates require substantial technical, financial, and human resources. If we are unable to identify suitable gene therapy

product candidates for preclinical and clinical development, we may not be able to successfully approved implement our business strategy, and may have to delay, reduce the scope of, suspend or eliminate one or more of our product candidates, clinical trials or future commercialization efforts, which would negatively impact our financial condition.

The disorders we seek to treat have low prevalence and it may be difficult to identify and enroll patients with these disorders. If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll and maintain a sufficient number of patients. Patient enrollment is affected by many factors, including the size and nature of the patient population and competition for earlier lines patients with other trials. Genetic diseases generally, and especially the rare diseases for which some of therapy, our current product candidates are targeted, have low incidence and prior prevalence. For example, we estimate global incidence of all 13 subtypes of Batten disease is approximately one in 100,000 live births, and the CLN5 Batten disease incidence, which is included in this estimate, is estimated to be even lower. Accordingly, it may be difficult for us to identify and timely recruit a sufficient number of eligible patients to conduct our clinical trials. Further, any such approvals, natural history studies that we or our collaborators may conduct may fail to provide us with patients for our clinical trials because patients enrolled in the natural history studies may not be good candidates for our clinical trials, or may choose to not enroll in our clinical trials.

Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the European Medicines Agency ("EMA") or other foreign regulatory authorities. We cannot predict how successful we will likely have be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the timely diagnosis of disease to conduct additional clinical trials, which are often very lengthy, expensive, and have a significant risk of failure. meet such eligibility criteria;

Preclinical studies• the size of the patient population and process for identifying patients;

- the perceived risks and benefits of the product candidate in the trial, especially by clinician experts and patient advocacy organizations, including relating to AAV9-based gene therapy and intracerebral spinal fluid delivery system;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials;
- the willingness of caregivers to enroll their children in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by pandemics or other public health crises, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Even if we are able to enroll a sufficient number of patients in our clinical trials, we may have difficulty maintaining enrollment of such patients. Our inability to enroll or maintain a sufficient number of patients would result in significant delays in completing clinical trials or receipt of marketing approvals and increased development costs, or may require us to abandon one or more clinical trials altogether.

We are substantially dependent on the success of our most advanced product candidates, NGN-401 and NGN-101, and our ongoing and anticipated clinical trials of our product such candidates may not be successful.

Our future success is substantially dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our most advanced product candidates, NGN-401 and NGN-101. We are investing a majority of our efforts and financial resources into the

research and development of these candidates. We are conducting a Phase 1/2 clinical trial of NGN-401 in patients with Rett syndrome and a Phase 1/2 clinical trial of NGN-101 in patients with CLN5 Batten disease. If topline results from our Phase 1/2 clinical trial of NGN-401 are successful, we anticipate initiating a pivotal clinical trial, pending future regulatory feedback on various aspects of development such as the pivotal trial design and manufacturing related requirements. If topline results from our Phase 1/2 clinical trial of NGN-101 are successful, we anticipate initiating a pivotal clinical trial or expanding the current Phase 1/2 clinical trial, pending future regulatory feedback on various aspects of development, such as the Phase 3 clinical trial design and manufacturing related requirements.

NGN-401 and NGN-101 will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate revenues from product sales, if we any. We are unable not permitted to commercialize market or promote these product candidates, or experience significant delays any other product candidates, before we receive marketing approval from the FDA and/or comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of NGN-401 and NGN-101 will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we cannot guarantee that we will ever be able to generate revenue through the sale of these candidates, even if approved. If we are not successful in commercializing NGN-401 or NGN-101, or are significantly delayed in doing so, our business will be materially harmed.

Our business programs are focused on the development of therapeutics for patients with neurological diseases, which is heavily dependent a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates is novel and may never lead to approved or marketable products.

The discovery and development of therapeutics for patients with neurological diseases is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our ability preclinical work, that our programs have the potential to be disease-modifying therapies, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain indications. The patient populations for our product candidates are limited to those with specific neurological diseases. We cannot be certain that the patient populations for each specific disease will be large enough to allow us to successfully obtain regulatory approval of, and then successfully launch and commercialize our product candidates. Following a corporate reorganization approved by candidates and achieve profitability. Further, both our Board of Directors in March 2023, we have suspended all research and development activities at the present time to focus on a review of strategic alternatives. Our ability to generate commercial product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of any product candidates we may develop in the future if we are able to resume research and development or acquire or in-licenses other product candidates. If we are able to bring any of our product candidates to Phase 1/2 clinical trial they of NGN-401 and Phase 1/2 clinical trial of NGN-101 will involve a small patient population. Because of the small sample sizes, the results of these trials may not be successful in those trials or, even if they are, they may not receive regulatory approval in a timely manner, or at all. Regulatory agencies, such as an FDA Advisory Committee or similar authority, may recommend non-approval or place restrictions on approval, which may also increase costs and delay commercialization. In addition, we may experience delays or rejections based upon additional government regulation from indicative of results of future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process. For example, the Oncology Center of Excellence within the FDA has advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which maximizes not only the efficacy of a drug but the safety and tolerability as well. This may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection. Other recent Oncology Center of Excellence initiatives include Project FrontRunner, a framework for identifying candidate drugs for initial clinical development in the earlier lines of therapies rather than only after exhausting available treatment options. We are considering these policy changes as they relate to our programs.

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

We expect to seek regulatory approval to commercialize any future product candidates we may bring forward for clinical development both in the United States and in selected foreign countries. In order to market and sell our product candidates in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. Approval by the FDA

does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The approval procedure varies among countries and can involve additional testing. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may be required to expend significant resources to obtain regulatory approval, which may not be on a timely basis or successful at all, and to comply with ongoing regulations in these jurisdictions.

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

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

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

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

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

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

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

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

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

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

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products NGN-401 or NGN-101 or any other product candidates 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 NGN-401 or NGN-101 or any other product candidates may be delayed or never achieved and, as a result, our stock price may decline.

Development of immunotherapies Preclinical and clinical development involves a lengthy and expensive process with an that is subject to delays and uncertain outcome, outcomes, and results of early earlier studies and trials may not be predictive of future clinical trial results. We If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies, which are a lengthy, time consuming and expensive process with risk of high failure. The length of time of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses. However, after conducting preclinical studies, we must then conduct extensive clinical trials to demonstrate the safety, purity, and efficacy or potency of our product candidates.

Following the decision candidate in November 2022 to discontinue development of NL-201, all of our product candidates are now in preclinical humans. Our clinical trials may not be conducted as planned or earlier development and their risk of failure is high. Moreover, in March 2023, completed on schedule, if at all. For example, we decided to suspend our research and development activities, and any future product candidates will depend on a resumption the availability of research and development activities and may come from an acquisition or in-licensing of other assets. If NHPs to conduct certain preclinical studies that we are able required to resume complete prior to submitting an IND and initiating clinical development. There is currently a global shortage of NHPs available for biological product development. This could cause the development cost of one or more product candidates, it is impossible to predict when or if any of obtaining NHPs for our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through

extensive future preclinical studies to increase significantly and, lengthy, complex, and expensive clinical trials that if the shortage continues, could also result in delays to our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and the outcome is inherently uncertain. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Failure development timelines.

Furthermore, failure can occur at any time during the preclinical study or clinical trial process, or we may decide, as we did with NL-201, to stop development for strategic reasons at any time. The results and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage later clinical trials, and differences in trial design between early-stage especially as our initial clinical trials and later-stage do not contain a control arm. In addition, we have designed our initial clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. We have limited experience with relatively small cohorts before expanding in designing clinical trials size and dosing in subsequent cohorts. If safety issues arise in an early cohort, we may be unable to design delayed or prevented from dose escalating or subsequently expanding into larger trial cohorts.

Moreover, preclinical and execute a clinical trial to support marketing approval. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and 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 product candidates. Earlier gene therapy 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 conducted by others also utilized AAV vectors. However, these studies should not be relied upon as evidence that commence clinical trials are never approved as products, and there can be no assurance that any of our planned clinical trials will ultimately succeed. In addition, we expect to rely on patients, caregivers and clinicians to provide feedback on measures, which are subjective and inherently difficult to evaluate. These measures can be successful or support clinical development influenced by factors outside of our product candidates. control, and can vary widely from day to day for a particular patient, and from patient to patient or caregiver to caregiver and from site to site within a clinical trial.

Commencement of any future clinical trials for our product candidates is subject to finalizing the trial design and receiving approval fromWe cannot be sure that the FDA to proceed with clinical testing or similar approval from the EMA or other comparable foreign regulatory authorities. Even after we submit our IND or comparable submissions in other jurisdictions, if the FDA, EMA, or comparable foreign regulatory authorities disagree that we have satisfied their requirements to commence will agree with our clinical development plan. We are conducting a Phase 1/2 clinical trial of NGN-401 in patients with Rett syndrome and a Phase 1/2 clinical trial of NGN-101 in patients with CLN5 Batten disease. If the FDA or comparable regulatory authorities requires us to conduct additional trials or disagree with enroll additional patients, our study design, we development timelines may be required to complete additional preclinical studies delayed. We cannot be sure that submission of an IND application, clinical trial application (“CTA”) or amend our protocols or impose stricter conditions on the commencement of clinical trials.

We may encounter substantial delays similar application will result in the commencement FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to require us to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of our clinical trials or may be required to terminate or suspend such trials, which could result in increased costs to us or delay or limit our ability to generate revenue, adversely affecting our commercial prospects.

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

- we may be unable include: inability to generate sufficient preclinical, toxicology or other*in vivo* or*in vitro* data to obtain regulatory authorizations to commence a support the initiation or continuation of clinical trial;
- we may experience issues trials; delays in reaching a consensus with regulatory authorities on trial design;
- regulators study design or institutional review boards, ethics committees, FDA, EMA, implementation of the clinical trials; delays or other applicable failure in obtaining regulatory authorities, may not authorize us or our investigators authorization to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience trial; delays in reaching or fail to reach, agreement on acceptable terms with prospective CROs and clinical 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 sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial protocol or drop out of a trial;
- site; difficulties in patient enrollment in our clinical trials for a variety of any product candidates may fail to show safety reasons; delays in manufacturing, testing, releasing, validating or efficacy, or may produce negative or inconclusive results, which in turn may cause us to decide, or regulators to require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial, or may be adversely impacted by global supply chain issues;
- we may be unable to obtain or manufacture importing/exporting sufficient stable quantities of our product candidates for use in clinical trials;
- reports trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practices ("GCPs") or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical testing protocols; selection of other therapies may raise safety clinical endpoints that require prolonged periods of observation or efficacy concerns about analyses of resulting data; transfer of manufacturing processes to larger-scale facilities operated by a CDMO and delays or failure by our product candidates; CDMOs or us to make any necessary changes to such manufacturing process; and
- we may fail third parties being unwilling or unable 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. satisfy their contractual obligations to us.

We could also encounter delays if a clinical trial is placed on clinical hold, suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, EMA the competent authorities and/or ethics committees of the UK, Australia, EU Member States or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board, DSMB or the DSMB, equivalent body for such trial. A suspension trial, or termination on account of changes to federal, state, or local laws. If we are required to conduct additional clinical trials or other testing of NGN-401 or NGN-101 or any other product candidates beyond those that we contemplate, if we are unable to successfully complete clinical trials of NGN-401 or NGN-101 or any other product candidates, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be imposed due adversely affected and we may incur significant additional costs.

In addition, even if we are able to a number successfully complete clinical trials for NGN-401 or NGN-101, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. This is particularly true for clinical trials in very rare diseases, such as with our Phase 1/2 clinical trial of factors, including failure NGN-101 for the treatment of CLN5 Batten disease and Phase 1/2 clinical trial of NGN-401 for the treatment of Rett syndrome, where the very small patient population makes it difficult to conduct two traditional, adequate and well-controlled studies. In such cases, the clinical trial FDA or comparable foreign regulatory authorities are often required or permitted to exercise flexibility in accordance with approving therapies for such diseases, but obtaining flexibility is uncertain and may never occur. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory requirements or our clinical protocols, inspection authority to support regulatory approval in the other jurisdiction. To the extent that the results of the clinical trial operations or trial site by trials are not satisfactory to the FDA EMA, or other applicable regulatory authorities resulting in the imposition for support of a clinical hold, unforeseen safety issues or adverse side effects, failure marketing application, we may be required to demonstrate a benefit from using a product or treatment, failure expend significant resources, which may not be available to establish or achieve clinically meaningful trial endpoints, changes us, to conduct additional trials in governmental regulations or administrative actions, lack support of adequate funding to continue the clinical trial or other reasons related to our overall business strategy. For example, prior to our discontinuation of development of NL-201, NL-201 was subject to an FDA clinical hold, which was later lifted. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory potential approval of our product candidates. Further, the FDA, EMA, or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

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

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

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

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

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

From time to time, we may publish publicly disclose preliminary, interim or topline data from our recently terminated or future preclinical studies and clinical trials, which is are based on a preliminary analysis of then-available data. Those data, and the results and any related findings and conclusions are subject to change following a more comprehensive review of the more complete data related to the particular study or trial. data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data and we may not have received or had without the opportunity to fully and carefully evaluate all complete data. As a result, the preliminary Preliminary, interim or topline results that we report may differ from future results of the same studies or clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously disclosed. These preliminary, interim or topline data we previously published. Results from prespecified interim analyses that we may conduct are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. available or as patients from our clinical trials continue other treatments. As a result, preliminary, interim and topline data and prespecified interim analyses should be viewed with caution until the final data are available. Adverse Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or commercialization of a particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, interim or topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, NGN-401 or NGN-101 or any other product candidate may be harmed, which could harm our business, operating results, prospects or financial condition. In addition, differences between preliminary, topline, interim or interim topline data and final data could significantly harm our reputation business prospects and business prospects. may cause the trading price of our common stock to fluctuate significantly.

Failure to obtain Our current or future clinical trials may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval would prevent or limit commercial potential or market acceptance of any future of NGN-401 or NGN-101 or any other product candidates from being marketed. or result in potential product liability claims.

In order Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While our Phase 1/2 clinical trials have not shown any such characteristics to market and sell date, we have not yet completed those clinical trials. If significant adverse events or other side effects are observed in any of our products, current or future clinical trials, we must obtain marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time may have difficulty recruiting patients to such trials, patients may drop out of our trials, patients may be harmed, or we may be required to obtain abandon the trials or our development efforts of one or more product candidates altogether, including NGN-401 or NGN-101. We, the FDA, EMA, or other applicable regulatory authorities, or an IRB, may require suspension of any clinical trials of NGN-401 or NGN-101 or any other product candidates at any time for various reasons, including a finding that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products 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 a product candidate from obtaining or maintaining marketing approval, differs substantially from jurisdiction undesirable side effects may inhibit market acceptance of an approved product due to jurisdiction. its tolerability versus other therapies. In many countries outside the United States, it is required that addition, as gene replacement has a potentially life-long activity, with no ability to withdraw the product be approved for reimbursement before as with other treatment modalities, this profile could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Treatment-emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product can be approved for sale in that

country. Approval by a single regulatory authority does not ensure approval by liability claims. Potential side effects associated with NGN-401 or NGN-101 or any other regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities. A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. We product candidates may not be able to file for marketing approvals and appropriately recognized or managed by the treating medical staff, as toxicities resulting from NGN-401 or NGN-101 or any other product candidates may not receive necessary approvals to commercialize our products be normally encountered in any market. If we are unable to obtain approval the general patient population and by medical personnel. Any of any of our future product candidates by regulatory authorities, the commercial prospects of that product candidate may be significantly diminished and these occurrences could harm our business, financial condition, results of operations and 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. significantly.

In addition, even if we successfully advance NGN-401 or NGN-101 or any other product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of follow up to such product candidates. As a result, we cannot be assured that adverse effects of NGN-401 or NGN-101 or any other product candidates will not be uncovered when a significantly larger number of patients are exposed to such product candidate after approval, or a significantly longer follow up post-dosing is obtained as part of regulators' recommendations for long-term follow up of clinical study subjects treated with gene therapy. Further, any clinical trials may not be sufficient to determine the United States effect and safety consequences of using our product candidates over a multi-year period.

We have expended substantial efforts and costs testing our EXACT technology in recent years, Congress has considered reductions in Medicare reimbursement for drugs administered by physicians. The Centers for Medicare and Medicaid Services, or CMS, preclinical studies of NGN-401, including completing toxicology studies prior to the agency that administers the Medicare program, also has the authority to revise reimbursement rates and to implement coverage restrictions for drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of, and reimbursement for, any approved products, which in turn could affect the price we can receive for those products. For example, on September 9, 2021, the Biden administration published a wide-ranging list of policy proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices, disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment FDA providing clearance of the IRA IND for NGN-401. However, we cannot guarantee that significant adverse effects will not be seen in August 2022, clinical trials for NGN-401, which will, among other things, allow the U.S. Department of Health and Human Services, or HHS, to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation.

In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will

take effect progressively starting in 2023, although they may be subject to legal challenges. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in establishing their own coverage polices and reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may could 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 clinical holds, delays, suspension or constrain the growth withdrawal of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. The Affordable Care Act, among other things, also expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program, imposed a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products, and enacted substantial provisions affecting compliance, which may affect our business practices with healthcare practitioners. Certain provisions IND.If any of the Affordable Care Act have been subject foregoing events occur or if NGN-401 or NGN-101 or any other product candidates prove to judicial and Congressional challenges to repeal or replace certain aspects of the Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the Affordable Care Act and in turn unsafe, our business, prospects, financial condition, or results of operations.

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

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

managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies, and pricing in general.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may expend our limited resources to pursue a particular product candidate, such as NGN-401 or NGN-101, and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must choose the product candidates on which we intend to focus our research and development efforts which on certain selected product candidates. For example, we are initially allocating significant resources to our most advanced product candidates, NGN-401 and NGN-101. As a result, we may require us to forgo or delay pursuit of opportunities with other product potential candidates that may ultimately later prove to have greater commercial potential. For instance, prior to November 2022, we were primarily focused on developing our lead product candidate, NL-201, and invested significant resources in the preclinical and Phase 1 clinical trial for that product candidate, but ultimately decided that our limited resources would be better spent on early stage research of the next generation *de novo* protein design and so elected to discontinue development of NL-201 even though that product candidate had demonstrated on target activity in reviews of preliminary data. In March 2023, our Board of Directors determined that continued investment in early stage *de novo* protein design was not in the best interests of our stockholders and suspended further allocation of our resources to our research and development efforts in order to focus our financial and managerial resources on pursuing a potential strategic alternative. Our resource allocation decisions may require us to make strategic decisions, which in turn may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on 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 candidate.

Even if regulatory approval is obtained, any approved products resulting from NGN-401 or NGN-101 or any other product candidate. candidate may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products.

We face substantial competition, including companies developing novel treatments and technology platforms in oncology. If these companies develop technologies Even if regulatory approval is obtained for NGN-401 or NGN-101 or any other product candidates, more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product can be adversely affected.

The development sold at a competitive cost and commercialization of drugs whether it will otherwise be accepted in the market. There is highly competitive. Our currently one FDA-approved product and multiple other product candidates if approved, will face in various stages of development for the treatment of Rett syndrome. Market participants with significant competition influence over acceptance of new treatments, such as clinicians and our failure to effectively compete third-party payors, may prevent us from achieving significant market penetration. Most not

adopt a gene therapy replacement with a target product profile such as that of our competitors have significantly greater resources than we do NGN-401 or NGN-101 or for their targeted indications, 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 convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any new treatments, product candidates developed by us or our existing or future collaborators. Market acceptance of NGN-401 or NGN-101 or any other product candidates will depend on many factors, including those based factors that are not within our control.

Sales of biological products also depend on novel technology platforms the willingness of clinicians to prescribe the treatment. We cannot predict whether clinicians, clinicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that enter the market. We believe that a significant number any of our approved products are currently under development safe, therapeutically effective or potent, cost effective or less burdensome as compared with competing treatments. If NGN-401 or NGN-101 or any other product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product and may not become commercially available or remain profitable.

We have never commercialized a product candidate and may lack the necessary expertise, personnel and resources to successfully commercialize a product candidate on our own or together with suitable collaborators.

We have never commercialized a product candidate and currently have no sales force, marketing or distribution capabilities. To achieve commercial success for a product candidate, we may opt to license such product candidate to others, in which case we may rely on the future for the treatment assistance and guidance of conditions our collaborators on that license arrangement. For a product candidate for which we are trying, or may try, retain commercialization rights and marketing approval, we will have to develop product candidates. There is intense our own sales, marketing and rapidly evolving competition in the biotechnology, biopharmaceutical, and interleukin and immunoregulatory therapeutics fields. Competition from many sources exists supply organization or outsource these activities to a third party. Factors that 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 affect our ability to develop commercialize a product candidate, if approved, on our own include recruiting and commercialize therapeutics that are safer retaining adequate numbers of effective sales and more effective than competing products. Our commercial opportunity marketing personnel, developing adequate educational and success marketing programs to increase public acceptance of our approved product candidate, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be reduced expensive and time-consuming and could delay the launch of a product candidate upon approval. Moreover, we may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or eliminated if competing products are safer, more effective, to find suitable partners for the commercialization of an approved product candidate, we may not generate revenues from them or less expensive than the therapeutics we develop. be able to reach or sustain profitability.

Many of our competitors We have significantly greater financial, technical, manufacturing, marketing, sales, never completed any late-stage clinical trials and supply resources may not be able to file an IND application or experience than other applications for regulatory approval to commence additional clinical trials on the timelines we have. If expect. Even 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 are able to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage, and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive, or marketed and sold more effectively than any products we may

develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

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

Our product candidates may face competition from other products that are the same as or similar to ours. For any product candidates that are biological products, if complete such trials, the FDA or comparable foreign regulatory authorities approve biosimilar versions may not permit us to proceed or could suspend or terminate any such trial after it has been initiated.

We are early in our development efforts and will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market our product candidates. Carrying out clinical trials and the submission of those product candidates, a successful IND or such authorities do CTA is a complicated process. We have not grant yet completed a Phase 1/2 clinical trial and have limited experience as a company in preparing, submitting and prosecuting regulatory filings. If topline results from our products appropriate periods Phase 1/2 clinical trial of regulatory exclusivity, the sales of those products could be adversely impacted.

The Biologics Price Competition and Innovation Act of 2009, or the BPCIA, was enacted as part of the Affordable Care Act NGN-401 are successful, we intend 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 engage with the FDA and other comparable foreign regulators to review and approve biosimilar biologics, including determine the possible designation requirements to support initiation of a biosimilar as "interchangeable" based on its similarity pivotal clinical trial. If topline results from our Phase 1/2 clinical trial of NGN-101 are successful, we intend to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by engage with 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 other comparable foreign regulators to uncertainty.

A biological product submitted for licensure under a BLA is eligible for a period of exclusivity that commences on the date of its licensure, unless its date of licensure is not considered a date of first licensure because it falls within an exclusion under the PBCIA. Our biological product candidates may qualify for the BPCIA's 12-year period of exclusivity, but determine if there is a risk that streamlined pathway to approval for NGN-101 for the FDA will not consider our product candidates treatment of CLN5 Batten disease. However, regulatory authorities may recommend changes to the study designs for NGN-401 or NGN-101, including the number and size of registrational clinical trials required to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. There is also conducted in such programs. In addition, regulatory authorities could require manufacturing changes or have us implement additional analytical processes prior to initiation of a risk that this exclusivity could future clinical trial. Consequently, we may be shortened due unable to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. For example, there have been efforts to decrease this period of exclusivity to a shorter timeframe—future proposed budgets, international trade agreements, successfully and other arrangements or proposals may affect periods of exclusivity. Most states have enacted substitution laws that permit substitution of only interchangeable biosimilars.The extent to which a highly similar biosimilar, once approved, will be substituted for any one of the reference products efficiently execute and complete necessary clinical trials in a way that is leads to regulatory submission and approval of our product candidates. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in a regulatory meeting, such regulatory authorities may change their requirements in the future. The FDA or comparable foreign regulatory authorities may require the analysis of data from trials assessing different doses of the product candidate alone or in combination with other therapies to justify the selected dose prior to the initiation of large trials in a specific indication. Any delays or failure to initiate clinical trials or obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. We are subject to similar risks related to traditional generic substitution the review and authorization of our protocols and amendments by comparable foreign regulatory authorities.

For our preclinical pipeline, if the IND-enabling studies support a decision to advance into clinical development, we would plan to submit an IND or CTA with a foreign regulatory authority. We may not be able to file the IND or CTA in accordance with our desired timelines for non-biological future product candidates. For example, we may experience manufacturing delays or other delays with IND-enabling studies, including with suppliers, study sites, or third-party contractors and vendors on which we depend. Moreover, we cannot be sure that submission of an IND application will result in the FDA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that lead us to suspend or terminate such clinical trials.

Risks Related to Manufacturing

Gene therapies are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in the development or commercialization of our product candidates or otherwise harm our business.

The manufacture of gene therapy products is not yet clear, technically complex and will depend necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical studies. While we are currently establishing our own manufacturing facility to provide clinical and commercial supply of our product candidates, we expect to rely on contract manufacturers for certain portions of our manufacturing needs for the foreseeable future, such as those related to research grade material for our early preclinical studies. We have also relied on a number third-party contract manufacturer to manufacture clinical supply for our Phase 1/2 clinical trial of marketplace NGN-101.

The manufacturers of biological and pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal regulations, as well as foreign requirements when applicable. Any failure of us or our CDMOs to adhere to or document compliance with such regulatory factors requirements could lead to a delay or interruption in the availability of our program materials for clinical trials or enforcement action from the FDA, EMA or other foreign regulatory authorities. If we or our manufacturers were to fail to comply with the FDA, EMA or other regulatory authority, it could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our potential future dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins and our ability to commercialize any product candidates that are still developing. receive regulatory approval on a timely and competitive basis.

Biological products are inherently difficult to manufacture. Although we believe that the manufacture of our product candidates may be simplified due to their shared raw materials and other similarities, we cannot be certain that this will be the case and we may be required to develop manufacturing methods that ultimately differ significantly between product candidates, which would require that we invest substantial time and capital to develop suitable manufacturing methods. Our program materials are manufactured using technically complex processes requiring specialized equipment and facilities, highly specific raw materials, cells, and reagents, and other production constraints. Our production process requires a number of highly specific raw materials, cells and reagents with limited suppliers. Even though we aim to have backup supplies of raw materials, cells and reagents whenever possible, we cannot be certain those supplies will be sufficient if our primary sources are unavailable. A shortage of a critical raw material, cell line, or reagent, or a technical issue during manufacturing, may lead to delays in clinical development or commercialization plans. We are particularly susceptible to any shortages, delays or inability to obtain suitable raw materials, given that all of our current and planned product candidates require this starting material. Any changes in the manufacturing of components of the raw materials we use could result in unanticipated or unfavorable effects in our manufacturing processes, resulting in delays.

Once the biological products are manufactured, the product must be analyzed utilizing assays and meet pre-determined specifications in order to be used in certain preclinical studies, in any clinical trial, and, if approval is obtained, for commercial distribution. This testing is performed in-house and at third-party contract manufacturers. Delays or other unexpected obstacles in developing analytical methods or in performing the tests and obtaining the results in-house or at a third-party contractor could result in unanticipated impact to our ability to supply material as needed for pre-clinical, clinical, or commercial needs.

We and our contract manufacturers for AAV9 are subject to significant regulation with respect to manufacturing of our products. The third-party manufacturing facilities on which we rely, our in-house manufacturing facility, and any manufacturing facility that we may have in the future, may have limited capacity or fail to meet the applicable stringent regulatory requirements.

We currently have relationships with a limited number of suppliers for the raw materials, including plasmids and virus banks, required by the manufacturing processes of our product candidates. Virus intended for use in our early preclinical studies has been and can be externally supplied; however, if we experience slowdowns or problems with our in-house manufacturing facility and are unable to establish or scale our internal manufacturing capabilities, we will need to continue to contract with manufacturers to produce the preclinical, clinical and commercial supply and such supply will be more uncertain and subject to delays. In addition, each supplier may require licenses to manufacture certain components of the supply if such processes are not owned by the supplier or in the public domain and we may be unable to license such

intellectual property rights on reasonable commercial terms or to transfer or sublicense the intellectual property rights we may have with respect to such activities.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for components of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including recordkeeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. 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. We or our contract manufacturers must supply all necessary documentation in support of a biologics license application ("BLA") or marketing authorization application ("MAA") on a timely basis. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our current or future product candidates. In addition, regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our current or future product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted, and they could put a hold on one or more of our clinical trials if the facilities of our CDMOs do not pass such audit or inspections. If these facilities do not pass a pre-approval plant inspection, the FDA or other foreign regulatory agency approval of the products will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, inspect or audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business. If we decide or any of our third-party manufacturers fail to pursue accelerated approval maintain regulatory compliance, the FDA or other foreign regulatory agencies can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA and/or MAA supplement, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully, if approved. Further, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose future potential revenue, if any.

We depend on third-party suppliers for materials used in the manufacture of our product candidates, and the loss of these third-party suppliers or their inability to supply us with adequate materials could harm our business.

We rely on third-party suppliers for certain materials and components required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing, availability and quality of supplies and delivery schedules. There is substantial demand and limited supply for certain of the raw materials used to manufacture gene therapy products. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our larger competitors. We cannot be certain that our suppliers will continue to provide us with the quantities of raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any

performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Delays in developing our manufacturing capabilities or failure to achieve operating efficiencies from such capabilities may require us to devote additional resources and management time to manufacturing operations and may delay our product development timelines.

We have a GMP manufacturing facility located in Houston, Texas that includes process, analytical and bioanalytical development labs with experienced teams. NGN-401 was manufactured at our Houston facility and clinical-grade product is available for dosing in the Phase 1/2 clinical trial of NGN-401 that is currently enrolling patients. However, we will need to conduct additional NGN-401 manufacturing campaigns to generate additional clinical supply, as well as supply for our preclinical studies for our discovery programs, and we may not be able to satisfy such supply through production at our own facility.

Other risks relating to the manufacture of biologics and drug products include: production interruptions, delays in quality/release testing, equipment malfunctions, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities, war, cases of force majeure, acts of god (such as public health crises) or other events beyond our control and, in each case, could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Any contamination or interruption in our manufacturing process, shortages of raw materials or failure of our suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of gene therapy manufacturing, there is a risk of contamination. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

We may not be able to successfully manufacture our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing resulting approved products, if any.

To date, we have manufactured NGN-401 in quantities and quality adequate for preclinical, toxicology and clinical studies. In order to conduct clinical trials for a product candidate and for commercialization of the resulting product if that product candidate is approved for sale, we will need to manufacture product candidates in additional cGMP campaigns or in larger batch sizes. We may not be able to successfully repeat or increase the manufacturing capacity for any of our product candidates it in a timely or cost-effective manner or at all. Significant changes or scale-up of manufacturing may not lead to a faster development require additional validation studies, which are costly and which regulatory authorities must review and approve. In addition, quality issues may arise during those changes or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. scale-up activities. If we are unable to obtain successfully manufacture any of our product candidates in sufficient quality and quantity, the development of that product candidate and regulatory approval under or commercial launch for any resulting products may be delayed or there may be a shortage in supply, which could significantly harm our business.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an accelerated pathway, effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or approval from the FDA or foreign regulatory agencies. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. In addition, we may be required to conduct additional clinical trials beyond those that we

contemplate, make significant changes to our upstream and downstream processes across our pipeline, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approvals.

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

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

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

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

Risks Related to Our Reliance on Third Parties

We have a number of academic collaborations, and currently rely on our collaboration with the University of Edinburgh for certain aspects of our preclinical research and development programs, including working in collaboration to discover and preclinically develop our lead product candidate for Rett syndrome and our near-term future pipeline. Failure or delay of the University of Edinburgh or any other collaborator to fulfil all or part of its obligations under our agreement, a breakdown in collaboration between the parties or a complete or partial loss of the relationship would materially harm our business.

Our discovery engine is supplemented by academic collaborations to expand our platform, which we rely upon to advance discovery and development of product candidates. For example, our collaboration with the University of Edinburgh is critical to our business. In December 2020,

we entered into a Master Collaboration Agreement (the "MCA") with the University of Edinburgh, which we rely on to conduct certain aspects of the preclinical development of our pipeline candidates, including NGN-401 and all of our early-stage pipeline product candidates. Further, in March 2022, we entered into an exclusive license agreement with the University of Edinburgh for, with respect to certain University of Edinburgh-owned technology, a worldwide, exclusive, sublicensable license to develop, have developed, use, manufacture, have manufactured, supply, have supplied, sell, have sold, offer for sale, commercialize, import, export, register, reproduce, dispose of or otherwise exploit any products, processes, components, services and/or technologies incorporating the technology for the prevention or treatment of disease or medical or genetic conditions in humans. We also currently rely on the University of Edinburgh for portions of preclinical research capabilities under the direction of Dr. Stuart Cobb, Professor in Translational Neuroscience at the University of Edinburgh and our Chief Scientific Officer. Pursuant to the MCA, we and the University of Edinburgh agreed to collaborate on certain research and development projects (the "Projects"), and we agreed to provide funding for such Projects. In exchange for such funding, the University of Edinburgh grants us an option to exclusively license any intellectual property arising from such Projects. Either party has the right in certain circumstances to terminate the collaboration pursuant to the terms of the MCA. If the MCA is not renewed or is terminated, our pipeline of product candidates would be significantly adversely affected, and our business would be materially harmed.

Following an amendment to the MCA in November 2023, the term of the research funding portion of the MCA, under which we have the ability to acquire exclusive rights to additional technology and gene therapy products, now expires in December 2026. If we need to extend the term of this provision beyond that date, we will need to negotiate an additional extension with the University of Edinburgh, and we may not be able to agree on such an extension on terms that are acceptable to us, or at all. We may have disagreements with the University of Edinburgh with respect to the interpretation of the MCA, use of resources or otherwise that could cause our relationship to deteriorate. As a result, the University of Edinburgh may reduce focus on, and resources allocated to, our programs, potentially delaying or terminating our ability to advance product candidates through preclinical studies. Additionally, if Dr. Cobb were to leave the University of Edinburgh or to otherwise no longer be meaningfully involved with us, our preclinical research and development capabilities may be substantially reduced.

Further, under the MCA, the University of Edinburgh is primarily responsible for prosecuting and maintaining our licensed intellectual property, and it may fail to properly prosecute, maintain or defend such intellectual property. In such event, if we are unable to otherwise maintain or defend such intellectual property, we could face the potential invalidation of the intellectual property or be subjected to litigation or arbitration, any of which would be time-consuming and expensive. To enforce the licensed intellectual property rights under the MCA, we will need to coordinate with the University of Edinburgh, which could slow down or hamper our ability to enforce our licensed intellectual property rights. If this happens, we could face increased competition that could materially and adversely affect our business. For a further description of the MCA, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations—License and Collaboration Agreements*."

Additionally, in May 2019, we entered into an exclusive license agreement with the University of North Carolina ("UNC") for, with respect to the UNC invention known as "Optimized *CLN5* Genes and Expression Cassettes and Their Use," a worldwide, exclusive, sublicensable license to make, use, sell, have made, have sold, offer for sale and import any method or process, composition, product, or component part thereof for the prevention or treatment of disease or medical or genetic conditions, including CLN5 Batten disease or other diseases stemming from dysfunction of the *CLN5* gene.

We also currently have or may in the future engage in other academic collaborations to supplement our internal discovery and product development program. While these academic institutions have contractual obligations to us, they are independent entities and are not under our control or the control of our officers or directors. Our research and licensing agreements with academic collaborators generally provide academic collaborators with license maintenance fees, development and regulatory milestone payments, royalties on net sales of products and a portion of sublicense income that we receive. Upon the scheduled expiration of any academic collaboration, we may not be able to renew the related agreement, or any renewal could be on terms less favorable to us than those contained in the existing agreement. Furthermore, either we or the academic institution generally may terminate the sponsored research agreement for convenience following a specified notice period. If any of these academic institutions decides to not renew or to terminate the related agreement or decides to devote fewer resources to such activities, our discovery efforts would be diminished, while our royalty obligations, if any, would continue unmodified.

We currently rely, and intend in the future to rely, on third parties to conduct a significant portion of our preclinical studies and existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We have engaged CROs or other third parties to conduct preclinical and IND enabling studies and our clinical trials, including our Phase 1/2 clinical trial of NGN-401 and Phase 1/2 clinical trial of NGN-101.

We expect to continue to rely on third parties, including CROs, medical institutions and clinical investigators, to conduct certain those clinical trials. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our preclinical studies and clinical trials. If those relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with CROs, there can be no assurance that we will not perform as contractually required, fail to satisfy legal encounter challenges or regulatory requirements, miss expected deadlines delays in the future or terminate the relationship, our development program could be delayed with potentially that these delays or challenges will not have a material and adverse effects impact on our business and financial condition, results of operations, and prospects. condition.

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

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not successfully carry out their contractual duties satisfy applicable legal and regulatory requirements or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our development programs clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Further, while our reliance on these third parties for research and otherwise adversely affected. In all events, development activities will reduce our control over these activities, we will not be relieved of our responsibilities for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are is conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The trial. Moreover, the FDA generally requires preclinical studies us to be conducted in accordance comply with Good Laboratory Practices, or GLPs, and clinical trials to be conducted in accordance with Good Clinical Practices, or GCPs including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance We also are required to register ongoing clinical trials and post the results of completed clinical trials on third parties that we a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do not control will not relieve us of these responsibilities so can result in fines, adverse publicity and requirements. civil and criminal sanctions. If we or any of our third-party service providers CROs or other third parties, including trial sites, fail to comply with applicable GCPs, or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional studies. Any adverse development or delay in our preclinical studies or clinical trials as before approving our marketing applications. We cannot assure you that upon inspection by 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 given regulatory authority, such regulatory authority will determine that any of our relationships clinical trials complies 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. GCP

regulations. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

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

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

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in advance of when we need it, which may impact our ability to budget or forecast expenditures, and may also hamper our ability to complete our preclinical trials on time, or at all.

The manufacturing process for a product candidate is subject to review by the FDA, EMA, or other applicable regulatory authorities. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices, or cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or other applicable regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates and approval may be delayed. Moreover, although we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements, we are responsible for ensuring that our products comply with regulatory requirements. If any of our manufacturers fails to comply connection with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do in a timely manner or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and services. Under certain circumstances, we may be required to repeat report some of these relationships to the development program. FDA. The costs FDA may conclude that a financial relationship between us and delays associated with a principal investigator has created a conflict of interest or otherwise affected interpretation of the verification trial. The FDA may therefore question the integrity of a new manufacturer the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could negatively affect our ability to develop product candidates result in a timely manner delay in approval, 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 rejection, of our products will be subject to periodic review and inspection marketing applications 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 ultimately lead to the FDA, EMA, denial of marketing approval of NGN-401 and NGN-101 or any other applicable regulatory authorities could adversely affect our business in a number of ways, including: product candidates.

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

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. For example, the global outbreak of the COVID-19 pandemic resulted in extended shutdowns of businesses trial sites in the United States, Canada, and many other countries currently rely on and had ripple effects expect in the future to businesses around the world. Global health concerns, such as the COVID-19 pandemic, and the ensuing impacts rely on financial markets and supply chain logistics could also result in adverse effects third parties to our manufacturing operations, including our ability to source raw materials and reagents. If our contract manufacturers were to encounter any of these difficulties, our ability to provide our distribute product candidates to patients in preclinical and supplies for our clinical trials, or as well as 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 store and distribute supply of our product candidates for clinical trials, our ability to obtain marketing approval, trial sites outside of the United States. Any performance failure on the part of us 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 distributors 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 development or marketing approval of our application until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, and out- or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration.

In addition, a significant number of recent business combinations among large pharmaceutical companies has resulted in a reduced number of potential future strategic partners. Our collaborators may consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA, or other applicable regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing, and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

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

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

Risks Related to Our Business and Operations

We In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in preparing managing this growth.

Over time, we expect to experience significant growth in the number of our employees and the scope of our operations, for potential particularly in the areas of preclinical and clinical biological product development, technical operations, clinical operations, regulatory affairs, manufacturing and, potentially, sales, marketing and distribution. To manage our anticipated future growth, which could adversely affect our business.

As of September 30, 2023, we had seven full-time employees, after taking into account a further corporate restructuring that we announced in March 2023, that reduced our headcount by approximately 70% of the workforce in place at that time and which was completed prior to June 30, 2023. We have also announced a shift to focusing on strategic alternatives for the Company and a suspension of our research and development programs in connection with that restructuring. If we are successful in completing a strategic transaction in the future, we expect that we will need to invest in additional growth for the Company, which may include potentially expanding our development and regulatory capabilities, contracting

with other organizations to provide manufacturing and other capabilities for us, and managing additional relationships with collaborators or partners, suppliers, and other organizations. Our ability to prepare for future growth will require us to continue to improve our operational, financial, and management controls, reporting systems, and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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

- the federal Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), physician assistants, certain types of advance practice nurses, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members; and
- analogous local, state, and foreign laws and regulations, including: state anti-kickback and false claims laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state

laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; local, state, and foreign laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities and file reports relating to pricing and marketing information and/or register their pharmaceutical sales representatives; and local, state, and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

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

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

We may form strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future drug candidates and programs because our research and development pipeline may be insufficient, our drug candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, anticipated growth, we may not be able to realize effectively manage the benefit expansion of such transactions if our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are unable not successful in attracting and retaining highly qualified personnel, we may not be able to successfully integrate them implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our managerial, scientific and medical personnel, including our Founder and Chief Executive Officer, President and Chief Financial Officer, and Chief Scientific Officer, as well as other key

members of our leadership team. Our executive officers may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our existing operations and company culture. We cannot be certain that, following a strategic transaction executives or license, we will achieve other employees. The loss of the revenues services of our executive officers or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to other key employees could impede the achievement of our drug candidates could also delay the research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time. Failure to attracting and retaining qualified personnel could materially and adversely affect our drug business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources on our employee recruitment and retention efforts.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize NGN-401 or NGN-101 or other product candidates in foreign markets for which we may rely on collaborations with third parties. We are not permitted to market or promote any product candidates before we receive regulatory approval from the applicable foreign regulatory authority, and may never receive such regulatory approval for any product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of NGN-401 or NGN-101 or other product candidates, and reduce their competitiveness we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of NGN-401 or NGN-101 or other product candidates will be harmed and our business will be adversely affected. Moreover, even if they reach we obtain approval of NGN-401 or NGN-101 or other product candidates and ultimately commercialize such product candidates in foreign markets, we would be subject to the market. risks and uncertainties of operating in such foreign markets, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, consultants, CDMOs, suppliers and 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. requirements.

We are exposed to the risk of fraud or other misconduct by that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, consultants, CDMOs, suppliers and vendors and collaboration partners, including intentional failures to comply with FDA regulations acting for or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA on our behalf may engage in misconduct 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 activities. It is not always possible to identify and deter misconduct by employees and other third these 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 comply with such these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, results of operations, financial condition, and cash flows from future prospects, including the imposition of significant fines or other sanctions.

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

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

- decreased demand for any product candidates that we may develop;

- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

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

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

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

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

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

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

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

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

Our internal computer systems have suffered a security breach and in the future our systems, or those of any of our CROs, manufacturers, other contractors, third party service providers or consultants or potential future collaborators, may fail or suffer additional security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, given the size and complexity of such systems and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials), third-party service providers and supply chain companies, consultants and other partners, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. From time to time, we are subject to business email compromise attack attempts. In August 2023, we discovered a business email compromise attack that resulted in the misappropriation of approximately $0.9 million. While we have implemented remedial measures in response to this incident, we cannot guarantee that such measures will prevent additional related, as well as unrelated incidents, or that we will be able to defend against or successfully remediate any such attacks that may occur in the future. If a material system failure, accident or security breach were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm.

Further, since we sponsor clinical trials, any breach that compromises patient data and identities causing a breach of privacy could have significant adverse consequences on our business. For example, the loss of clinical trial data from completed or future clinical trials could affect trust in us, negatively impacting our ability to recruit for future clinical trials, 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 were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or inappropriate disclosure of confidential proprietary information, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of NGN-101 or NGN-401 or other product candidates could be delayed.

As our employees work remotely and use network connections, computers, and devices outside of our premises or network, including working at home, while in transit and in public locations, there are risks to our information technology systems and data. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders, patients or other individuals, regulators or, in certain circumstances, the media of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences, including damage to our reputation.

We rely on third-party service providers and technologies to operate critical business systems, including to process sensitive information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences as a result. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our monetary, reputational and other damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been and will not be compromised.

If we (or a third party upon whom we rely) experiences a security incident or is perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing personal information (including sensitive data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our

operations (including availability of data); increased investigation and compliance costs; financial loss; and other similar harms. Security incidents and attendant consequences may cause our stakeholders (including investors and potential customers) to stop supporting our business, deter new customers from our products, deter patients from participating in clinical trials and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices or from disruptions in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation, injunctive restrictions on data processing and/or adverse publicity and could negatively affect our operating results and business.

We, and third parties with whom we work, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which are changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. In addition, there is proposed legislation in the U.S. Congress that could restrict working with certain biotech providers who are deemed "companies of concern" which may impact the ability of certain third parties with whom we work to meet their performance obligations. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability,subject us to injunctive restrictions on data processing, adversely impact our ability to appropriately manage third parties with whom we work and otherwise cause a material adverse effect on our business, financial condition, and results of operations. See "*Business—Government Regulation—Data Privacy and Security" and "—Other Regulatory Matters*" in our Annual Report on Form 10-K for a more detailed description of the laws that may affect our ability to operate.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

As of December 31, 2023, we had net operating loss carryforwards for federal and state income tax purposes of $277.9 million and $35.1 million, respectively. The federal net operating losses will not be subject to expiration and can be carried forward indefinitely; however, they are limited to a deduction to 80% of annual taxable income. The state net operating losses begin to expire in 2038. To the extent that our taxable income exceeds any current year operating losses, we plan to use our U.S. carryforwards to offset income that would otherwise be taxable. Also, for state income tax purposes, the extent to which states will conform to the federal laws is uncertain and there may be periods during which the use of net operating losses loss carryforwards are suspended or otherwise limited, which could accelerate or permanently increase state taxes

owed. In addition, under Section 382 of the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset future taxable income will be subject to Section 382 limitations and may be limited by other factors.

As of December 31, 2022, we had U.S. net operating losses, or NOLs, of $124.9 million, for federal tax purposes, for which we have recorded a full valuation allowance, and R&D credit carryovers of $3.9 million, which may be offset by future taxable income. The R&D credit carryforwards and certain of our NOL carryforwards will expire in various years beginning in 2028 if not used. Unused losses incurred in taxable years beginning on or prior to December 31, 2017 will carry forward to offset future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of more than 50% (as measured by value) among a stockholder or one or more groups of stockholders who own at least 5% of our stock within a three-year period. We have not performed an analysis to determine whether there has been an ownership change pursuant to Section 382. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Any such limitation, whether as the result of a public offering, private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or our stockholders. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any until assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such unused losses expire. Under proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States recently enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act as modified by eliminates the CARES Act, unused currently available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years. The U.S. federal NOLs generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but Congress is considering legislation that would restore the current deductibility of such federal NOLs (particularly those generated in taxable years beginning after December 31, 2020) research and development expenditures, however, there is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to no assurance that the Tax Cuts and Jobs Act or the CARES Act. Furthermore, use of certain of our NOLs and R&D credit carryforwards provision will be subject to annual limitations on their use as a result repealed or otherwise modified. Such changes, among others, may adversely affect our effective tax rate, results of ownership changes under the rules of Sections 382 operation and 383 of the Internal Revenue Code, general business condition.

We may acquire businesses or the Code that have historically occurred. Based on our Section 382 analysis to date, we underwent ownership changes in August 2015 and August 2019. As a result of these ownership changes, we believe that certain of our NOLs will be likely to expire before they are able to be used under Section 382. In addition, we may experience ownership changes products, or form strategic alliances, in the future, as and may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new product candidates or products resulting from a result of future changes strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in our stock ownership, some of order to justify the transaction, which changes are outside of our control, and as a result, our ability to utilize NOL and R&D credit carryforwards could become further limited under Sections 382 and 383, and the tax benefits related to our NOLs and R&D credits may be diminished or lost. Any such disallowances may result in greater tax liabilities than we would incur a material adverse effect on our business and prospects.

We maintain our cash at financial institutions, at times in the absence balances that exceed federally-insured limits. The failure of such a limitation and any increased liabilities financial institutions could adversely affect our business, results ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts at financial institutions can at times exceed the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of operations, financial condition, cash flow and those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future prospects. As a result, bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we attain profitability, may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

At the end of August 2023, we identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results, prevent fraud or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our share price.

Our internal controls related to the cash disbursements process were not adequately designed to identify unauthorized payment requests, resulting in the identification of a material weakness. Specifically, at the end of August 2023, we discovered that we were subject to a business email compromise attack by a third party. This deficiency in our controls resulted in the diversion of payments to fraudulent bank accounts.

We determined that certain internal controls required for safeguarding our cash assets were not properly designed due to insufficient specificity regarding our policies and procedures surrounding supplier banking information changes, not identifying segregation of duties, and insufficient training on exercising professional skepticism. We therefore implemented steps to remediate this control deficiency, including increasing communication of and training around our controls relating to changes made to information, emphasizing security awareness and the importance of professional skepticism and designing a process to review supplier information changes prior to release of payments. While our management determined based on the assessment of internal control over financial reporting that as of December 31, 2023, this material weakness had been remediated, there can be no assurance that the remediation plans we implemented relating to this business email compromise attack will be successful in preventing a repeat of that attack or that we will be able to avoid potential future material weaknesses. If we are unable to successfully remediate existing or any future material weakness in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to use all maintain compliance with securities law and applicable stock exchange listing requirements regarding timely filing of periodic reports, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows. regulatory authorities.

Risks Related to Intellectual Property

If we are not able Our ability to obtain, maintain, protect our patents and enforce patent other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

We rely and expect to continue to rely upon a combination of patents, trademarks, trade secret protection and other confidentiality agreements to protect the intellectual property rights for related to our product candidates our Neoleukin design process technology, or other proprietary and technologies we may develop, the development and commercialization of our product candidates may be adversely affected.

to prevent third parties from unfairly competing with us. Our success depends in large part on our ability to obtain and maintain patents patent protection for platform technologies, including our EXACT gene regulation platform, product candidates and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, their uses, as well as our the ability to preserve our

trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon on or violating the proprietary rights of others. Under our License Agreement with the University As of Washington, dated July 8, 2019, as amended on October 29, 2020, effective July 24, 2020, and again on December 27, 2021, effective December 15, 2021 March 31, 2024, we have an exclusive license to develop and commercialize products covered by 17 patent applications, with claims covering including U.S. patent applications, international patent applications under the composition of matter of certain molecule families as well as methods of using Patent Cooperation Treaty or otherwise, and expect to continue to file patent applications in the computational algorithms United States and abroad related to discoveries and technologies that form the basis of the Neoleukin design process. are important to our business. However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on product candidates worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions may be less extensive than those in the United States. As such, we do not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Competitors may operate in countries where we do not have patent protection and could then freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where patent protection has not been requested.

Our intellectual property portfolio is at an early stage. As of March 31, 2024, we do not own or in-license any issued patents. Our pending and future patent applications may not result in patents on certain aspects being issued. Any issued patents may not afford sufficient protection of our product candidates or methods their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Even if these patents are granted, they may be difficult to enforce. Further, any issued patents that may be licensed or owned covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the United States Patent and Trademark Office ("USPTO"). Further, if we encounter delays in any clinical trials or delays in obtaining regulatory approval, the period of time during which we could market product candidates under patent protection would be reduced. Thus, the patents that we may own or license may not afford any meaningful competitive advantage.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share facilities or third-party consultants and vendors that we engage to perform researches, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a timely fashion cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in the market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at all. Further, heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to prosecute all assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary or desirable patent applications, to enforce and determine the scope of our proprietary rights and failure to obtain or maintain enforce, trade secret protection could adversely affect our competitive business position.

Lastly, if our trademarks and license any patents that trade names are not registered or adequately protected, then we may issue from such patent applications, at a reasonable cost or not be able to build name recognition in a timely manner. It is also possible that we will fail to identify patentable aspects markets of interest and our research and development output before it is too late to obtain patent protection. business may be adversely affected.

We may not be successful in obtaining or maintaining necessary rights to product candidates through acquisitions and in-licenses.

Because our development programs require and may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or

maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we will normally seek to obtain the right to control prosecution, maintenance and enforcement of the preparation, patents relating to a product candidate, there may be times when the filing and prosecution of all activities for patents and patent applications that relating to a product candidate are controlled by future licensors or collaboration partners. For example, we currently license several patent families from third parties, the University of Edinburgh covering the EXACT gene regulation platform, as well as the NGN-401 product candidate and its uses. We also license a patent family covering the NGN-101 product candidate and its uses from UNC. If any of such licensors or collaboration partners fail to prosecute, maintain the rights to patents licensed to third parties. Therefore, these and enforce such patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Patents business, including by payment of all applicable fees for patents covering a product candidate, we currently hold, could lose rights to the intellectual property or in the future exclusivity with respect to those rights, our ability to develop and commercialize such candidates may obtain, be adversely affected and we may not be sufficiently broad able to prevent others competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications which may be licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of licensees, future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to future in-licensed patents, they may be able to license such patents to our technology or from developing competitors, and the competitors could market competing products and technology. There This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is no guarantee possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing the same, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology or manufacturing methods, our product candidates, or future methods or product candidates, resulting in either an injunction prohibiting manufacture or future sales, or, with respect to future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation-related issues; whether and to what extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship and ownership of inventions and know-how resulting from the joint creations or use of intellectual property by future licensors and us and/or our partners; and the priority date of an invention of patented technology.

Certain of our current product candidates and research programs are licensed from or based upon licenses from a third party and are field limited to certain indications. If these license agreements are terminated or interpreted to narrow our rights, our ability to advance our current product candidates or develop new product candidates based on these technologies will be materially adversely affected.

We depend on, and will continue to depend on, our current licenses with UNC, the University of Edinburgh, Virovek, Inc. (“Virovek”) and Sigma-Aldrich Co. LLC (“Sigma”), and on licenses and sublicenses from other third parties, as well as potentially on other strategic relationships with third parties, for the research, development, manufacturing and commercialization of our current product candidates. If any of our pending licenses or relationships or any in-licenses on which our licenses are based are terminated or breached, we may:

- lose our rights to develop and market our current product candidates;
- lose patent applications will or trade secret protection for our current product candidates;

- experience significant delays in the development or commercialization of our current product candidates;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- incur liability for damages.

Additionally, even if not terminated or breached, our intellectual property licenses or sublicenses may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations.

If we experience any of the foregoing, it could have a materially adverse effect on our business and could force us to cease operations.

If we fail to comply with our obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are party to license agreements with UNC, the University of Edinburgh, Virovek and Sigma and may from time to time in the future be party to other license and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. Despite our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

If these licenses are terminated for any reason, or if the underlying patents fail to provide the intended exclusivity, we could lose significant rights and our ability to commercialize our current or future product candidates may be harmed, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to the development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and by us and our other partners.

In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize

the affected current or future product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in issued substantial costs, liability and diversion of resources, and prevent or granted patents, delay us from commercializing potential products.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate and guarantee that any we can operate without infringing on or violating third party rights. If certain of our future issued product candidates are ultimately granted regulatory approval, patent rights held by third parties, if found to be valid and enforceable, could be alleged to render one or granted more of such product candidates infringing. We cannot be certain that patents owned or licensed by us will not later be found challenged by others in the course of litigation. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon any affected product candidate and/or seek a license from the patent holder. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our business.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that our intellectual property, methods or products infringes their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a

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case, we could ultimately be forced to cease use of such marks. In any future issued intellectual property litigation, even if we are successful, any award of monetary damages or granted other remedy received may not be commercially valuable.

Further, we may be required to protect our patents will include claims that through procedures created to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

If we are sufficiently broad required to cover defend intellectual property actions brought by third parties, or if we sue to protect our product candidates own intellectual property rights 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 otherwise to protect our proprietary rights information and to prevent its disclosure, or if we are involved in other litigation, whether as a plaintiff or defendant, and whether or not successful, we may incur substantial legal expenses and the attention of our management and key personnel may be diverted from unauthorized use by third parties only business operations. Further, some of our competitors may be able to sustain the extent that costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources.

In addition, if our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If found to infringe the intellectual property rights of third parties, disclose these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or misappropriate defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use, and may not be able to obtain such licenses on terms acceptable to us, if at all.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the biotechnology industry, in addition to employees, we engage consultants to assist in the development of our product candidates. Many of these consultants, and many of our employees, were or may have been previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees or consultants working on our behalf have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary rights, it information, know-how or trade secrets of others in their work for us, we may materially become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

We may litigate to defend ourselves against these claims, and even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our position reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, operations and financial condition.

Changes to patent laws in the market. United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Our pending Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), could increase the uncertainties and costs surrounding the prosecution of our owned and any future in-licensed patent applications cannot be enforced against third parties practicing and the technology claimed in such maintenance, enforcement or defense of our owned and any future in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications unless are prosecuted, redefine prior art, provide more efficient and until cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution along with additional procedures to attack the validity of a patent issues from such applications. at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming the that 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 the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

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

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

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

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

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

The patent prosecution process is expensive and time-consuming, and we or our future potential licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future potential licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is

too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We may also elect not to continue pursuing prosecution of our patents in one or more countries if we determine that the value of the protection we are seeking is outweighed by the cost, or if we determine that our resources would be better allocated in a different way. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

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

The standards that the USPTO and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our product candidates. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the validation enforceability, or term of our patent. For example, the U.S. Supreme Court has recently modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U.S. patent system have come into force under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, which was signed into law in September 2011. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, After March 16, 2013, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent. Third parties are allowed patent on an invention regardless of whether a third party was the first to submit prior art before invent 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 claimed invention. As 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 its implementation 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, our operations and cash flows prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future prospects. actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. Accordingly, our competitive position may be impaired, and our business, financial condition, operations and prospects may be adversely affected.

In addition, a European Unified Patent Court ("UPC") came into force in June 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. We currently have three pending European applications, and if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents obtained. We may decide to opt out from the UPC for any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

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

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our pending applications or any future issued patents, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

We may become subject to claims by third parties claiming challenging the inventorship or ownership of what we regard as our own patents and other intellectual property, which may prevent, delay or otherwise interfere with our product discovery and development efforts. 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 We may be subject to claims that we, or these former employees, have used or disclosed confidential information or intellectual property, including trade secrets collaborators 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 have an interest in our intellectual property, patents or we may get into disputes with licensors or licensees of our intellectual property rights over the interpretation of the license terms. If a third party claims that we infringe, misappropriate or otherwise violate their intellectual property rights, we may face a number of issues, including, but not limited to:

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

- application can result in the requirement that we redesign patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or processes so they do not infringe, which as a result of questions regarding co-ownership of potential joint inventions. Litigation may not be possible necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may require substantial monetary expenditures and time; and
- there could be public announcements of enter into agreements to clarify the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price scope of our common stock.

Our licensors may have the right to terminate their license agreements with us or pursue damages or other legal remedies. rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or personnel or sustain damages. right to use, valuable intellectual property. Such intellectual property

rights an outcome could be awarded to have a third party, and we could be required to obtain a license from such third party to commercialize material adverse effect on our technology or products. Such a license may not be available on commercially reasonable terms or at all. business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, any uncertainties resulting management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the initiation U.S. government or academic institutions, such that our licensors are not the sole and continuation exclusive owners of any litigation the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our competitive position, business, financial condition, results of conditions, operations, and prospects.

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

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

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

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

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

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

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

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

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

Filing, prosecuting and defending patents competitive position on our product candidates throughout the world would be prohibitively expensive. for an adequate amount of time.

Patents have a limited lifespan. 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 if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from selling or importing products made using our inventions in and into its earliest U.S. non-provisional filing date. Various extensions may be available, but the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained life of a 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, protection it affords, is limited. Even if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents requiring

us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

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

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

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

The growth of our business may depend in part on our ability exclude others from commercializing products similar or identical to acquire, license or use third-party proprietary rights.

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

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

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

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

Inventions contained within some Certain of our in-licensed patents and patent applications may the intellectual property rights we have been made using licensed are generated through the use of U.S. government funding or other non-governmental funding. and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980 or Bayh-Dole Act, (the "Bayh-Dole Act") and implementing regulations. We rely on These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require our licensors or our licensors' to ensure compliance with applicable obligations arising from such funding, such as timely reporting, an obligation associated with in-licensed patents and patent applications. The failure grant exclusive, partially exclusive, or non-exclusive licenses to any of our licensors these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet their obligations may lead public health or safety needs; or (iii) government action is necessary to a loss of rights meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail, or the unenforceability of relevant patents. For example, applicable licensor, fails to disclose the invention to the government could and fails to file an application to register the intellectual property within specified time limits. These time limits

have certain rights recently been changed by regulation, and may change in such in-licensed patents, including the future. Intellectual property generated under a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non-commercial purposes. In addition, our rights in such in-licensed government-funded inventions may be funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to manufacture expend substantial resources. In addition, the U.S. government requires that any products embodying such inventions the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. Any The manufacturing preference requirement can be waived if the owner of the foregoing could harm intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our business, financial condition, results ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of operations and prospects significantly. our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

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. Government Regulation

The trading price regulatory approval processes of our common stock has been, the FDA and is likely other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to continue to be, volatile obtain, or if there are delays in obtaining, required regulatory approvals for the foreseeable future. The trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- results of clinical trials, including both safety and efficacy, of any of our current or future product candidates, we will not be able to commercialize, or those will be delayed in commercializing, such product candidates, and our ability to generate revenue will be materially impaired.

The process of our competitors;

- obtaining regulatory or legal developments approvals, both in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the recruitment or departure type, complexity and novelty 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 involved. We cannot commercialize 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 United States without first obtaining regulatory approval from the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions, such as market volatility and economic uncertainty due to rising interest rates, instability in the global banking system, inflation, and the ongoing conflicts in Ukraine and Israel.

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

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

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

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

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware

law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

Our certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or the DGCL, our certificate of incorporation, or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act of 1933, as amended, or the Securities Act, inasmuch as Section 22 of the Securities Act, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

In April 2020, we amended and restated our bylaws to provide that the federal district courts outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of America will, our product candidates, including our most advanced product candidates, NGN-401 and NGN-101, we must demonstrate through lengthy, complex and expensive preclinical and clinical trials that such product candidates are safe, pure and effective or potent for each targeted indication. Securing regulatory approval also requires the submission of information about the biological product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, a product candidate may not be effective or potent, may be only moderately effective or potent or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. A product candidate could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the fullest extent permitted by law, be satisfaction of the exclusive forum FDA or comparable foreign regulatory authorities that a product candidate is safe, pure, and effective or potent for resolving any complaint asserting a cause its proposed indication; the results of action arising under clinical trials may not meet the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision level of statistical significance required by the Supreme Court FDA or comparable foreign regulatory authorities for approval; serious and unexpected product-related side effects may be experienced by participants in our clinical trials or by individuals using drugs or biological products similar to a product candidate; we may be unable to demonstrate that a candidate’s clinical and other benefits outweigh its safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of a product candidate may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of a product candidate; the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal FDA or state courts will follow the

holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced comparable foreign regulatory authorities may significantly change in a particular case, application manner rendering our clinical data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the Federal Forum Provision means that suits brought by our stockholders FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to enforce any duty obtain regulatory approval to market NGN-401 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, NGN-101 or other employees, product candidates, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could would significantly harm our business, results of operations and financial condition. prospects.

If we were to obtain approval, regulatory authorities may approve any such product candidate for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for a product candidate, we will not be able to commercialize, or will be delayed in commercializing, such product candidate and our ability to generate revenue may be materially impaired.

Because gene therapy is novel and the regulatory landscape that governs any product candidates we may develop is rigorous, complex, uncertain and subject to change, we cannot predict the time and cost of obtaining regulatory approval, if received at all, for any product candidates we may develop.

The regulatory requirements that will govern any novel gene therapy product candidates we develop are not entirely clear and are subject to change. Within the broader genetic medicine field, very few therapeutic products have received marketing authorization from the FDA or the EMA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial overlap in those responsible for review and regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Therapeutic Products within its Center for Biologics Evaluation and Research (“CBER”), as part of its reorganization of the Office of Tissues and Advanced Therapies, to consolidate the review of gene therapy and related products. In addition, the Cellular, Tissue and Gene Therapies Advisory Committee advises CBER on its review.

Our product candidates will need to meet safety, purity and efficacy or potency standards applicable to any new biologic under the regulatory framework administered by the FDA. In addition to FDA oversight and oversight by IRBs under guidelines promulgated by the National Institutes of Health (“NIH”) gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee (“IBC”), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

The same applies in the European Union. The EMA’s Committee for Advanced Therapies (“CAT”) is responsible for assessing the quality, safety, and efficacy of advanced-therapy medicinal products. Advanced-therapy medicinal products include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a gene therapy product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the

development and marketing authorization for gene therapy products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any gene therapy product candidate we may develop, but that remains uncertain at this point.

Adverse developments in preclinical studies or clinical trials conducted by others in the field of gene therapy and gene regulation products may cause the FDA, the EMA, and other regulatory authorities to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing gene regulation technologies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety, purity and efficacy or potency of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as those being developed by us can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel potential treatments for diseases in which, in some cases, there is little clinical experience with potential new endpoints and methodologies, heightened risk that the FDA, the EMA or other regulatory authorities may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. In addition, we may not be able to identify or develop appropriate animal disease models to enable or support planned clinical development. Any natural history studies that we may conduct or rely upon in our clinical development may not be accepted by the FDA, EMA or other regulatory authorities. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene regulation technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Disruptions at the FDA and other regulatory authorities could negatively affect the review of our regulatory submissions, which could negatively impact our business.

The ability of the FDA and other regulatory authorities to review and approve regulatory submissions can be affected by a variety of factors, including understaffing, disruptions caused by government shutdowns and public health crises. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are no longer able to characterize, control and manufacture our biological products safely and in accordance with regulatory requirements. This includes manufacturing the drug substance, developing an “emerging growth company,” however, acceptable formulation, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, and demonstrating that ourbiological products meet stability requirements. Meeting these chemistry, manufacturing and control (“CMC”) requirements is a complex task that requires specialized expertise. If we are still not able to meet the CMC requirements, we may not be successful in getting our products approved.

We intend to deliver our product candidates via a "smaller reporting company," drug delivery device that will have its own regulatory, development, supply and other risks.

We intend to deliver our product candidates via a drug delivery device, such as a catheter or other delivery system. There may be unforeseen technical complications related to the development activities required to bring such a product to market, including primary container compatibility and/or dose volume requirements. Our product candidates may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, some drug delivery devices are provided by single-source unaffiliated third-party companies. We may be dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications.

We currently and may in the future conduct clinical trials for our product candidates at sites outside the United States, and the reduced disclosure requirements FDA may not accept data from trials conducted in such locations.

We plan to conduct clinical trials outside the United States, including in Australia, the UK, Europe or other foreign jurisdictions. For example, we currently intend to conduct our Phase 1/2 clinical trial for NGN-401 in the United States and outside the United States. Our Phase 1/2 clinical trial for NGN-101 is currently being conducted in the United States and in the UK. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to smaller reporting companies the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and (iii) the data may make our common stock less attractive to investors.

Although we ceased be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an "emerging growth company," as defined on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the Jumpstart need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction. Even if the FDA accepts such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated.

Other risks inherent in conducting international clinical trials include: foreign regulatory requirements, differences in healthcare services, and differences in cultural customs that could restrict or limit our ability to conduct our clinical trials; administrative burdens of conducting clinical trials under multiple sets of foreign regulations; foreign exchange fluctuations; diminished protection of intellectual property in some countries; and political and economic risks relevant to foreign countries.

Our Business Startups product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, includes a subtitle called the Biologics Price Competition and Innovation Act of 2012, 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or JOBS Act, interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on December 31, 2019, which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

Our investigational biological products, if approved, could be considered reference products entitled to 12-year exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider a product candidate to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the

BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any 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.

Even if we receive regulatory approval of NGN-401 or NGN-101 or other product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we may receive for NGN-401 or NGN-101 or other product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety, purity and efficacy or potency of such product candidates, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy in order to approve a product candidate, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve a product candidate, the products and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, purity, efficacy or potency, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

If we or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring the addition of labeling statements, such as a “black box” warning or a contraindication, requiring creation of a medication guide outlining the risk of such side effects for distribution to patients, withdrawal or suspension of existing approvals or licenses, refusal to approve pending applications or supplements, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize NGN-401 or NGN-101 or other product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

We may face difficulties from healthcare legislative reform measures.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of NGN-401 or NGN-101 or other product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are a “smaller reporting company,” meaning that slow or unable to adapt to changes in existing requirements or the market value adoption 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 new requirements or policies, or if we are not able 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, maintain regulatory compliance, we may continue to rely on exemptions from certain disclosure requirements lose any marketing approval that are available to smaller reporting companies. Specifically, we may choose to present only the two most recent fiscal years of audited financial statements have obtained and we may not achieve or sustain profitability. See “*Business—Government Regulation—Healthcare Reform*” in our Annual Report on Form 10-K for a more detailed description of healthcare reforms measures that may prevent us from being able to generate revenue, attain profitability, or commercialize product candidates.

Our business operations and similar current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject 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 applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers 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 expose us to broadly-applicable fraud and our stock price may be more volatile.

We may become a "large accelerated filer" abuse and have to comply with more rigorous disclosure and reporting requirements*other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. See "Business—Government Regulation—Other Healthcare Laws and Compliance Requirements" in our Annual Report on Form 10-K for a more detailed description of the laws that may affect our ability to operate.*

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If we cease our operations are found to be a "smaller reporting company" in violation of any of these laws or a "non-accelerated filer" in the future, any other governmental laws and regulations that may apply to us, we may be subject to certain disclosure requirements that are applicable significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to other public companies that had not been applicable to us previously. These requirements include:

- compliance with resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the auditor attestation requirements in the assessment curtailment or restructuring of our internal control over financial reporting once operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are an accelerated filer or large accelerated filer;
- compliance with successful in defending against any requirement such actions 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 brought against us, our business may be no assurance that we will be able to comply with the applicable regulations in a timely manner, if at all. Inability to comply with these regulations could impact our ability to raise additional capital. impaired.

Even if we are able to commercialize NGN-401 or NGN-101 or other product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such products at competitive prices which would seriously harm our business.

We intend to seek approval to market NGN-401 and NGN-101 and other product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for such product candidates, we will be subject to rules and regulations in those jurisdictions. Our ability to successfully commercialize any product candidates that we may develop will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. These entities may create preferential access policies for a competitor's product, including a branded or generic/biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. Additionally, if any of our product candidates are approved and

we are found to have improperly promoted off-label uses of those programs, we may become subject to significant liability, which would materially adversely affect our business and financial condition. See "*Business—Government Regulation—Coverage and Reimbursement" and "—Regulation in the European Union*" in our Annual Report on Form 10-K for a more detailed description of the government regulations and third-party payor practices that may affect our ability to commercialize product candidates.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. In addition, the U.S. Congress is currently contemplating legislation that could have the impact of limiting the ability of us and certain of our vendors to work with certain designated biotech companies from China and other nations.

Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Governments outside the United States may impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a therapeutic. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators of ours may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of a product to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the UK determines which EU laws to replicate or replace. If the UK were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs.

While we have received Fast Track designation for NGN-401 for the treatment of Rett syndrome and for NGN-101 for the treatment of CLN5 Batten disease and we may seek certain designations for our other product candidates, including Breakthrough Therapy and Priority Review designations in the United States, we may not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

The FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such

a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. We have received Fast Track designation in the United States for NGN-401 for the treatment of Rett syndrome and for NGN-101 for the treatment of CLN5 Batten disease, and we may seek additional designations for one or more of our other product candidates that could expedite review and approval by the FDA.

We may seek to have one or more of our products designated as a Breakthrough Therapy, which is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life threatening disease or condition where preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers a treatment for a serious condition, and if approved, would provide a significant improvement in safety or effectiveness where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA, including the Fast Track designation we received for NGN-401 and NGN-101. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek Regenerative Medicine Advanced Therapy ("RMAT") designation by the FDA for any of our product candidates, however, such designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek an RMAT designation for our product candidates if the clinical data support such a designation for one or more product candidates. The RMAT designation program is intended to fulfill the requirement of the 21st Century Cures Act that the FDA facilitate an efficient development program for, and expedite review of, any product that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or may be able to rely upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT designation does not change the standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

We have received orphan drug designation for NGN-401 for the treatment of Rett syndrome and for NGN-101 for the treatment of CLN5 Batten disease, and we may seek orphan drug designation for certain future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

We have received orphan drug designation from the FDA for NGN-401 for the treatment of Rett syndrome and have also received orphan drug designation from the FDA and European Medicines Agency for NGN-101 for the treatment of CLN5 Batten disease. Although we may seek orphan product designation for some or all of our other product candidates, we may never receive such designations. Under the Orphan Drug Act, the FDA may designate a drug or biological product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even with an orphan drug designation for our current and potential future product candidates, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for an existing or future product candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties still can be approved for the same condition even with an orphan drug designation. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

We have received Rare Pediatric Disease designation by the FDA for NGN-401 for the treatment of Rett syndrome and for NGN-101 for the treatment of CLN5 Batten disease. However, Rare Pediatric Disease designation for any of our product candidates does not guarantee that the BLA for the product will qualify for a priority review voucher upon approval, and it does not lead to a faster development or regulatory review process, or increase the likelihood that our product candidates will receive marketing approval.

Under the Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying BLA for the treatment of a rare pediatric disease, the sponsor of such an application would be eligible for a rare pediatric disease priority review voucher that can be used to obtain priority review for a subsequent BLA or NDA. If a product candidate is designated before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026. While we have obtained Rare Pediatric Disease designations for NGN-401 for the treatment of Rett syndrome and for NGN-101 for the treatment of CLN5 Batten disease, it is unlikely that these product candidates will be approved by September 30, 2026. If approval is not obtained by then, we would not be in a position to obtain a priority review voucher, unless Congress further reauthorizes the program beyond the current sunset date in September 2024. Additionally, designation of a biological product for a rare pediatric disease does not guarantee that a BLA will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a Rare Pediatric Disease designation does not lead to faster development or regulatory review of the product or increase the likelihood that it will receive marketing approval.

General Risk Factors

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

We may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinical or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of a product candidate in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be subject made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to securities litigation, which is expensive defend and could divert management attention.

The trading price materially and adversely affect the market for our products or any prospects for commercialization of our common stock has been products. Although we believe we currently maintain adequate product liability insurance for NGN-401 and will continue to be volatile. In the past, companies NGN-101 and other product candidates, it is possible 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 our liabilities could result in substantial costs and divert exceed 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% insurance coverage or more of our capital stock and their respective affiliates together beneficially own a majority of our outstanding voting stock. These stockholders are able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders are able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

If we fail to maintain an effective system of internal control over financial reporting in the future we may not be able to accurately report maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, employment matters, security of patient and employee personal information, contractual relations with collaborators and intellectual property rights. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, may continue

to be necessary, which could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as the COVID-19 pandemic, political crises, geopolitical events, such as conflicts between Russia and Ukraine and between Israel and the surrounding regions, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition condition.

The global economy, including credit and cash flows financial markets, has experienced extreme volatility and future prospects, which disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may not reduce interest rates in the near term or may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine, as well as the conflict between Israel and the surrounding regions, and rising tensions with China have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect investor confidence in us our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of economic or political uncertainty, political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Risks Related to Owning Our Stock

The market price of our common stock may continue to be volatile.

The market price of our common stock following the merger has been and may continue to be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- timing and results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections that we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- failure to achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;

- changes in the market valuations of similar companies;
- general market, macroeconomic or geopolitical conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our products; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results, financial condition and cash flows.

If our legacy lease obligations are not subleased, assigned, terminated or otherwise addressed or the legacy assets subject to the CVR Agreement are not sold, respectively, in a timely manner, we may have to incur time and resources to take such actions.

On December 18, 2023, we completed our business combination with our wholly owned subsidiary incorporated in the state of Nevada and also named Neurogene Inc. ("Neurogene OpCo") in accordance with the terms of the Agreement and Plan of Merger, dated as of July 17, 2023 (the "Merger Agreement"), by and among the Company, Project North Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Merger Sub"), and Neurogene OpCo, pursuant to which, among other matters, Merger Sub merged with and into Neurogene OpCo, with Neurogene OpCo surviving as a wholly owned subsidiary of the Company (the "Reverse Merger").

In connection with the Reverse Merger, we declared a dividend, to each person who, as of immediately prior to the effective time of the Reverse Merger, was a stockholder of the Company or had the right to receive our common stock pursuant to an existing pre-funded warrant, of the right to receive one non-transferable contingent value right (each, a "CVR") for each then outstanding share of our common stock (before giving effect to a 1-for-4 reverse stock split (the "Reverse Stock Split") that was implemented immediately prior to the effective time), each representing the non-transferable contractual right to receive certain contingent payments from the Company upon the occurrence of certain events within agreed time periods. Holders of options to purchase our common stock outstanding immediately prior to the effective time of the merger will also receive four CVRs for each share of our common stock that may be issued upon exercise of such option, such that they will receive the same number of CVRs as they would have received if the option had been exercised before the Reverse Stock Split, subject to certain conditions set forth in the CVR Agreement. Further, pursuant to the terms of the CVR Agreement, the holders of our common stock prior to the effective time of the Reverse Merger, including holders of existing pre-funded warrants and holders of options to purchase our common stock outstanding immediately prior to the effective time of the merger and exercised after the effective time of the merger, rather than all of our current holders of our common stock, are the primary recipients of any net proceeds of the disposition of the legacy assets related the business of Neoleukin Therapeutics, Inc. as it existed prior to the effective time of the Reverse Merger, the mitigation of legacy lease obligations related the business of Neoleukin Therapeutics, Inc. as it existed prior to the effective time of the Reverse Merger or receipt of any sales tax refund from the State of Washington based on tax returns filed by the Company prior to the effective time of the Reverse Merger. Accordingly, we may be required to allocate a portion of our funds, time and resources to such activities and not our core programs and the foregoing could be a distraction to our management and employees. As a result, our operations and financial condition may be adversely affected.

We have incurred, and will continue to incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company that may not be reflected in our historical financial statements, which reflect our operation as a private company. Some of these additional expenses include costs associated with public company reporting obligations under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our management team consists of our executive officers prior to the merger. These executive officers and other personnel will need to devote substantial time to complying with public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. We expect to still qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, which allows us to take advantage of many exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Once we are no longer a smaller reporting company or otherwise no longer qualify for this exemption, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant additional legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, any of which would require additional financial and management resources.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. 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 internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting. This assessment needs reporting to include disclosure of any material weaknesses identified by our allow 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 to report on the effectiveness of our internal control over financial reporting. However, for reporting in each Annual Report on Form 10-K, as long as we are not an accelerated filer or large accelerated filer, we intend to take advantage required by Section 404 of the exemption permitting us Sarbanes-Oxley Act. Prior to the merger in December 2023, our operating and finance teams were part of a private company, and therefore were not previously required to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that test internal controls within a specified period. As a result, we have incurred and may continue to incur substantial professional fees and internal costs to expand our accounting expense and finance functions as well as to expend significant management efforts. We currently do not have an may discover weaknesses in our system of internal audit group, financial and we will need to

hire additional accounting controls 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 procedures that could result 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 misstatement of our financial statements. Our internal control over financial reporting we will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be unable met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to assert error or fraud will not occur or that all control issues and instances of fraud will be detected.

For example, our internal controls related to the cash disbursements process were not adequately designed to identify unauthorized payment requests, resulting in the identification of a material weakness. Specifically, at the end of August 2023, we discovered that we were subject to a business email compromise attack by a third party. This deficiency in our controls resulted in the diversion of payments to a fraudulent bank account. While management has determined in its assessment of our internal control over financial reporting is effective. We cannot assure you as of December 31, 2023, that we have remediated this material weakness, there can be no assurance that the remediation will prevent similar attacks in the future or that we will not be identify other material weaknesses or significant deficiencies in the future. If we are unable to successfully remediate a material weakness in our internal control over financial reporting, in or if we identify any other material weaknesses, the future. Any failure accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain internal control over compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could severely inhibit our ability become subject to accurately report our financial condition, results investigations by Nasdaq, the SEC or other regulatory authorities.

If we are not able to comply with the requirements of operations Section 404 of the Sarbanes-Oxley Act, or cash flows. If if we are unable to conclude maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If 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, were to happen, 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

Our certificate of incorporation and bylaws, as well as provisions under Delaware law, could make an acquisition of the company more difficult and may prevent attempts by our stockholders to remedy any material weakness replace or remove management.

Provisions in our internal certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control over financial reporting, or to implement or maintain other effective control systems required of public companies, the company that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price for their shares. These provisions could also restrict limit the price that investors might be willing to pay in the future for shares of our future access common stock, thereby depressing the market price of our common stock. In addition, because our board of directors will be responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the capital markets. board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

Our disclosure controls governing documents provide that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the sole and procedures may not prevent exclusive forum for certain legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or detect all errors our directors, officers, employees or acts agents.

Our governing documents provide that, unless we consent in writing to an alternative forum, the Court of fraud.

We are Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on the company's behalf, (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to the company or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, the certificate of incorporation or the bylaws, (iv) any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or bylaws, or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the periodic reporting requirements Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, which for purposes of this risk factor refers to herein as the "Delaware Forum Provision." Our governing documents further provide that, unless we consent in writing to an alternative forum, the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which for purposes of this risk factor refers to herein as the "Federal Forum Provision." Neither the Delaware Forum Provision nor the Federal Forum Provision will apply to any causes of action arising under the Exchange Act. Our disclosure controls In addition, any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and procedures are designed consented to reasonably assure the foregoing Delaware Forum Provision and Federal Forum Provision; *provided*, however, that information required stockholders cannot and will not be deemed to be disclosed by us in reports we file or submit under have waived our compliance with the Exchange Act is accumulated U.S. federal securities laws and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on our stockholders in pursuing any such claims, particularly if such stockholders do not reside in or near the State 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. Delaware. 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 these forum selection clauses may limit our control system, misstatements or insufficient disclosures due stockholders' ability to error or fraud may occur and not be detected.

Our internal computer and information systems, or those used by our CROs, or other contractors or consultants, may fail or suffer security incidents (e.g., cyber-attacks) or other technical failures, which could result bring a claim in a material disruption of judicial forum that they find favorable for disputes with us or our development programs and directors, officers or employees, which may result in extensive and costly legal compliance requirements.

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

While we have not experienced any discourage such material system failure or security breach to date,if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs lawsuits against us and our business operations. For example, the loss directors, officers and employees even though an action, if successful, might benefit our stockholders.

Future sales of data from completed or future preclinical studies and clinical trials shares by existing stockholders could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be significantly delayed.

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

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

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

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, global health crises such as the COVID-19 pandemic and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We do not carry insurance for all categories of risk that our business may encounter.

The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters. Further, any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, results of operations, financial condition and cash flows from future prospects.

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

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

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

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

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

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

Sales decline. Based on shares outstanding as of a substantial number ofMarch 31, 2024, there are approximately 16,924,356 shares of our common stock outstanding or issuable on exercise of prefunded warrants to purchase common stock. Of these shares, approximately 3,637,374 shares outstanding or issuable upon exercise of prefunded warrants or vested options to purchase common stock will be available for sale in the public market could occur at beginning June 15, 2024, which is 180 days after the closing of the mergeron December 18, 2023 (the "Closing"), as a result of the expiration of lock-up agreements between us and certain of our securityholders. All other outstanding shares of common stock and any time. These sales, shares issuable on exercise of prefunded warrants or the perception vested options to purchase our common stock, other than shares held by our affiliates or otherwise subject to restrictions on vesting and exercise, are freely tradable, without restriction, in the market that public market. If these shares are sold, the holders of a large number of shares intend to sell shares, could reduce the market trading price of our common stock. stock could decline.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers, directors and principal stockholders beneficially own a significant percentage of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent our acquisition on terms that other stockholders may desire.

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 2,107,218 shares of our common stock (after giving effect to the one-for-five reverse stock split effected on September 25, 2023) 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. On July 17, 2023, we entered into a Letter Agreement with Baker Bros Advisory, L.P. pursuant to which we have agreed to enter into a new registration rights agreement if requested by any Baker Entities in the future, which agreement would replace the existing registration rights agreement.

We have registered all currently reserved shares of common stock that we may issue under our equity compensation plans and intend to register in the future any additional reserved or issued shares of common stock. These registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We have also filed a shelf registration statement covering the sale of up to $400.0 million of any combination of our common stock, preferred stock, debt securities, or warrants and may conduct one or more sales of securities pursuant to such registration statement, from time to time. In November 2021, we entered into an ATM "at-the-market" Equity Offering Sales Agreement, or Sales Agreement, with BofA Securities, Inc., or BofA, pursuant to which, from time to time, we may offer and sell through BofA up

to $40.0 million of the common stock registered under the shelf registration statement pursuant to one or more “at the market” offerings. Sales of our common stock under the Sales Agreement with BofA could be subject to business, economic or competitive uncertainties and contingencies, many of which may be beyond our control, and exposed to increased litigation, including stockholder litigation, which could cause actual results from the sale of our common stock to differ materially from expectations.

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

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

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

We may be exposed to increased litigation from stockholders, suppliers and other third parties, which may have an adverse impact on our business and results of operations or may cause disruptions to our operations. In the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market price prices of these companies’ stock, and we may also be subject to threats of litigation based on our common stock. recent merger activity. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management’s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

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

The trading market for our common stock depends in part on will be influenced by the research and reports that securities or industry equity research analysts publish about us or and our business. Equity research analysts may elect to not provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. If we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more of the securities or industry equity research 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 ceases coverage of our company us or fail fails to publish reports on us regularly, demand for our common stock could decrease, which might in turn could cause our stock price and or trading volume to decline.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or our stockholders. We continue to assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations or employees to determine the potential effect on our business and any assumptions we make about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States recently enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years. The U.S. Congress is considering legislation that would restore the current deductibility of research and

development expenditures; however, there is no assurance that the current provision will be repealed or otherwise modified. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

(c) Trading Plans

During the quarter ended March 31, 2024, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement.

Item 6. Exhibits

Exhibit Number		Description
10.1	Executive Employment Agreement with Rachel McMinn dated April 1, 2024	
	Description	
Number 10.2	Executive Employment Agreement with Christine Mikail Cvijic dated April 1, 2024	
10.3	Amended and Restated Consulting Agreement with Stuart Cobb Consulting Ltd. dated April 19, 2024	
31.1	Certification of Interim the Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a).	
31.2	Certification of Interim the Chief Financial Officer (Principal Financial Officer) pursuant to Rule 13a-14(a). 13a-14(a)	
32.1# 32.1*	Certification of Interim Chief Executive Officer (Principal Executive Officer) and Interim Chief Financial Officer (Principal Financial Officer) pursuant to 18 U.S.C. Section 1350. 1350	
101.INS	Inline XBRL Instance Document	
101.SCH	Inline XBRL Taxonomy Extension Schema Document. Document	
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document. Document	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document. Document	
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document. Document	
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document. Document	
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	

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* 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 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.

Date: May 10, 2024 **Neurogene Inc.**
(Registrant)

By: /s/ Rachel McMinn
Name: Rachel McMinn, Ph.D.
Title: Chief Executive Officer (Principal Executive Officer)

Date: May 10, 2024 **Neurogene Inc.**
(Registrant)

By: /s/ Christine Mikail
Name: Christine Mikail, J.D.
Title: President and Chief Financial Officer (Principal Financial Officer)

Exhibit 10.1

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "**Agreement**") is entered into as of April 1, 2024 (the "**Effective Date**"), by and between Rachel McMinn, PhD ("**Executive**") and Neurogene Inc. (the "**Company**"). This Agreement supersedes in its entirety the employment letter dated as of January 7, 2019.

WHEREAS, Executive is currently employed by the Company as its Chief Executive Officer, and Company desires to have Executive's employment continue in such capacity, and Executive desires to continue to serve in such capacity, pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, it is hereby agreed by and between the parties hereto as follows:

ARTICLE I

I.1. For purposes of the Agreement, the following terms are defined as follows:

I.2. "**Board**" means the Board of Directors of the Company.

I.3. "**Cause**" means a good faith determination by the Board that Executive's employment be terminated, other than due to illness, injury, incapacity or Disability, for any one of the following: (i) Executive's indictment or conviction, or Executive's entry of a pleading of guilty or no contest, with respect to a felony or another crime involving fraud, dishonesty or moral turpitude, (ii) Executive's material misconduct or gross negligence in the performance of Executive's

duties to the Company (or any of its affiliates), (iii) Executive's material failure or refusal to (A) follow policies or the lawful directives established by the Board or (B) perform Executive's duties or obligations hereunder (iv) any act of fraud, embezzlement, theft or dishonesty by Executive in the course of Executive's employment with the Company (or any of its affiliates), (v) Executive's material breach of this Agreement, the Company's policies or any other agreement with the Company (or any of its affiliates), including, without limitation, the Employee Proprietary Information and Inventions Assignment Agreement (the "**PIIAA**"), or (vi) Executive's failure to comply in any material respect with applicable laws with respect to the operation of the business of the Company (or any of its affiliates). Notwithstanding the foregoing, in the case of any conduct described in clauses (iii), (v) or (vi) of the immediately preceding sentence, if such conduct is reasonably susceptible of being cured, then Executive's termination shall be for "Cause" only if Executive fails to cure such conduct to the Company's reasonable satisfaction within thirty (30) days after receiving written notice from the Company describing such conduct in reasonable detail.

I.4. "**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

I.5. "**Code**" means the Internal Revenue Code of 1986, as amended.

I.6. "**Covered Termination**" means (i) an Involuntary Termination Without Cause or (ii) a voluntary termination for Good Reason. For the avoidance of doubt, the termination of Executive's employment as a result of Executive's death or Disability will not be deemed to be a Covered Termination.

I.7. "**Disability**" means a termination of Executive's employment due to Executive's absence from Executive's duties with the Company on a full-time basis for at least 180 consecutive days as a result of Executive's incapacity due to physical or mental illness which is determined to be total and permanent by a physician selected by the Company or its insurers.

I.8. "**Good Reason**" means any one of the following taken without Executive's prior written consent: (i) failure or refusal by the Company to comply in any material respect with the material terms of this Agreement; (ii) a material diminution in Executive's duties, title, authority, status or responsibilities reduction, including a change in Executive's reporting responsibilities so that Executive no longer reports directly to the Board; (iii) a material reduction in Executive's Base Salary as in effect immediately prior to such reduction (unless such reduction is part of a reduction that applies to and affects all similarly situated executive officers of the Company substantially the same and proportionately); (iv) a material diminution in Executive's annual cash bonus opportunity, unless such reduction is part of a reduction that applies to and affects all similarly situated executive officers of the Company substantially the same and proportionately; or (v) the Company requiring Executive to be located at any office or location more than 50 miles from the Company's current headquarters, provided that any request or directive from the Company to not work in such office pursuant to any stay-at-home or work from home or similar law, order, directive, request or recommendation from a governmental entity shall not give rise to Good Reason under this Agreement. Notwithstanding the foregoing, Executive's resignation shall

not constitute a resignation for "Good Reason" as a result of any event described in the preceding sentence unless (x) Executive provides written notice thereof to the Company within thirty (30) days after Executive's knowledge of such event, (y) to the extent correctable, the Company fails to remedy such circumstance or event within thirty (30) days following the Company's receipt of such written notice and (z) the effective date of Executive's resignation for "Good Reason" is not later than ninety (90) days after the initial existence of the circumstances constituting Good Reason.

I.9. "**Involuntary Termination Without Cause**" means Executive's dismissal or discharge by the Company other than for Cause or by reason of Executive's death or Disability.

I.10. "**Section 409A**" means Section 409A of the Code and the Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Effective Date.

I.11. "**Separation from Service**" means Executive's termination of employment constitutes a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h).

ARTICLE II
EMPLOYMENT BY THE COMPANY

II.1. **Position and Duties.** Subject to terms set forth herein, Executive shall continue to serve in an executive capacity and shall continue to perform such duties as are customarily associated with the position of Chief Executive Officer and such other duties as are reasonably assigned to Executive consistent with Executive's position by the Board. During the term of Executive's employment with the Company, except as otherwise permitted under Section 5.1 below, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention (except for vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies or as otherwise set forth in this Agreement) to the business of the Company.

II.2. **Term.** The term of this Agreement shall commence on the Effective Date and shall terminate on the termination of Executive's employment under this Agreement. The period from the Effective Date until the termination of Executive's employment under this Agreement is referred to as the "**Term**."

II.3. **Employment at Will.** Both the Company and Executive shall have the right to terminate Executive's employment with the Company at any time, with or without Cause or Good Reason, and with or without prior notice. Upon certain terminations of Executive's employment with the Company, Executive may become eligible to receive the severance benefits provided in Article IV of this Agreement.

II.4. **Employment Policies.** The employment relationship between the parties shall also be subject to the general employment policies and practices of the Company, including those relating to protection of confidential information and

assignment of inventions, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control. In addition, the PIIAA entered into in connection with Executive's initial engagement by the Company, as attached hereto as Exhibit A, shall remain in full force and effect in accordance with its terms.

II.5. Place of Performance. During the employment period, Executive's principal place of employment shall be the Company's corporate offices in New York, NY, unless Executive has been permitted to work remotely so long as such remote work does not materially impair Executive's ability to perform Executive's duties as provided for in Section 2.1. It is understood that reasonable travel may be required as may be necessary to fulfill Executive's responsibilities.

II.6. Expenses; Indemnification. The Company will reimburse Executive promptly for reasonable travel expenses in connection with all authorized work travel under the policies and procedures then in effect and established by the Company for its executives. The Company will indemnify Executive for Executive's service as an officer of the Company in accordance with the Company's governing documents and as provided by the Board. In the event of a lawsuit in connection with Executive's service as an officer of the Company, the Company will advance Executive's reasonable costs and attorney fees incurred during the course of such lawsuit. The

/s/ Donna M. Cochener

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

obligations under this Section 2.6 shall be in addition to any indemnification rights Executive may have under the Company's bylaws or any other agreement or policy.

ARTICLE III
COMPENSATION

III.1. Base Salary. As of the Effective Date,Executive shall receive for services to be rendered hereunder an annual base salary of $595,000 ("**Base Salary**"), payable on the regular payroll dates of the Company (but no less often than monthly), subject to annual review for increase in the sole discretion of the Board or a committee of the Board, taking into account all of Executive's duties as may be assigned from time to time.

III.2. Annual Bonus. For each calendar year ending during the Term and beginning with the calendar year ending December 31, 2024,Executive shall be eligible to receive an annual performance bonus (the "**Annual Bonus**") targeted at fifty-five percent (55%) of Base Salary or such other higher amount as determined in the sole discretion of the Board or a committee of the Board (the "**Target Bonus**"), on such terms and conditions determined by the Board or a committee of the Board. The actual amount of the Annual Bonus (if any) will be determined in the discretion of the Board or a committee of the Board and will be (i) subject to achievement of any applicable bonus objectives and/or conditions determined by the Board or a committee of the Board and (ii) subject to Executive's continued employment with the Company through the date the Annual Bonus is paid. The Annual Bonus for any calendar year will be paid at the same time as bonuses to other Company executives related to annual bonuses generally are paid.

III.3. Standard Company Benefits. During the Term,Executive shall be entitled to all rights and benefits for which Executive is eligible under the terms and conditions of the standard Company benefits and compensation practices that may be in effect from time to time and are provided by the Company to its executive employees generally, as well as any additional benefits provided to Executive consistent with past practice. Notwithstanding the foregoing, this Section 3.3 shall not create or be deemed to create any obligation on the part of the Company to adopt or maintain any benefits or compensation practices at any time.

III.4. Paid Time Off. During the Term, Executive shall be entitled to such periods of paid time off ("**PTO**") each year as provided from time to time under the Company's PTO policies and as otherwise provided for executive officers, as it may be amended from time to time.

III.5. Equity Awards. Executive will be eligible annually to receive stock options and other equity incentive grants as determined by the Board or a committee of the Board in its sole discretion, in each case subject to the terms and conditions of the Company's 2023 Equity Incentive Plan (or any successor equity incentive plan, the "**Plan**") and the applicable award agreement approved by the Board or a committee thereof.

ARTICLE IV
SEVERANCE BENEFITS

IV.1. Severance Benefits. Upon Executive's termination of employment, Executive shall receive any accrued but unpaid Base Salary and other accrued and unpaid compensation. If the termination is due to a Covered Termination, provided that Executive (A) delivers an effective general release of all claims against the Company and its affiliates in a form attached hereto as Exhibit C (with such modifications as determined by the Company due to changes in law or market practice after the date of this Agreement, a "**Release of Claims**") that becomes effective and irrevocable within sixty (60) days following the Covered Termination and (B) continues to comply with the PIIAA and Articles V through VI of this Agreement, Executive shall be entitled to receive the following severance benefits:

(a) An amount equal to twelve (12) months of Executive's Base Salary at the rate in effect (or required to be in effect before any diminution that is the basis of Executive's termination for Good Reason) at the time of Executive's termination of employment, payable in a lump sum payment, less applicable withholdings, as soon as administratively practicable following the date on which the Release of Claims becomes effective and, in any event, no later than the sixtieth (60th) day following the date of the Covered Termination; provided, however, if such sixty (60) day period falls in two different calendar years, payment will be made in the later calendar year.

(b) Any unpaid annual bonus amount that was earned by Executive with respect to the calendar year ended prior to the termination of Executive's employment, as determined by the Board, subject to applicable tax withholding and payable substantially at the same time as other annual bonuses are paid to then-current members of the Company's leadership team (but in any event no later than June 30 of the applicable year).

(c) Payment of a pro-rata portion of the annual cash bonus (the "**Pro-Rata Annual Bonus**") that would have been earned by Executive for the year in which the Covered Termination occurs based on the number of days between and including the first day of the fiscal year of the Company in which the Covered Termination occurs and the date of the Covered Termination, payable on the date when such bonuses are otherwise paid to Company executives generally and in all events by no later than June 30 of the calendar year following the year in which such termination occurs.

(d) Subject to Executive's timely election of continuation coverage under COBRA, the Company shall directly pay, or reimburse Executive, for the premium for Executive and Executive's covered dependents to maintain continued health coverage pursuant to the provisions of COBRA through the earlier of (i) the 12-month anniversary of the date of Executive's termination of employment and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Notwithstanding the foregoing, if the Company provided, however, that if the Company determines that it cannot provide the foregoing COBRA benefit without potentially violating applicable law or incurring an excise tax, the Company shall in lieu thereof pay Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and Executive's covered dependents' group health coverage in effect on Executive's termination date (which amount shall be based on the premium for the first month of

COBRA coverage), which payments shall commence in the month following the month in which the Company makes such determination and shall end on the earliest of (x) the date that is twelve (12) months after Executive's termination date and (y) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s).

(e) Notwithstanding anything to the contrary herein or in any applicable or award agreement or the Plan, if the Covered Termination occurs during the period commencing 3 months prior and ending 12 months following the date of a Change in Control (as defined in the Plan): (i) the lump sum payment described in Section 4.1(a) shall be increased to 1.5 times the sum of Executive's Base Salary and Target Bonus, (ii) the Pro-Rata Annual Bonus described in Section 4.1(c) shall be based on the Target Bonus and payable at the same time as the lump sum payment described in Section 4.1(a), (iii) the COBRA coverage paid by the Company shall extend until up to eighteen (18) months following the date of Executive's termination of employment, and (iv) all of Executive's then-outstanding and unvested equity or equity-based awards shall become vested in full upon such Covered Termination (with any performance-based vesting criteria deemed achieved based on actual performance through the date of the Covered Termination).

IV.2. 280G Provisions. Notwithstanding anything in this Agreement to the contrary, if any payment, benefit or distribution Executive would receive pursuant to this Agreement or otherwise from the Company or any of its affiliates ("**Payment**") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then such Payment shall either be (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such

Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the largest payment, notwithstanding that all or some portion of the Payment may be taxable under Section 4999 of the Code. The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The accounting firm shall provide its calculations to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any reasonable determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive. Any reduction in payments and/or benefits pursuant to this Section 4.2 will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits payable to Executive. Nothing in this Section 4.2 shall require the Company or any of its affiliates to be responsible for, or have any liability or obligation with respect to, Executive's excise tax liabilities under Section 4999 of the Code.

IV.3. Section 409A. Notwithstanding any provision to the contrary in this Agreement:

(a) All provisions of this Agreement are intended to comply with Section 409A or an exemption therefrom and shall be construed and administered in accordance with such intent. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement are exempt from, or compliant with, Section 409A and in no event shall the Company or any of its affiliates be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by Executive on account of non-compliance with Section 409A.

(b) If Executive is deemed at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code which would subject Executive to a tax obligation under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six- month period measured from the date of Executive's Separation from Service or (ii) the date of Executive's death. Upon the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 4.3(b) shall be paid in a lump sum to Executive, and any remaining payments due under the Agreement shall be paid as otherwise provided herein.

(c) Any reimbursements payable to Executive pursuant to the Agreement shall be paid to Executive no later than 30 days after Executive provides the Company with a written request for reimbursement, and to the extent that any such reimbursements are deemed to constitute "nonqualified deferred compensation" within the meaning of Section 409A (i) such amounts shall be paid or reimbursed to Executive promptly, but in no event later than December 31 of the year following the year in which the expense is incurred, (ii) the amount of any such payments eligible for reimbursement in one year shall not affect the payments or expenses that are eligible for payment or reimbursement in any other taxable year, and (iii) Executive's right to such payments or reimbursement shall not be subject to liquidation or exchange for any other benefit; provided,that the foregoing clause shall not be violated with regard to expenses reimbursed under any arrangement covered by Section 105(b) of the Code solely because such expenses are subject to a limit related to the period in which the arrangement is in effect.

(d) For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive installment payments under the Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

IV.4. Mitigation. Executive shall not be required to mitigate damages or the amount of any payment provided under this Agreement by seeking other employment or otherwise, nor shall the

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amount of any payment provided for under this Agreement be reduced by any compensation earned by Executive as a result of employment by another employer or by any retirement benefits received by Executive after the date of the Covered Termination, or otherwise.

ARTICLE V
OUTSIDE ACTIVITIES

V.1. Other Activities.

(a) Except as otherwise provided in Section 5.1(b), Executive shall not, during the term of this Agreement undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor, unless Executive obtains the prior written consent of the Board.

(b) Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder. In addition, subject to advance approval by the Board (which approval shall not be unreasonably withheld), Executive shall be allowed to serve as a member of the board of directors of other for-profit entities at any time during the term of this Agreement, in each case so long as such service does not materially interfere with the performance of Executive's duties hereunder; provided, however, that the Board, in its discretion, may require that Executive resign from such director position upon not less than thirty days written notice if

it determines that such resignation would be in the best interests of the Company. Notwithstanding the foregoing, Executive's current outside activities set forth in Exhibit B attached hereto have been approved by the Board and have been determined not to interfere with Executive's duties under this Agreement or to be inconsistent with the Company's interest.

V.2. Competition/Investments. During the term of Executive's employment by the Company, in order to protect the Company's legitimate business interests, including the value of the Company's confidential information, trade secrets, goodwill and training, which Executive acknowledges and agrees Executive has received and will continue to receive, Executive shall not (except on behalf of the Company) directly or indirectly, whether as an officer, director, stockholder, partner, proprietor, associate, representative, consultant, or in any capacity whatsoever engage in, become financially interested in, be employed by or have any business connection with any other person, corporation, firm, partnership or other entity whatsoever which is known by Executive to compete directly with the Company, throughout the world, in any line of business engaged in (or planned to be engaged in) by the Company, including, without limitation, the business of researching, developing, and/or manufacturing genetic medicines in neurology indications or any related services as currently engaged in by the Company; provided, however, that anything above to the contrary notwithstanding, Executive may own, as a passive investor, securities of any competitor corporation, so long as Executive's direct holdings in any one such corporation do not, in the aggregate, constitute more than 1% of the voting stock of such corporation. If it is determined by a court of competent jurisdiction in any state that any restriction in this Section 5.2 is excessive in duration or scope or is unreasonable or unenforceable under the laws of that state, it is the intention of the parties that

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such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted by the law of that state.

ARTICLE VI
COOPERATION

Executive shall reasonably cooperate with the Company, during Executive's employment (and following Executive's termination of employment for any reason for a period of three years thereafter), by making Executive reasonably available to testify on behalf of the Company or any affiliate in any action, suit, or proceeding, whether civil, criminal, administrative, or investigative, and to reasonably assist the Company or any such affiliate in any such action, suit, or proceeding or other matters involving the work Executive performed for the Company and Executive's responsibilities and duties during Executive's employment with the Company by providing information and meeting and consulting with the Board or its representatives or counsel, or representatives or counsel to the Company or any such affiliate, as reasonably requested; provided, however, that the same does not materially interfere with Executive's then current professional activities. The Company will reimburse Executive for all expenses reasonably incurred by Executive in connection with Executive's provision of testimony or assistance (including the fees of any counsel that may be retained by Executive).

ARTICLE VII
GENERAL PROVISIONS

VII.1. Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by email or fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

VII.2. Tax Withholding. Executive acknowledges that all amounts and benefits payable under this Agreement are subject to deduction and withholding to the extent required by applicable law.

VII.3. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

VII.4. Waiver. If either party should waive any breach of any provisions of this Agreement, they shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

VII.5. Complete Agreement. This Agreement, along with the PIIAA, constitutes the entire agreement between Executive and the Company and is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter, and will supersede all prior

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agreements, understandings, discussions, negotiations and undertakings, whether written or oral, between the parties with respect to the subject matter hereof, [including the employment letter between the Company and Executive executed on January 7, 2019. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein or therein, and cannot be modified or amended except in a writing signed by a duly-authorized officer of the Company and Executive.

VII.6. Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

VII.7. Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

VII.8. Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that

Executive may not assign Executive's rights or delegate Executive's duties or obligations hereunder without the prior written consent of the Company.

VII.9. Executive Acknowledgement. Executive acknowledges that (a) Executive has consulted with or has had the opportunity to consult with independent counsel of Executive's own choice concerning this Agreement, and has been advised to do so by the Company, and (b) that Executive has read and understands the Agreement, is fully aware of its legal effect, and has entered into it freely based on Executive's own judgment.

VII.10.Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the law of the State of Delaware without regard to the conflicts of law provisions thereof. Should any dispute under this Agreement be resolved by arbitration, the Company will cover Executive's fees and expenses arising from the resolution of such arbitration proceeding (including any reasonably incurred attorneys' fees and expenses of Executive); provided, that Executive shall reimburse the Company on a net after-tax basis to cover expenses incurred by Executive for claims brought by Executive that are judicially determined to be frivolous or advanced in bad faith.

[Signature page follows]

In Witness Whereof, the parties have executed this Agreement as of the date first written above.

Neurogene Inc.

By: /s/ Christine Mikail
Christine Mikail

Title: President and Chief Financial Officer

Accepted and Agreed:

/s/ Rachel McMinn
Rachel McMinn, PhD

Exhibit 10.2

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "**Agreement**") is entered into as of April 1, 2024 (the "**Effective Date**"), by and between Christine Mikail Cvijic ("**Executive**") and Neurogene Inc. (the "**Company**"). This Agreement supersedes in its entirety the employment letter dated as of September 1, 2019.

WHEREAS, Executive is currently employed by the Company as its President and Chief Financial Officer, and Company desires to have Executive's employment continue in such capacity, and Executive desires to continue to serve in such capacity, pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, it is hereby agreed by and between the parties hereto as follows:

ARTICLE I

I.1. For purposes of the Agreement, the following terms are defined as follows:

I.2. "**Board**" means the Board of Directors of the Company.

I.3. "**Cause**" means a good faith determination by the Board that Executive's employment be terminated, other than due to illness, injury, incapacity or Disability, for any one of the following: (i) Executive's indictment or conviction, or Executive's entry of a pleading of guilty or no contest, with respect to a felony or another crime involving fraud, dishonesty or moral turpitude, (ii) Executive's material misconduct or gross negligence in the performance of Executive's duties to the Company (or any of its affiliates), (iii) Executive's material failure or refusal to (A) follow policies or the lawful directives established by the Chief Executive Officer or the Board or (B) perform Executive's duties or obligations hereunder (iv) any act of fraud, embezzlement, theft or dishonesty by Executive in the course of Executive's employment with the Company (or any of its affiliates), (v) Executive's material breach of this Agreement, the Company's policies or any other agreement with the Company (or any of its affiliates), including, without limitation, the Employee Proprietary Information and Inventions Assignment Agreement (the "**PIIAA**"), or (vi) Executive's failure to comply in any material respect with applicable laws with respect to the operation of the business of the Company (or any of its affiliates). Notwithstanding the foregoing, in the case of any conduct described in clauses (iii), (v) or (vi) of the immediately preceding sentence, if such conduct is reasonably susceptible of being cured, then Executive's termination shall be for "Cause" only if Executive fails to cure such conduct to the Company's reasonable satisfaction within thirty (30) days after receiving written notice from the Company describing such conduct in reasonable detail.

I.4. "**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

I.5. "**Code**" means the Internal Revenue Code of 1986, as amended.

I.6. "**Covered Termination**" means (i) an Involuntary Termination Without Cause or (ii) a voluntary termination for Good Reason. For the avoidance of doubt, the termination of Executive's employment as a result of Executive's death or Disability will not be deemed to be a Covered Termination.

I.7. "**Disability**" means a termination of Executive's employment due to Executive's absence from Executive's duties with the Company on a full-time basis for at least 180 consecutive days as a result of Executive's incapacity due to physical or mental illness which is determined to be total and permanent by a physician selected by the Company or its insurers.

I.8. "**Good Reason**" means any one of the following taken without Executive's prior written consent: (i) failure or refusal by the Company to comply in any material respect with the material terms of this Agreement; (ii) a material diminution in Executive's duties, title, authority, status or responsibilities reduction, including a change in Executive's reporting responsibilities so that Executive no longer reports directly to the Chief Executive Officer of the Company; (iii) a material reduction in Executive's Base Salary as in effect immediately prior to such reduction (unless such reduction is part of a reduction that applies to and affects all similarly situated executive officers of the Company substantially the same and proportionately); (iv) a material diminution in Executive's annual cash bonus opportunity, unless such reduction is part of a reduction that applies to and affects all similarly situated executive officers of the Company substantially the same and proportionately; or (v) the Company requiring Executive to be located at any office or location more than 50 miles from the Company's current headquarters, provided that any request or directive from the Company to not work in such office pursuant to any stay-at-home or work from home or similar law, order, directive, request or recommendation from a governmental entity shall not give rise to Good Reason under this Agreement. Notwithstanding the foregoing, Executive's resignation shall not constitute a resignation for "Good Reason" as a result of any event described in the preceding sentence unless (x) Executive provides written notice thereof to the Company within thirty (30) days after Executive's knowledge of such event, (y) to the extent correctable, the Company fails to remedy such circumstance or event within thirty (30) days following the Company's receipt of such written notice and (z) the effective date of Executive's resignation for "Good Reason" is not later than ninety (90) days after the initial existence of the circumstances constituting Good Reason.

I.9. "**Involuntary Termination Without Cause**" means Executive's dismissal or discharge by the Company other than for Cause or by reason of Executive's death or Disability.

I.10. "**Section 409A**" means Section 409A of the Code and the Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Effective Date.

I.11. "**Separation from Service**" means Executive's termination of employment constitutes a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h).

ARTICLE II
EMPLOYMENT BY THE COMPANY

II.1. Position and Duties. Subject to terms set forth herein, Executive shall continue to serve in an executive capacity and shall continue to perform such duties as are customarily associated with the position of President and Chief Financial Officer and such other duties as are reasonably assigned to Executive consistent with Executive's position by the Board and/or the Company's Chief Executive Officer. During the term of Executive's employment with the Company, except as otherwise permitted under Section 5.1 below, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention (except for vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies or as otherwise set forth in this Agreement) to the business of the Company.

II.2. Term. The term of this Agreement shall commence on the Effective Date and shall terminate on the termination of Executive's employment under this Agreement. The period from the Effective Date until the termination of Executive's employment under this Agreement is referred to as the "**Term**."

II.3. Employment at Will. Both the Company and Executive shall have the right to terminate Executive's employment with the Company at any time, with or without Cause or Good Reason, and with or without prior notice. Upon certain terminations of Executive's employment with the Company, Executive may become eligible to receive the severance benefits provided in Article IV of this Agreement.

II.4. Employment Policies. The employment relationship between the parties shall also be subject to the general employment policies and practices of the Company, including those relating to protection of confidential information and assignment of inventions, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control. In addition, the PIIAA entered into in connection with Executive's initial engagement by the Company, as attached hereto as Exhibit A, shall remain in full force and effect in accordance with its terms.

II.5. Place of Performance. During the employment period, Executive shall be permitted to work remotely so long as such remote work does not materially impair Executive's ability to perform Executive's duties as provided for in Section 2.1. It is understood that reasonable travel may be required as may be necessary to fulfill Executive's responsibilities.

II.6. Expenses; Indemnification. The Company will reimburse Executive promptly for reasonable travel expenses in connection with all authorized work travel under the policies and procedures then in effect and established by the Company for its executives. The Company will indemnify Executive for Executive's service as an officer of the Company in accordance with the Company's governing documents and as provided by the Board. In the event of a lawsuit in connection with Executive's service as an officer of the Company, the Company will advance Executive's reasonable costs and attorney fees incurred during the course of such lawsuit. The

/s/
Sean
Smith

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

obligations under this Section 2.6 shall be in addition to any indemnification rights Executive may have under the Company's bylaws or any other agreement or policy.

ARTICLE III
COMPENSATION

III.1. Base Salary. As of the Effective Date,Executive shall receive for services to be rendered hereunder an annual base salary of $515,000 ("**Base Salary**"), payable on the regular payroll dates of the Company (but no less often than monthly), subject to annual review for increase in the sole discretion of the Board or a committee of the Board, taking into account all of Executive's duties as may be assigned from time to time.

III.2. Annual Bonus. For each calendar year ending during the Term and beginning with the calendar year ending December 31, 2024,Executive shall be eligible to receive an annual performance bonus (the "**Annual Bonus**") targeted at forty-five percent (45%) of Base Salary or such other higher amount as determined in the sole discretion of the Board or a committee of the Board (the "**Target Bonus**"), on such terms and conditions determined by the Board or a committee of the Board. The actual amount of the Annual Bonus (if any) will be determined in the discretion of the Board or a committee of the Board and will be (i) subject to achievement of any applicable bonus objectives and/or conditions determined by the Board or a committee of the Board and (ii) subject to Executive's continued employment with the Company through the date the Annual Bonus is paid. The Annual Bonus for any calendar year will be paid at the same time as bonuses to other Company executives related to annual bonuses generally are paid.

III.3. Standard Company Benefits. During the Term,Executive shall be entitled to all rights and benefits for which Executive is eligible under the terms and conditions of the standard Company benefits and compensation practices that may be in effect from time to time and are provided by the Company to its executive employees generally, as well as any additional benefits provided to Executive consistent with past practice. Notwithstanding the foregoing, this Section 3.3 shall not create or be deemed to create any obligation on the part of the Company to adopt or maintain any benefits or compensation practices at any time.

III.4. Paid Time Off. During the Term, Executive shall be entitled to such periods of paid time off ("**PTO**") each year as provided from time to time under the Company's PTO policies and as otherwise provided for executive officers, as it may be amended from time to time.

III.5. Equity Awards. Executive will be eligible annually to receive stock options and other equity incentive grants as determined by the Board or a committee of the Board in its sole discretion, in each case subject to the terms and conditions of the Company's 2023 Equity Incentive Plan (or any successor equity incentive plan, the "**Plan**") and the applicable award agreement approved by the Board or a committee thereof.

IV.1. Severance Benefits. Upon Executive's termination of employment, Executive shall receive any accrued but unpaid Base Salary and other accrued and unpaid compensation. If the termination is due to a Covered Termination, provided that Executive (A) delivers an effective general release of all claims against the Company and its affiliates in a form attached hereto as Exhibit C (with such modifications as determined by the Company due to changes in law or market practice after the date of this Agreement, a "**Release of Claims**") that becomes effective and irrevocable within sixty (60) days following the Covered Termination and (B) continues to comply with the PIIAA and Articles V through VI of this Agreement, Executive shall be entitled to receive the following severance benefits:

(a) An amount equal to twelve (12) months of Executive's Base Salary at the rate in effect (or required to be in effect before any diminution that is the basis of Executive's termination for Good Reason) at the time of Executive's termination of employment, payable in a lump sum payment, less applicable withholdings, as soon as administratively practicable following the date on which the Release of Claims becomes effective and, in any event, no later than the sixtieth (60th) day following the date of the Covered Termination; provided, however, if such sixty (60) day period falls in two different calendar years, payment will be made in the later calendar year.

(b) Any unpaid annual bonus amount that was earned by Executive with respect to the calendar year ended prior to the termination of Executive's employment, as determined by the Board, subject to applicable tax withholding and payable substantially at the same time as other annual bonuses are paid to then-current members of the Company's leadership team (but in any event no later than June 30 of the applicable year).

(c) Payment of a pro-rata portion of the annual cash bonus (the "**Pro-Rata Annual Bonus**") that would have been earned by Executive for the year in which the Covered Termination occurs based on the number of days between and including the first day of the fiscal year of the Company in which the Covered Termination occurs and the date of the Covered Termination, payable on the date when such bonuses are otherwise paid to Company executives generally and in all events by no later than June 30 of the calendar year following the year in which such termination occurs.

(d) Subject to Executive's timely election of continuation coverage under COBRA, the Company shall directly pay, or reimburse Executive, for the premium for Executive and Executive's covered dependents to maintain continued health coverage pursuant to the provisions of COBRA through the earlier of (i) the 12-month anniversary of the date of Executive's termination of employment and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Notwithstanding the foregoing, if the Company provided, however, that if the Company determines that it cannot provide the foregoing COBRA benefit without potentially violating applicable law or incurring an excise tax, the Company shall in lieu thereof pay Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to

continue Executive's and Executive's covered dependents' group health coverage in effect on Executive's termination date (which amount shall be based on the premium for the first month of

COBRA coverage), which payments shall commence in the month following the month in which the Company makes such determination and shall end on the earliest of (x) the date that is twelve (12) months after Executive's termination date and (y) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s).

(e) Notwithstanding anything to the contrary herein or in any applicable or award agreement or the Plan, if the Covered Termination occurs during the period commencing 3 months prior and ending 12 months following the date of a Change in Control (as defined in the Plan): (i) the lump sum payment described in Section 4.1(a) shall be increased to 1.25 times the sum of Executive's Base Salary and Target Bonus, (ii) the Pro-Rata Annual Bonus described in Section 4.1(c) shall be based on the Target Bonus and payable at the same time as the lump sum payment described in Section 4.1(a), (iii) the COBRA coverage paid by the Company shall extend until up to eighteen (18) months following the date of Executive's termination of employment, and (iv) all of Executive's then-outstanding and unvested equity or equity-based awards shall become vested in full upon such Covered Termination (with any performance-based vesting criteria deemed achieved based on actual performance through the date of the Covered Termination).

IV.2. 280G Provisions. Notwithstanding anything in this Agreement to the contrary, if any payment, benefit or distribution Executive would receive pursuant to this Agreement or otherwise from the Company or any of its affiliates ("**Payment**") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then such Payment shall either be (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the largest payment, notwithstanding that all or some portion of the Payment may be taxable under Section 4999 of the Code. The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The accounting firm shall provide its calculations to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any reasonable determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive. Any reduction in payments and/or benefits pursuant to this Section 4.2 will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits payable to Executive. Nothing in this Section 4.2 shall require the Company or any of its affiliates to be responsible for, or have any liability or obligation with respect to, Executive's excise tax liabilities under Section 4999 of the Code.

IV.3. Section 409A. Notwithstanding any provision to the contrary in this Agreement:

(a) All provisions of this Agreement are intended to comply with Section 409A or an exemption therefrom and shall be construed and administered in accordance with such intent. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement are exempt from, or compliant with, Section 409A and in no event shall the Company or any of its affiliates be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by Executive on account of non-compliance with Section 409A.

(b) If Executive is deemed at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code which would subject Executive to a tax obligation under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six- month period measured from the date of Executive's Separation from Service or (ii) the date of Executive's death. Upon the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 4.3(b) shall be paid in a lump sum to Executive, and any remaining payments due under the Agreement shall be paid as otherwise provided herein.

(c) Any reimbursements payable to Executive pursuant to the Agreement shall be paid to Executive no later than 30 days after Executive provides the Company with a written request for reimbursement, and to the extent that any such reimbursements are deemed to constitute "nonqualified deferred compensation" within the meaning of Section 409A (i) such amounts shall be paid or reimbursed to Executive promptly, but in no event later than December 31 of the year following the year in which the expense is incurred, (ii) the amount of any such payments eligible for reimbursement in one year shall not affect the payments or expenses that are eligible for payment or reimbursement in any other taxable year, and (iii) Executive's right to such payments or reimbursement shall not be subject to liquidation or exchange for any other benefit; provided,that the foregoing clause shall not be violated with regard to expenses reimbursed under any arrangement covered by Section 105(b) of the Code solely because such expenses are subject to a limit related to the period in which the arrangement is in effect.

(d) For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive installment payments under the Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

IV.4. Mitigation. Executive shall not be required to mitigate damages or the amount of any payment provided under this Agreement by seeking other employment or otherwise, nor shall the

amount of any payment provided for under this Agreement be reduced by any compensation earned by Executive as a result of employment by another employer or by any retirement benefits received by Executive after the date of the Covered Termination, or otherwise.

ARTICLE V
OUTSIDE ACTIVITIES

V.1. Other Activities.

(a) Except as otherwise provided in Section 5.1(b), Executive shall not, during the term of this Agreement undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor, unless Executive obtains the prior written consent of the Chief Executive Officer of the Company.

(b) Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder. In addition, subject to advance approval by the Chief Executive Officer of the Company (which approval shall not be unreasonably withheld), Executive shall be allowed to serve as a member of the board of directors of other for-profit entities at any time during the term of this Agreement, in each case so long as such service does not materially interfere with the performance of Executive's duties hereunder; provided, however, that the Chief Executive Officer of the Company, in her discretion, may require that Executive resign from such director position upon not less than thirty days written notice if it determines that such resignation would be in the best interests of the Company. Notwithstanding the foregoing, Executive's current outside activities set forth in Exhibit B attached hereto have been approved by the Chief Executive Officer of the Company and have been determined not to interfere with Executive's duties under this Agreement or to be inconsistent with the Company's interest.

V.2. Competition/Investments. During the term of Executive's employment by the Company, in order to protect the Company's legitimate business interests, including the value of the Company's confidential information, trade secrets, goodwill and training, which Executive acknowledges and agrees Executive has received and will continue to receive, Executive shall not (except on behalf of the Company) directly or indirectly, whether as an officer, director, stockholder, partner, proprietor, associate, representative, consultant, or in any capacity whatsoever engage in, become financially interested in, be employed by or have any business connection with any other person, corporation, firm, partnership or other entity whatsoever which is known by Executive to compete directly with the Company, throughout the world, in any line of business engaged in (or planned to be engaged in) by the Company, including, without limitation, the business of researching, developing, and/or manufacturing genetic medicines in neurology indications or any related services as currently engaged in by the Company; provided, however, that anything above to the contrary notwithstanding, Executive may own, as a passive investor, securities of any competitor corporation, so long as Executive's direct holdings in any

one such corporation do not, in the aggregate, constitute more than 1% of the voting stock of such corporation. If it is determined by a court of competent jurisdiction in any state that any restriction in this Section 5.2 is excessive in duration or scope or is unreasonable or unenforceable under the laws of that state, it is the intention of the parties that

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such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted by the law of that state.

ARTICLE VI
COOPERATION

Executive shall reasonably cooperate with the Company, during Executive's employment (and following Executive's termination of employment for any reason for a period of three years thereafter), by making Executive reasonably available to testify on behalf of the Company or any affiliate in any action, suit, or proceeding, whether civil, criminal, administrative, or investigative, and to reasonably assist the Company or any such affiliate in any such action, suit, or proceeding or other matters involving the work Executive performed for the Company and Executive's responsibilities and duties during Executive's employment with the Company by providing information and meeting and consulting with the Board or its representatives or counsel, or representatives or counsel to the Company or any such affiliate, as reasonably requested; provided, however, that the same does not materially interfere with Executive's then current professional activities. The Company will reimburse Executive for all expenses reasonably incurred by Executive in connection with Executive's provision of testimony or assistance (including the fees of any counsel that may be retained by Executive).

ARTICLE VII
GENERAL PROVISIONS

VII.1. Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by email or fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll

VII.2. Tax Withholding. Executive acknowledges that all amounts and benefits payable under this Agreement are subject to deduction and withholding to the extent required by applicable law.

VII.3. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

VII.4. Waiver. If either party should waive any breach of any provisions of this Agreement, they shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

VII.5. Complete Agreement. This Agreement, along with the PIIAA, constitutes the entire agreement between Executive and the Company and is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter, and will supersede all prior

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agreements, understandings, discussions, negotiations and undertakings, whether written or oral, between the parties with respect to the subject matter hereof, including the employment letter between the Company and Executive executed on September 1, 2019. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein or therein, and cannot be modified or amended except in a writing signed by a duly-authorized officer of the Company and Executive.

VII.6. Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

VII.7. Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

VII.8. Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign Executive's rights or delegate Executive's duties or obligations hereunder without the prior written consent of the Company.

VII.9. Executive Acknowledgement. Executive acknowledges that (a) Executive has consulted with or has had the opportunity to consult with independent counsel of Executive's own choice concerning this Agreement, and has been advised to do so by the Company, and (b) that Executive has read and understands the Agreement, is fully aware of its legal effect, and has entered into it freely based on Executive's own judgment.

VII.10.Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the law of the State of Delaware without regard to the conflicts of law provisions thereof. Should any dispute under this Agreement be resolved by arbitration, the Company will cover Executive's fees and expenses arising from the resolution of such arbitration proceeding (including any reasonably incurred attorneys' fees and expenses of Executive); provided, that Executive shall reimburse the Company on a net after-tax basis to cover expenses incurred by Executive for claims brought by Executive that are judicially determined to be frivolous or advanced in bad faith.

[Signature page follows]

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In Witness Whereof, the parties have executed this Agreement as of the date first written above.

Neurogene Inc.

By: /s/ Rachel McMinn
Rachel McMinn, PhD

Title: Chief Executive Officer

Accepted and Agreed:

/s/ Christine Mikail Cvijic
Christine Mikail Cvijic

Exhibit 10.3

AMENDED AND RESTATED CONSULTING AGREEMENT

THIS AMENDED AND RESTATED CONSULTING AGREEMENT (the “Agreement”), made this 19th day of April 2024 is entered into by Neurogene Inc., a Nevada corporation (the “Company”) with offices at 535 West 24th Street, 5th Floor, New York, NY, 10011 and Stuart Cobb Consulting Ltd, a limited company registered at Office 8, Hardengreen Park, Eskbank, Midlothian, Scotland EH22 3NX (the “Consultant”). This Agreement amends and restates in its entirety the consulting agreement entered into by the Consultant and the Company as of December 12, 2018, as amended.

INTRODUCTION

The Consultant is currently engaged by the Company to provide services, including causing Stuart Cobb (“Cobb”) to provide services, to the Company, the Company desires to have the Consultant’s engagement continue in such capacity, and the Consultant desires to continue to serve in such capacity, pursuant to the terms and conditions set forth in this Agreement. In consideration of the mutual covenants and promises

contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties hereto, the parties agree as follows:

1. Definitions:

1.1 For purposes of the Agreement, the following terms are defined as follows:

(a) "Board" means the Board of Directors of the Company.

(b) "Cause" means a good faith determination by the Board that the Consultation Period (as defined below) be terminated, other than due to illness, injury, incapacity or Disability, for any one of the following: (i) the Consultant's or Cobb's indictment or conviction, or the Consultant's or Cobb's entry of a pleading of guilty or no contest, with respect to a felony or another crime involving fraud, dishonesty or moral turpitude, (ii) the Consultant's or Cobb's material misconduct or gross negligence in the performance of the Services (as defined below) to the Company (or any of its affiliates), (iii) the Consultant's material failure or refusal, or Cobb's material failure or refusal in performing duties on behalf of the Consultant, to (A) follow policies or the lawful directives established by the Chief Executive Officer or the Board or (B) perform the Consultant's duties or obligations hereunder, (iv) any act of fraud, embezzlement, theft or dishonesty by the Consultant in the course of the Consultation Period, (v) the Consultant's material breach, or Cobb's material breach in performing duties on behalf of the Consultant, of this Agreement, the Company's policies applicable to the Consultant or any other agreement with the Company (or any of its affiliates), or (vi) the Consultant's or Cobb's failure to comply in any material respect with applicable laws with respect to the operation of the business of the Company (or any of its affiliates). Notwithstanding the foregoing, in the case of any conduct described in clauses (iii), (v) or (vi) of the immediately preceding sentence, if such conduct is reasonably susceptible of being cured, then the termination of the Consultation Period shall be for "Cause" only if the Consultant fails to cure such conduct to the Company's reasonable satisfaction within thirty (30) days after receiving written notice from the Company describing such conduct in reasonable detail.

(c) "Code" means the Internal Revenue Code of 1986, as amended.

(d) "Covered Termination" means (i) an Involuntary Termination Without Cause or (ii) a voluntary termination for Good Reason. For the avoidance of doubt, the termination of the Consultation Period as a result of Cobb's death or Disability will not be deemed to be a Covered Termination.

(e) "Disability" means a termination of the Consultation Period due to the Consultant's inability to perform the Services for at least 180 consecutive days as a result of Cobb's incapacity due to physical or mental illness which is determined to be total and permanent by a physician selected by the Company.

(f) "Good Reason" means any one of the following taken without the Consultant's prior written consent: (i) failure or refusal by the Company to comply in any material respect with the material terms of this Agreement; (ii) a material diminution in the Consultant's responsibilities, including a change in the Consultant's reporting responsibilities so that the Consultant no longer reports directly to the Chief Executive Officer of the Company; (iii) a material reduction in the Consultant's consulting fee as in effect immediately prior to such reduction; or (iv) the Company requiring the Consultant to be located at any location more than 50 miles from the Consultant's principal place of business, located at Office 8, Hardengreen Park, Eskbank, Midlothian, Scotland EH22 3NX. Notwithstanding the foregoing, the Consultant's resignation shall not constitute a resignation for "Good Reason" as a result of any event described in the preceding sentence unless (A) the Consultant provides written notice thereof to the Company within thirty (30) days after the Consultant's knowledge of such event, (B) to the extent correctable, the Company fails to remedy such circumstance or event within thirty (30) days following the Company's receipt of such written notice and (C) the effective date of the Consultant's resignation for "Good Reason" is not later than ninety (90) days after the initial existence of the circumstances constituting Good Reason.

(g) "Involuntary Termination Without Cause" means the termination of the Consultation Period other than for Cause or by reason of Cobb's death or Disability.

(h) "Section 409A" means Section 409A of the Code and the Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date

hereof.

(i) "Separation from Service" means a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h).

2. Services. The Consultant agrees to continue to perform, and to cause Cobb to perform, such consulting, advisory and related services to and for the Company as may be reasonably requested from time to time by the Company, including, but not limited to, the services specified on Exhibit A to this Agreement (the "Services"). During the Consultation Period and for a period of six (6) months thereafter, the Consultant shall not, and shall cause Cobb to not, engage in any activity that has a conflict of interest with the Company, including any competitive employment, business, or other activity, and it shall not, and shall cause Cobb to not, assist any other person or organization that competes, or intends to compete, with the Company.

3. Term. The term of this Agreement shall be two (2) years from the date of the last signature provided on this Agreement, which may be extended upon mutual written agreement between the parties, unless earlier terminated in accordance with the provisions of Section 5 (the term of effectiveness of this Agreement being referred to herein as the "Consultation Period"). To the extent there are ongoing Services at the time of expiration of this Agreement, this Agreement will remain in effect only with respect to, and until completion, of those Services.

4. Compensation.

1.1 Consulting Fees.

The Company shall pay to the Consultant consulting fees of $36,667,67 per month, payable in arrears following each month in which the Services were provided by the Consultant under this Agreement within 7 days following presentation of invoice. Payment for any partial month shall be prorated. These fees will be reviewed, upon completion of 12 months duration, solely for the purposes of evaluating inflationary impacts.

1.2 Success Fee. For each calendar year ending during the Consultation Period and beginning with the calendar year ending December 31, 2024, the Consultant shall be eligible to receive an additional fee (the "Success Fee") targeted at 40% of the Consultant's annualized consulting fee (or such other higher target level as determined in the sole discretion of the Board or a committee of the Board) (the "Target Success Fee"), on such terms and conditions determined by the Board or a committee of the Board. The actual amount of the Success Fee (if any) will be determined in the discretion of the Board or a committee of the Board and will be (a) subject to achievement of any applicable objectives and/or conditions determined by the Board or a committee of the Board

and (b) subject to the Consultant's continued active engagement with the Company through the date the Success Fee is paid.

1.3 Reimbursement of Expenses. The Company shall reimburse the Consultant for all reasonable and necessary documented out of pocket expenses incurred or paid by the Consultant in connection with, or related to, the performance of the Consultant's Services under this Agreement with the prior written approval of the Company. The Consultant shall submit to the Company itemized statements on a bi-weekly basis, in a form satisfactory to the Company, of such expenses incurred in the previous two-week period. The Company shall pay to the Consultant amounts shown on each such statement within 30 days after receipt thereof.

1.4 Benefits. Neither the Consultant nor Cobb shall be entitled to any benefits, coverages or privileges, including, without limitation, social security, unemployment, medical or pension payments, that the Company provides exclusively to employees of the Company.

5. Termination.

1.1 Termination by the Company for Cause. The Company may, without prejudice to any right or remedy it may have due to any failure of the Consultant to perform the Consultant's obligations, including any failure to cause Cobb to perform the Consultant's obligations on its behalf, under this Agreement, terminate the Consultation Period for Cause at any time without prior written notice to the Consultant. In the event of such termination, the Consultant shall be entitled to payment of any unpaid consulting fees earned hereunder, prorated for any partial month, and for expenses paid or incurred prior to the effective date of termination. Such payments shall constitute full settlement of any and all claims of the Consultant of every description against the Company.

1.2 Termination by the Company without Cause. The Company may terminate the Consultation Period without Cause for any reason, effective 30 days following written notice to the Consultant. Upon such an Involuntary Termination Without Cause, the Consultant may become eligible to receive the payments described in Section 9 of this Agreement.

1.3 Termination by Consultant without Good Reason. The Consultant may terminate the Agreement without Good Reason subject to providing 30 days written notice to the Company. In the event of such termination, the Consultant shall be entitled to payment of any unpaid consulting fees earned hereunder, prorated for any partial month, and for expenses paid or incurred prior to the effective date of termination. Such payments shall constitute full settlement of any and all claims of the Consultant of every description against the Company.

1.4 Termination by Consultant for Good Reason. The Consultant may terminate the Consultation Period for Good Reason. Upon such a termination of the Consultation Period, the Consultant may become eligible to receive the payments described in Section 9 of this Agreement.

1.5 Termination Upon Death or Disability. The Consultation Period will terminate upon Cobb's death or Disability. Upon such termination, the Consultant or its beneficiaries, as applicable, shall be entitled to payment of any unpaid consulting fees earned hereunder, prorated for any partial month, and for expenses paid or incurred prior to the effective date of termination. Such payments shall constitute full settlement of any and all claims of the Consultant or its beneficiaries, as applicable, of every description against the Company.

6. Cooperation. The Consultant shall use its best efforts, and shall cause Cobb to use his best efforts on its behalf, in the performance of the Consultant's obligations under this Agreement. The Company shall provide such access to its information and property as may be reasonably required in order to permit the Consultant to perform the Consultant's obligations hereunder. The Consultant shall, and shall cause Cobb to, (a) cooperate with the Company's personnel, (b) not interfere with the conduct of the Company's business and (c) observe all rules, regulations and security requirements of the Company concerning the safety of persons and property.

7. Inventions and Proprietary Information.

1.1 Inventions.

(a) All inventions, discoveries, computer programs, data, technology, designs, innovations and improvements (whether or not patentable and whether or not copyrightable) which are made, conceived, reduced to practice, created, written, designed or developed by the Consultant or Cobb, solely or jointly with others and whether during normal business hours or otherwise, (i) during the Consultation Period if related to the business of the Company or (ii) after the Consultation Period if resulting or directly derived from Proprietary Information (as defined below) (collectively under clauses (i) and (ii), "Inventions"), shall be the sole property of the Company. The Consultant hereby assigns to the Company all Inventions and any and all related patents, copyrights, trademarks, trade names, and other industrial and intellectual property rights and applications therefor, in the United States and elsewhere and appoints any officer of the Company as the Consultant's duly authorized attorney to execute, file, prosecute and protect the same before any government agency, court or authority. Upon the request of the Company and at the Company's expense, the Consultant shall, and shall cause Cobb to, execute such further assignments, documents and other instruments as may be necessary or desirable to fully and completely assign all Inventions to the Company and to assist the Company in applying for, obtaining and enforcing patents or copyrights or other rights in the United States and in any foreign country with respect to any Invention. The Consultant also hereby waives all claims to moral rights in any Inventions.

(b) The Consultant shall promptly disclose to the Company all Inventions and will maintain adequate and current written records (in the form of notes, sketches, drawings and as may be specified by the Company) to document the conception and/or first actual reduction to practice of any Invention. Such written records shall always be available to and remain the sole property of the Company.

(c) For the sake of clarity, programs that fall outside of the scope of this Agreement include the ongoing work in Cobb's laboratory at the University of Edinburgh. A list of the programs has been included in Exhibit B. Any intellectual property developed as part of the Trans-splicing sponsored research agreement is subject to the rights and terms described within the sponsored agreements without subordination to the terms of this contract.

1.2 Proprietary Information.

(a) The Consultant acknowledges that its relationship with the Company is one of high trust and confidence and that in the course of the Consultant's service to the Company it and Cobb will have access to and contact with Proprietary Information. The Consultant agrees that it will not, will cause Cobb to not, during the Consultation Period or at any time thereafter, disclose to others, or use for its or his benefit or the benefit of others, any Proprietary Information or Invention.

(b) For purposes of this Agreement, Proprietary Information shall mean, by way of illustration and not limitation, all information (whether or not patentable and whether or not copyrightable) owned, possessed or used by the Company, including, without limitation, any Invention, formula, vendor information, customer information, apparatus, equipment, trade secret, process, research, report, technical data, know-how, computer program, software, software documentation, hardware design, technology, marketing or business plan, forecast, unpublished financial statement, budget, license, price, cost and employee list that is communicated to, learned of, developed or otherwise acquired by the Consultant or Cobb in the course of the Consultant's service as a consultant to the Company.

(c) The Consultant's obligations under this Section 7.2 shall not apply to any information that (i) is or becomes known to the general public under circumstances involving no breach by the Consultant or others of the terms of this Section 7.2, (ii) is generally disclosed to third parties by the Company without restriction on such third parties, (iii) is approved for release by written authorization of an officer of the Company or (iv) is required to be disclosed by applicable law, regulation, recognized subpoena power, any governmental authority or agency, or any other legal process (provided that, to the extent permitted by applicable law, regulation, recognized subpoena power, any governmental authority or agency, or any other legal process, the Consultant provides the Company with prior notice of the contemplated disclosure and cooperates with the

Company in seeking a protective order or other appropriate protection of such information). Under the Defend Trade Secrets Act of 2016, the Company hereby provides notice and the Consultant hereby acknowledges that the Consultant may not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (A) is made (1) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (2) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

(d) Upon termination of this Agreement or at any other time upon request by the Company, the Consultant shall, and shall cause Cobb to, promptly deliver to the Company all records, files, memoranda, notes, designs, data, reports, price lists, customer lists, drawings, plans, computer programs, software, software documentation, sketches, laboratory and research notebooks and other documents (and all copies or reproductions of such materials) relating to the business of the Company.

(e) The Consultant represents that its retention as a consultant with the Company and the Consultant's performance under this Agreement does not, and shall not, breach any agreement that obligates it or Cobb to keep in confidence any trade secrets or confidential or proprietary information of the Consultant, Cobb or of any other party or to refrain from competing, directly or indirectly, with the business of any other party or otherwise conflict with any of its or his agreements or obligations to any other party. The Consultant shall not, and shall cause Cobb not to, disclose to the Company any trade secrets or confidential or proprietary information of any other party.

(f) The Consultant acknowledges that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, that impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. The Consultant agrees to be bound by all such obligations and restrictions that are known to it and to take all actions necessary, and to cause Cobb to take all actions necessary, to discharge the obligations of the Company under such agreements.

1.3 Remedies. The Consultant acknowledges that any breach of the provisions of this Section 7 shall result in serious and irreparable injury to the Company for which the Company cannot be adequately compensated by monetary damages alone. The Consultant agrees, therefore, that, in addition to any other remedy it may have, the Company shall be entitled to enforce the specific performance of this Agreement by the Consultant and to seek both temporary and permanent injunctive relief (to the extent permitted by law) without the necessity of proving actual damages.

1.4 Portfolio Reference. Upon termination of this Agreement, the Consultant may disclose to prospective third party contractors or employers the fact that Consultant performed certain Services for the Company, subject to the receipt of prior written permission

from the Company with respect to such disclosure and the scope thereof.

8. Non-Solicitation. During the Consultation Period and for a period of six (6) months thereafter, the Consultant shall not, and shall cause Cobb to not, either alone or in association with others, (a) solicit, or permit any organization directly or indirectly controlled by the Consultant or Cobb to solicit, any employee of the Company to leave the employ of the Company, or (b) solicit for employment, hire or engage as an independent contractor, or permit any organization directly or indirectly controlled by the Consultant or Cobb to solicit for employment, hire or engage as an independent contractor, any person who was employed by the Company at any time during the term of the Consultant's engagement with the Company; provided, that this clause (b) shall not apply to any individual whose employment with the Company has been terminated for a period of six (6) months or longer.

9. Payments upon Covered Terminations.

1.1 Upon termination of the Consultation Period, the Consultant shall receive any accrued but unpaid consulting fee and other accrued and unpaid remuneration. If the termination is due to a Covered

Termination, provided that the Consultant (A) delivers an effective general release of all claims against the Company and its affiliates in a form attached hereto as Exhibit C (with such modifications as determined by the Company due to changes in law or market practice after the date of this Agreement, a "Release of Claims") that becomes effective and irrevocable within sixty (60) days following the Covered Termination and (B) continues to comply with Sections 7 and 8 of this Agreement, the Consultant shall be entitled to receive the following payments:

(a) An amount equal to twelve (12) months of the consulting fee at the rate in effect (or required to be in effect before any diminution that is the basis of the termination of the Consultation Period for Good Reason) at the time of termination of the Consultation Period, payable in a lump sum payment, as soon as administratively practicable following the date on which the Release of Claims becomes effective and, in any event, no later than the sixtieth (60th) day following the date of the Covered Termination; provided, however, if such sixty (60) day period falls in two different calendar years, payment will be made in the later calendar year.

(b) Any unpaid Success Fee amount that was earned by Consultant with respect to the calendar year ended prior to the termination of the Consultation Period, as determined by the Board, and payable substantially at the same time as annual bonuses are paid to then-current members of the Company's leadership team (but in any event no later than June 30 of the applicable year).

(c) Payment of a pro-rata portion of the Success Fee (the "Pro-Rata Success Fee") that would have been earned by the Consultant for the year in which the Covered Termination occurs based on the number of days between and including the first day of the fiscal year of the Company in which the Covered Termination occurs and the date of the Covered Termination, payable on the date when such bonuses are otherwise paid to then-current members of the Company's leadership team and in all events by no later than June 30 of the calendar year following the year in which such termination occurs.

(d) Notwithstanding anything to the contrary herein or in any applicable award agreement or the Company's 2018 Equity Incentive Plan or the Neurogene Inc. 2023 Equity Incentive Plan, which is an equity plan of the Company's parent corporation, Neurogene Inc., a Delaware corporation (the "2023 Plan"), if the Covered Termination occurs during the period commencing three (3) months prior and ending twelve (12) months following the date of a Change in Control (as defined in the 2023 Plan): (i) the Pro-Rata Success Fee described in Section 9.1(c) shall be based on the Target Success Fee and payable at the same time as the lump sum payment described in Section 9.1(a), and (ii) all of the Consultant's then-outstanding and unvested equity or equity-based awards shall become vested in full upon such Covered Termination (with any performance-based vesting criteria deemed achieved based on actual performance through the date of the Covered Termination).

1.2 280G Provisions. Notwithstanding anything in this Agreement to the contrary, if any payment, benefit or distribution the Consultant would receive pursuant to this Agreement or otherwise from the Company or any of its affiliates ("Payment") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall either be (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the

applicable federal, state and local income taxes and the Excise Tax, results in the receipt by the Consultant on an after-tax basis, of the largest payment, notwithstanding that all or some portion of the Payment may be taxable under Section 4999 of the Code. Unless the Company in its sole discretion elects to engage a different firm for the purposes of performing a 280G analysis, the accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The accounting firm shall provide its calculations to the Company and the Consultant within fifteen (15) calendar days after the date on which the Consultant's right to a Payment is triggered (if requested at that time by the Company or the Consultant) or such other time as requested by the Company or the Consultant. Any reasonable determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and the Consultant. Any reduction in payments and/or benefits pursuant to this Section 9.2 will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; and (3) cancellation of accelerated vesting of stock options.

Nothing in this Section 9.2 shall require the Company or any of its affiliates to be responsible for, or have any liability or obligation with respect to, the Consultant's excise tax liabilities under Section 4999 of the Code.

1.3 Section 409A. Notwithstanding any provision to the contrary in this Agreement:

(a) All provisions of this Agreement are intended to comply with Section 409A or an exemption therefrom and shall be construed and administered in accordance with such intent. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement are exempt from, or compliant with, Section 409A and in no event shall the Company or any of its affiliates be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by the Consultant on account of non-compliance with Section 409A.

(b) If Cobb is deemed at the time of the Consultant's Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which the Consultant is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code which would subject the Consultant to a tax obligation under Section 409A, such portion of the Consultant's benefits shall not be provided to the Consultant prior to the earlier of (i) the expiration of the six (6)-month period measured from the date of the Consultant's Separation from Service or (ii) the date of Cobb's death. Upon the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 9.3(b) shall be paid in a lump sum to the Consultant, and any remaining payments due under the Agreement shall be paid as otherwise provided herein.

(c) Any reimbursements payable to the Consultant pursuant to the Agreement shall be paid to the Consultant no later than thirty (30) days after the Consultant provides the Company with a written request for reimbursement, and to the extent that any such reimbursements are deemed to constitute "nonqualified deferred compensation" within the meaning of Section 409A (i) such amounts shall be paid or reimbursed to the Consultant promptly, but in no event later than December 31 of the year following the year in which the expense is incurred, (ii) the amount of any such payments eligible for reimbursement in one year shall not affect the payments or expenses that are eligible for payment or reimbursement in any other taxable year, and (iii) the Consultant's right to such payments or reimbursement shall not be subject to liquidation or exchange for any other benefit; provided, that the foregoing clause shall not be violated with regard to expenses reimbursed under any arrangement covered by Section 105(b) of the Code solely because such expenses are subject to a limit related to the period in which the arrangement is in effect.

(d) For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), the Consultant's right to receive installment payments under the Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

1.4 Mitigation. The Consultant shall not be required to mitigate damages or the amount of any payment provided under this Agreement by seeking another engagement, employment or otherwise, nor shall the amount of any payment provided for under this Agreement

be reduced by any compensation earned by the Consultant as a result of engagement by another company or employment.

10. Other Agreements. The Consultant hereby represents that, except as the Consultant has disclosed in writing to the Company, neither the Consultant nor Cobb is bound by the terms of any agreement with any current or prior employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of the Consultant's relationship with the Company, to refrain from competing, directly or indirectly, with the business of such employer or any other party or to refrain from soliciting employees, customers or suppliers of such employer or other party. The Consultant agrees to furnish the Company with a copy of any such agreement upon request.

11. Independent Contractor Status. The Consultant shall perform all Services under this Agreement as an "independent contractor" and not as an employee or agent of the Company and, as an independent contractor, the Consultant will be solely responsible for complying with all applicable laws, rules and regulations concerning income, employment and other tax withholding, social security contributions, pension fund contributions, unemployment contributions and similar matters on behalf of the Consultant and Cobb, and the Company shall not be required to withhold income, employment or other taxes from payments to the Consultant. Neither the Consultant nor Cobb are authorized to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of, the Company or to bind the Company in any manner.

12. Notices. All notices required or permitted under this Agreement shall be in writing and shall be deemed effective upon personal delivery or upon deposit in the United States Post Office, by registered or certified mail, postage prepaid, addressed to the other party at the address shown above, or at such other address or addresses as either party shall designate to the other in accordance with this Section 12.

13. Pronouns. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

14. Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement, including, but not limited to, the consulting agreement entered into by the Consultant and the Company as of December 12, 2018, as amended.

15. Amendment. This Agreement may be amended or modified only by a written instrument executed by both the Company and the Consultant.

16. Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the laws of the State of New York without regard to conflict of law principles that would result in the application of any law other than the State of New York.

17. Successors and Assigns. This Agreement shall be binding upon, and inure to the benefit of, both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to its assets or business, provided, however, that the obligations of the Consultant shall not be assigned by it.

18. Interpretation. If any restriction set forth in Section 2 or Section 8 is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

19. Miscellaneous.

1.1 No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar or waiver of any right on any other occasion.

1.2 The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

1.3 In the event that any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

1.4 This Agreement may be executed in multiple counterparts by facsimile or other reliable electronic reproduction (including, without limitation, transmission by pdf), each of which shall be taken together as one and the same instrument.

1.5 The Consultant, and Cobb on the Consultant's behalf, may be provided from time to time with access to the Company's IT enterprise systems, accounts and equipment. The Consultant agrees, and agrees to cause Cobb, to use these in accordance with existing and/or any future Company policies and practices. The Consultant further agrees that it shall not, and shall cause Cobb to not, provide access to these systems, accounts and equipment to anyone else, either employee or third party.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year set forth above.

NEUROGENE INC.

By: /s/ Christine Mikail April 19, 2024
Name: Christine Mikail
Title: President, Chief Financial Officer

STUART COBB CONSULTING LTD

/s/ Stuart Cobb April 19, 2024
Stuart Cobb

Exhibit 31.1

CERTIFICATIONS

I, Donna M. Cochener, Rachel McMinn, certify that:

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

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 14, 2023 May 10, 2024

/s/ Donna M Cochener Rachel McMinn

Donna M Cochener Rachel McMinn

Interim Chief Executive Officer (Principal Executive Officer)

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Sean Smith, Christine Mikail, certify that:

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

   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 14, 2023 May 10, 2024

/s/ Sean Smith Christine Mikail

Sean Smith Christine Mikail

Interim President and Chief Financial Officer (Principal Financial Officer)

(Principal Financial Officer)

Exhibit 32.1

NEOLEUKIN THERAPEUTICS, NEUROGENE 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 on Form 10-Q of Neoleukin Therapeutics, Neurogene Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2023 March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Donna M. Cochener, Interim Rachel McMinn, Chief Executive Officer of the Company, and Sean Smith, Interim Christine Mikail, President and Chief Financial Officer of the Company, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his her 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 November 14, 2023 May 10, 2024.

/s/ Donna M. Cochener Rachel McMinn	/s/ Sean Smith Christine Mikail
Donna M. Cochener Rachel McMinn	Sean Smith Christine Mikail
Interim Chief Executive Officer	*Interim President and Chief Financial Officer*
(Principal Executive Officer)	(Principal Financial Officer)

This certification accompanies is being furnished solely to accompany the Form 10-Q Report pursuant to which it relates, 18 U.S.C. Section 1350, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Neoleukin Therapeutics, Neurogene 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.

Note: A signed original of this written statement required by §906 has been provided to Neurogene Inc. and will be retained by Neurogene Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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