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

FORM 10-Q

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

For the quarterly period ended March 31, 2025

OR

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

For the transition period from _____ to _____

Commission file number 001-42567

NEONC TECHNOLOGIES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**95-1954864**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
23975 Park Sorrento Suite 205 Calabasas, CA	**91302**
(Address of Principal Executive Offices)	(Zip Code)

(310) 663-7831
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value per share	NTHI	Nasdaq Global Market

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

There were 19,026,776 shares of common stock outstanding as of May 9, 2025.

Explanatory Note

In this report, the term "Company", "we", "us", and "our refers to ***NEONC TECHNOLOGIES HOLDINGS, INC.*** *and its wholly-owned subsidiary.*

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of the federal securities laws. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the operating results and financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to, statements about:

- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our estimates of the size of our market opportunities;
- our ability to effectively manage our growth;
- our ability to successfully enter new markets, manage our growth expansion and comply with any applicable laws and regulations;
- the effects of increased competition from our market competitors;
- significant disruption in, or breach in security of, our information technology systems and resultant interruptions in service and any related impact on our reputation;
- the attraction and retention of qualified employees and key personnel;
- the effectiveness of our internal controls;
- changes in laws and government regulation affecting our business;
- the impact of adverse economic conditions;
- the sufficiency of our cash and cash equivalents to meet our liquidity needs and service our indebtedness; and
- outcomes of legal or administrative proceedings.

In addition, in this report, the words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "predict," "potential" and similar expressions, as they relate to our Company, our business and our management, are intended to identify forward-looking statements. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

Forward-looking statements speak only as of the date of this report. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable laws. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

You should read this report and the documents that we reference in this report and have filed with the Securities and Exchange Commission ("SEC") as exhibits to this report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

NEONC TECHNOLOGIES HOLDINGS, INC.
Condensed Consolidated Balance Sheets

	March 31, 2025 (Unaudited)	December 31, 2024
Assets		
Current Assets		
Cash and cash equivalents	$ 5,439,210	$ 64,893
Deferred offering costs - current	96,880	1,071,947
Debt issuance costs - current	671,804	671,804
Prepaid expenses and other	1,152,297	410,085
Total Current Assets	7,360,191	2,218,729
Non-Current Assets		
Debt issuance costs - net of current portion	1,030,561	1,198,512
Deferred offering costs - net of current portion	50,939	-
Total Assets	**$ 8,441,691**	**$ 3,417,241**
Liabilities and Shareholders' Deficit		
Current Liabilities		
Accounts payable	$ 4,025,244	$ 2,917,801
Accounts payable - related parties	118,011	628,277
Accrued advisory fee - related party	8,828,565	-
Litigation settlement payable	4,648,750	4,641,250
Accrued compensation	444,766	734,874
Total Current Liabilities	18,065,336	8,922,202
Commitments and contingencies		
Shareholders' Deficit:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; no shares were issued and outstanding as of March 31, 2025 and December 31, 2024	-	-
Common stock, $0.0001 par value, 100,000,000 shares authorized; 19,026,776 and 18,090,526 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	1,903	1,809
Additional paid in capital	78,984,884	45,101,675
Accumulated deficit	(88,610,432)	(50,608,445)
Total Shareholders' Deficit	(9,623,645)	(5,504,961)
Total Liabilities and Shareholders' Deficit	**$ 8,441,691**	**$ 3,417,241**

See accompanying notes to the condensed consolidated financial statements.

NEONC TECHNOLOGIES HOLDINGS, INC.
Condensed Consolidated Statements of Operations (Unaudited)

	For the Three Months Ended March 31,	
	2025	**2024**
Revenues:		
Revenue	$ 39,990	$ 43,000
Operating Expenses:		
Research and development	998,222	614,517
Legal and professional	957,545	564,354
General and administrative	849,485	415,612
Share based compensation	23,073,745	-
Advisory fees	11,737,806	-
Total Operating Expenses	37,616,803	1,594,483
Loss From Operations	(37,576,813)	(1,551,483)
Other Income and Expense:		
Interest income	51,699	-
Amortization of debt issuance costs	(167,951)	-
Interest expense - related parties	(308,922)	(1,387,493)
Net Loss	$ (38,001,987)	$ (2,938,976)
Loss per share:		
Net loss per share - basic and diluted	$ (2.10)	$ (0.18)
Weighted average number of common shares outstanding during the period - basic and diluted	18,135,317	16,560,000

See accompanying notes to the condensed consolidated financial statements.

NEONC TECHNOLOGIES HOLDINGS, INC.
Condensed Consolidated Statements of Changes in Shareholders' Deficit (Unaudited)

	Common Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance - January 1, 2024	16,560,000	$ 1,656	$ 24,720,072	$ (38,709,981)	$ (13,988,253)
Net loss	-	-	-	(2,938,976)	(2,938,976)
Balance - March 31, 2024	16,560,000	$ 1,656	$ 24,720,072	$ (41,648,957)	$ (16,927,229)
Balance - January 1, 2025	18,090,526	$ 1,809	$ 45,101,675	$ (50,608,445)	$ (5,504,961)
Sale of common stock, net of offering costs	727,750	73	10,252,425	-	10,252,498
Common stock issued for advisory services	46,000	5	557,055	-	557,060
Cashless exercise of warrants	162,500	16	(16)	-	-
Stock based compensation	-	-	23,073,745	-	23,073,745
Net loss	-	-	-	(38,001,987)	(38,001,987)
Balance - March 31, 2025	19,026,776	$ 1,903	$ 78,984,884	$ (88,610,432)	$ (9,623,645)

See accompanying notes to the condensed consolidated financial statements.

NEONC TECHNOLOGIES HOLDINGS, INC.
Condensed Consolidated Statements of Cash Flows (Unaudited)

	For the Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (38,001,987)	$ (2,938,976)
Adjustments to reconcile net loss to net cash used in operating activities:		
Increase in bridge loan - expenses paid by bridge loan provider on behalf of the Company	-	476,393
Accretion of original issue discount on bridge loans - related party	300,000	1,387,493
Share based compensation - restricted stock	23,073,745	-
Amortization of debt issuance costs and deferred offering costs	577,192	-
Changes in operating assets and liabilities:		
Prepaid expenses	(765,738)	103,271
Accrued compensation	(290,108)	116,500
Accrued advisory fee	8,828,565	-
Accounts payable - related parties	628,276	1,001,066
Net cash provided by (used in) operating activities	(5,650,055)	145,747
Cash flows from financing activities:		
Proceeds from the sale of common stock	11,324,372	-
Proceeds from related party loan	300,000	670,954
Repayment of related party loan	(600,000)	(718,708)
Deferred offering costs	-	(124,841)
Net cash provided by (used in) financing activities	11,024,372	(172,595)
Net increase (decrease) in cash and cash equivalents	5,374,317	(26,848)
Cash and cash equivalents - beginning of period	64,893	31,862
Cash and cash equivalents - end of period	$ 5,439,210	$ 5,014
Supplemental disclosure of non-cash financing activities:		
Original issue discount on bridge loan - related party	$ 300,000	$ 7,116,335
Common stock issued in connection with private placement	$ 557,060	$ -
Right of use asset, at lease commencement	$ -	$ 536,605
Reclassification of deferred offering costs to APIC at the completion of the offering	$ 1,391,580	$ -

See accompanying notes to the condensed consolidated financial statements.

Note 1 – Description of Business and Liquidity

NeOnc Technologies, Inc. ("NTI") was incorporated on April 13, 2005, as a California corporation. On April 7, 2023, NTI merged into NeOnc Technologies Holdings, Inc. ("NTHI" and the combined entities "NeOnc" or the "Company"). NTHI was incorporated January 5, 2023, as a Delaware Corporation.

NeOnc is the developer of a novel molecular technology that provides enhanced targeted delivery of technologies for treating central nervous system diseases. The Company's lead product, NEO100 is in clinical trials treating glioblastoma, and has Orphan Drug and Fast Track designation from the United States Food and Drug Administration ("FDA"). The Company licensed the underlying technology from the University of Southern California. ("USC").

On October 11, 2024, the Company entered into an agreement with a broker dealer to serve as placement agent and provide broker services in connection with the proposed sale of common stock up to $10,000,000. Under this agreement, through December 31, 2024, the Company closed on commitments from investors to purchase 625,000 shares of common stock of the Company at $16 per share for total commitments of $10,000,000, which were to be held in escrow until the Company's registration statement was declared effective. During the three months ended March 31, 2025, prior to the Company having an effective registration statement, the Company closed on an additional commitment to purchase 102,750 shares of common stock of the Company at $16 per share, for total commitments of $1,644,000, On March 10, 2025, the Company's registration statement was declared effective at which time the $11,644,000 in escrow was released to the Company. On March 26, the Company was listed ("Listing") on the NASDAQ global markets.

Liquidity

The accompanying financial statements have been prepared on the basis that the Company is a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. At March 31, 2025, the Company had cash totalling $5,439,210. For the three months ended March 31, 2025, the Company incurred a net loss of $38,001,987 and has an accumulated deficit of $88,610,432 at March 31, 2025. The Company has financed its working capital requirements to date primarily through the sale of common stock, preferred stock, shareholder loans and related party bridge loans.

The Company does not have sufficient available capital to fund operations for a period of twelve months from the issuance date of these financial statements. The Company does not know whether additional financing will be available when needed, whether it will be available on favorable terms, or if it will be available at all. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Other risks and uncertainties

The Company is subject to risks common to biopharmaceutical companies, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, and the uncertainty of market acceptance of products and the potential need to obtain additional financing. The Company is dependent on third-party suppliers and, in some cases, single-source suppliers. The Company's products require approval or clearance from the FDA prior to commencing commercial sales in the United States. Approvals or clearances are also required in foreign jurisdictions where the Company may license or sell its products. There can be no assurance that the Company's products will receive all required approvals or clearances.

There can be no assurance that the Company's products, if approved, will be accepted in the marketplace, nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost with appropriate performance characteristics or that such products will be successfully marketed, if at all.

Note 2 – Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

The unaudited condensed consolidated financial statements contained herein have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Certain information and note disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to SEC rules and regulations, although the Company believes that the disclosures made are adequate to make the information not misleading. Accordingly, the condensed consolidated financial statements reflect all normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the results of interim periods and may not include all disclosures required by accounting principles generally accepted in the United States ("GAAP"). The information as of March 31, 2025, and for the three months ended March 31, 2025, is unaudited, whereas the consolidated balance sheet as of December 31, 2024, is derived from the Company's audited condensed consolidated financial statements as of that date. These condensed consolidated financial statements and notes hereto should be read in conjunction with the consolidated financial statements and notes thereto included in the audited financial statements for the year ended December 31, 2024, included on Form S-1, filed with the SEC on February 26, 2025.

The results of operations for the interim periods presented are not necessarily indicative of results to be expected for any other interim period or for the year.

Principles of consolidation

The accompanying condensed consolidated financial statements and related notes to the condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

In preparing the Company's financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents

The Company, from time to time during the period covered by these financial statements, may have had bank account balances in excess of federally insured limits. The Company has not experienced losses in such accounts. For the statements of cash flows, the Company considers all short-term investments purchased with a maturity of three months or less to be cash equivalents. At March 31, 2025 and 2024, the Company has money market funds in the amount of approximately $5,440,000 and $0, respectively.

Deferred offering costs

The Company complies with the requirements of the ASC 340-10-S99-1 and SEC Staff Accounting Bulletin ("SAB") Topic 5A "*Expenses of Offering*". Offering costs consist principally of professional and registration fees incurred through the condensed consolidated balance sheet dated December 31, 2024 that are related to the planned public offering of its securities (See Note 3). These costs have been capitalized and were recognized in equity upon the completion of the securities offering. At March 31, 2025, deferred offering costs consist of the fair value of shares issued in conjunction with the issuance of an equity purchase agreement. These costs have been capitalized and are being amortized over the term of the availability of the equity purchase agreement (Note 6). If planned offerings are terminated, the related capitalized deferred offering costs are written off.

Debt issuance costs

Debt issuance costs represent costs directly attributable to warrants issued for a line of credit commitment. Such costs represent the fair value of warrants issued to the debt facility provider, and are amortized to the statement of operations on a straight-line basis which approximates the effective interest rate method, over the term of the debt instrument. The debt issuance costs, net of accumulated amortization is classified as a long-term asset until the Company begins to draw funds from the debt facility in accordance with ASC 815: "*Derivatives and Hedging*". At such time, the pro-rata portion of amounts borrowed as compared to the total debt facility will be reclassified as a contra-debt account.

Warrants

The Company evaluates the terms of warrants issued and determines if the instrument requires liability or equity accounting classification under ASC 815: Derivatives and Hedging and ASC 480: "*Distinguishing Liabilities from Equity*".

Leases

The Company classifies its leases either as operating or financing lease at inception. The company has an operating lease. This lease is recorded as an operating lease, right of use (ROU) assets and operating lease liabilities on the accompanying consolidated balance sheets.

Operating lease ROU assets and the related lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The operating lease ROU assets also include lease incentives and initial direct costs incurred. For operating leases, interest on the lease liability and the amortization of ROU asset result in straight-line rent expense over the lease term. Leases may include options to extend or terminate the lease which are included in the ROU operating lease assets and operating lease liability when they are reasonably certain of exercise. Certain leases include lease and non-leased components, which are accounted for as one single lease component. Operating lease expense associated with minimum lease payments is recognized on a straight-line basis over the lease term.

Fair value measurements

FASB ASC Topic 820, "*Fair Value Measurements and Disclosures*" ("ASC 820"), defines fair value, the methods used to measure fair value and the expanded disclosures about fair value measurements. Fair value is the price received to sell an asset or paid to transfer a liability in an orderly transaction between the buyer and the seller at the measurement date. In determining fair value, the valuation techniques consistent with the market approach, income approach and cost approach shall be used to measure fair value. ASC 820 establishes a fair value hierarchy for inputs, representing the assumptions the buyer and seller use in pricing the asset or liability. These inputs are further defined as observable and unobservable inputs. Observable inputs are those that the buyer and seller would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs reflect the Company's assumptions about the inputs the buyer and seller would use to price the asset or liability developed based on the best information available in the circumstances.

The Company's money market funds are valued at quoted prices in active markets and are classified as Level 1 within the fair value hierarchy. The carrying value of the Company's accounts payable approximates its fair value because of the short-term nature of these financial instruments. The note payable - related party is reported at fair value as the Company elected the fair value option for such note (see Note 4).

The fair value hierarchy is categorized into three levels based on the inputs as follows:

- Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access. Valuation adjustments and block discounts are not being applied. Since valuations are based on quoted prices that are readily and regularly available in an active market, the valuation of these securities does not entail a significant degree of judgment.

- Level 2 — Valuations based on (i) quoted prices in active markets for similar assets and liabilities, (ii) quoted prices in markets that are not active for identical or similar assets, (iii) inputs other than quoted prices for the assets or liabilities, or (iv) inputs that are derived principally from or corroborated by the market through correlation or other means.

- Level 3 — Valuations based on unobservable inputs and significant to the overall fair value measurement.

Revenue

The Company recognized point-in-time revenue of $39,900 and $43,000 for the three months ended March 31, 2025 and 2024, respectively, for the sale/license of technology where the Company has no further performance obligations.

Research and development

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors performing research, conducting clinical trials, and manufacturing drug supplies and materials.

Patent costs

All patent-related costs incurred in filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as legal and professional expenses in the accompanying consolidated statements of operations.

Share-based compensation

The Company has granted stock options and common shares to employees, non-employee consultants and non-employee members of our Board of Directors. The Company measures the compensation cost associated with all share-based payments based on the grant date fair values. Compensation costs associated with grants of common shares are measured at fair value at the date of grant, which has historically been the most recent price paid by investors to purchase shares of the Company's common stock prior to such grant. The Company recognizes share-based compensation expense over the requisite service period of each award, which generally equals the vesting period, using the straight-line method for awards that contain only service conditions. If the stock grant is contingent upon events that have not yet happened, then the grant is not considered issued. If an award holder leaves the company prior to vesting, and adjustment of the compensation expense will be made to reflect only those awards that vested.

The Company recognizes the stock-based compensation expense for the restricted stock units ("RSU") based upon the fair value of the common stock at the date of the grant. The expense is recognized over the service period provided in the RSU awards, however expense will not be recognized until the Listing date, as prior to such date it was not probable that condition to commence vesting would be met.

When the vesting contingency is met, the Company will commence to recognize expense related to the RSU's. For time based vested RSU's, the expense will be recognized on a straight-line basis from the grant date to the last vesting date. The expense recognized will include the expense from the date of the grant over the total vesting period and reflect the portion attributable to the service provided prior to the listing. For performance based RSU's, the Company will determine the probability of the contingency being met each quarter end based upon an assessment of progress made under such performance criteria.

Net loss per share

Basic net loss per share is computed by dividing net loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the sum of the weighted average number of common shares outstanding during the period. For periods in which the Company reports a net loss, the diluted net loss per share is the same as basic net loss per share.

For the three months ended March 31, 2025 there are potentially dilutive securities outstanding of 150,000 and 3,110,000 potentially dilutive restricted stock units which are not included in the diluted net loss per share calculation since their effect is anti-dilutive. For the three months ended March 31, 2024, there were no potentially dilutive warrants outstanding and no potentially dilutive restricted stock units.

Income taxes

The Company recognizes federal, state, and foreign current tax liabilities or assets based on its estimate of taxes payable to or refundable by tax authorities in the current fiscal year. For the periods ended March 31, 2025 and 2024, there is no current tax provision due to losses generated. The Company also recognizes federal and state deferred tax liabilities or assets based on the Company's estimate of future tax effects attributable to temporary differences and carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years those temporary differences are expected to be recovered or settled.

Deferred tax assets are reduced by valuation allowances if, based on the consideration of all available evidence, it is more likely than not that some portion of the deferred tax asset will not be realized. The Company evaluates deferred income taxes quarterly to determine if valuation allowances are required by considering available evidence. If the Company is unable to generate sufficient future taxable income in certain tax jurisdictions, or if there is a material change in the actual effective tax rates or time period within which the underlying temporary differences become taxable or deductible, the Company could be required to increase its valuation allowance against its deferred tax assets which could result in an increase in the Company's effective tax rate and an adverse impact on operating results. The Company will continue to evaluate the necessity of the valuation allowance based on the remaining deferred tax assets. The difference between the statutory and effective rates for the years ended March 31, 2025 and 2024 is a result of the Company applying a full valuation allowance against any deferred tax assets as a result of net operating losses due to uncertainties surrounding the usability of such net operating losses. The ability to utilize such net operating loss carry forwards may be limited due to possible changes in ownership as defined under Internal Revenue Code section 382.

The Company follows the accounting guidance related to financial statement recognition, measurement and disclosure of uncertain tax positions. The Company recognizes the impact of an uncertain income tax position on an income tax return at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it is less than 50% likely to be sustained. Uncertain tax positions are recognized in the first subsequent financial reporting period in which that threshold is met or from changes in circumstances such as the expiration of applicable statutes of limitations. The Company will recognize interest and penalties related to tax positions in income tax expense.

Segment Reporting

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, "*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*." The standard expands reportable segment disclosure requirements for public business entities primarily through enhanced disclosures about significant segment expenses that are regularly provided to the chief operating decision maker ("CODM") and included within each reported measure of segment profit (referred to as the "significant expense principle"). The standard has been adopted for our fiscal year 2024 annual financial statements and interim financial statements thereafter and have applied this standard retrospectively for all prior periods presented in the financial statements.

Note 3 – Related party transactions

AFH Holdings and Advisory, LLC advisory agreement

On December 19, 2022, the Company entered into an advisory agreement with AFH Holdings and Advisory, LLC ('AFH') an affiliate to assist the Company in connection with its intent to affect a public listing. AFH was retained to assist the Company with investor presentations and decks, coordinate the retention of an investment banker for an initial public offering, identify legal and accounting professionals to assist in connection with such public offering, identify investor relations/public relations firms, advise on private capital markets activities prior to the initial public offering and coordinate the closing process for the offering.

On July 12, 2024, the Company amended the AFH advisory agreement section to allow for an upfront payment on the listing date of $2,500,000 and the remaining amount of the fee to be paid in equal monthly instalments for one year. AFH was paid a fee of $500,000 for the amendment.

On March 26, 2025, and as a result of the listing of the Company on Nasdaq, the Company incurred $11,328,565 for the fee earned in accordance with the AFH advisory agreement which was recorded as advisory fee expense in the condensed consolidated statement of operations. In accordance with the amendment, the Company paid $2,500,000 of such fee on March 26, 2025. The remaining balance of $8,828,565, recorded on the condensed consolidated balance sheet at March 31, 2025 within accrued advisory fee – related party, is payable in 12 equal monthly installments commencing in April 2025.

In addition, the Company agreed to retain AFH as an exclusive advisor to the Company on all financing and mergers and acquisitions for a period of two (2) years from the closing of the private securities offering.

Transactions with USC

The Company maintains a license agreement with USC, under which the Company will pay USC an annual patent maintenance fee of $20,000 and nonrefundable earned royalties of 4% on Net Sales (as defined in the Amended Agreement) of Licensed Products covered by the licensed patents in all countries in which the manufacture, use, sale, offer for sale, or import of such Licensed Products, as such capitalized terms are defined in the Amended Agreement. To date, no sales have been made using Licensed Products, and no royalties are due to USC. In addition, the Company will assume responsibility for patent-related costs.

The Company also utilizes laboratory and patent maintenance services from USC. The Company incurred $102,224 and $72,234 related to such services for the three months ended March 31, 2025 and 2024, respectively, of which $82,224 and $72,234 are recorded within research and development expenses and $20,000 and $0 are recorded within general administrative expenses on the condensed consolidated statements of operations. At March 31, 2025 and December 31, 2024, the Company has outstanding payables to USC for such services of $118,011 and $272,328 respectively, which is included in accounts payable - related parties in the accompanying consolidated balance sheets.

Accrued compensation

The amount accrued for the management team, including related payroll taxes, was $444,766 and $734,874 as March 31, 2025 and December 31, 2024, respectively.

Note 4 – Related Party Loans Payable

Bridge Loan

In April 2023, the Company entered into a non-interest bearing, non-convertible promissory note with HCWG LLC (the "Bridge Loan"). Borrowings under the Bridge Loan carry a 50% (or 1 times cash amounts borrowed) original issue discount ("OID") on principal and through subsequent amendments the maximum cash borrowing was increased to $10,000,000. The outstanding amounts under this Bridge Loan were payable at the earlier of the date the Company completes an IPO or December 4, 2024 (the "Maturity Date").

Through March 31, 2024, the Company had received under the Bridge Loan an aggregate of $7,116,335. The OID was recognized ratably over the term of each draw-down under the Bridge Loan through the Maturity Date unless settled earlier, at which point the accretion is accelerated. Accretion of the OID for the three months ended March 31, 2024, amounted to $1,387,493, which is included in interest expense in the accompanying consolidated statement of operations. Summary of the bridge loan activity for the three months ended March 31, 2024 is as follows:

	For the three months ended March 31, 2024
Bridge loan – carrying value	
Balance – January 1, 2024	$ 9,802,697
Borrowings	1,147,347
OID	1,147,347
Repayments	(718,708)
Balance – March 31, 2024	$ 11,378,683

On June 14, 2024, the Company reached an agreement with HCWG LLC to convert the outstanding principal and interest on the Bridge Loan into 979,039 shares of common stock. As a result of this conversion, the Bridge Loan was terminated and is no longer available to the Company for borrowing. The Company has a receivable due from HCWG LLC totaling $148,705 which is recorded within prepaid expenses and other on the condensed consolidated balance sheet at March 31, 2025 and December 31, 2024.

Advances from Executive Chairman

In February 2025, our Executive Chairman advanced the Company approximately $300,000. The advances carry a 50% (or 1 times amounts borrowed) original issue discount (“OID”) on the principal. On March 10, 2025, the advance and 1x interest was repaid. Interest expense in the amount of $300,000 is included in the condensed consolidated statement of operations as interest expense – related parties for the three months ended March 31, 2025.

NOTE 5 – LEASES

On February 1, 2024, the Company entered a 24-month lease for office space, which calls for a monthly base rent of $25,000, increasing at 3% per annum. The Company has only one operating lease and has no financing leases. The Company’s lease does not contain options to renew or extend the lease term or options to terminate leases early, except for insolvency. In calculating the present value of future lease payments, the Company utilized its incremental borrowing rate based on the lease term. The Company’s net lease non-lease components (e.g., standard area maintenance, maintenance, consumables, etc.) are paid separately from rent based on actual costs incurred and, therefore, are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. On November 27, 2024, the Company amended the lease expiration date from January 31, 2026, to January 31, 2025.

As of December 31, 2024, the consolidated balance sheet reflects a right-of-use asset of $23,526 and a lease liability of $24,722 included in the condensed consolidated statement of operations in general and administrative expenses. The Company recorded lease expense of $24,722 and $55,468 during the three months ended March 31, 2025, and 2024, respectively, within general and administrative expenses on the consolidated statements of operations. Cash paid for amounts included in the measurement of lease liability was $25,000 and $55,000, respectively, during the three months ended March 31, 2025 and the year ended December 31, 2024, respectively. The lease liability was computed using an interest rate of 13.49% and as of December 31, 2024, the lease has a remaining life of one month .

NOTE 6 – COMMON AND PREFERRED STOCK

The total number of shares of common stock available for issue by NTHI is 100,000,000 shares of common stock at $0.0001 par value per share and the total number of shares of preferred stock is 10,000,000 at a par value of $0.0001. As of March 31, 2025, no preferred shares have been issued. The board of directors is authorized, subject to any limitations prescribed by law, to provide for the issuance of shares of Preferred Stock in one or more series, and by filing a certificate pursuant to the applicable law of the State of Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences, and rights of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereof. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the Common Stock, without a vote of the holders of the Preferred Stock, or any series thereof, unless a vote of any such holders is required pursuant to the terms of any Preferred Stock Designation.

During the three months ended March 31, 2025, the Company sold 727,750 shares of common stock at a price of $16 per share for gross proceeds of $11,644,005 pursuant to a private placement of its securities, issued 46,000 shares as part of advisory services related to the listing and as part of the private placement fee for our equity line of credit, 162,500 shares were issued for the cashless exercise of warrants, and the release of 3,110,000 shares for restricted stock units.

The net proceeds from the sale of common stock were calculated as follows:

Gross proceeds from sale of common stock	$ 11,644,005
Less:	
Reclassification of deferred offering costs to APIC at the completion of the offering	(1,391,580)
Net proceeds from the sale of common stock	$ 10,252,425

Private Placement

On October 11, 2024, the Company entered into an agreement with RBW Capital Partners LLC, a division of Dawson James Securities, Inc. ("Broker") to serve as placement agent and provide broker services in connection with the possible sale of common stock up to $10 million. If a sale is made between the Company and any institutional or individual third-party funding source introduced by the placement agent, the Company will pay a placement fee of 8% of the gross proceeds. In addition, the company agrees to pay; (a) 1.0% of the gross proceeds for non-accountable expenses; and (b) out of pocket expenses plus the costs associated with the use of a third-party electronic road show service up to $10,000. The agreement expired on January 11, 2025 and was amended and restated on January 29, 2025 to extend the term for another six months through July 29, 2025 and increasing the placement fee to 12% from 8% of the gross proceeds, and eliminated the 1% non-accountable expense fee.

Under this agreement, through December 31, 2024, the Company closed on commitments from investors to purchase 625,000 shares of common stock of the Company at $16 per share for total commitments of $10,000,000, which were to be held in escrow until the Company's registration statement was declared effective. During the three months ended March 31, 2025, prior to the Company having an effective registration statement, the Company closed on an additional commitment to purchase 102,750 shares of common stock of the Company at $16 per share, for total commitments of $1,644,005, also to be held in escrow until the Company's registration statement was declared effective. On March 25, 2025, the Company's registration statement was declared effective at which time the $11,644,005 in escrow was released to the Company.

In connection with the agreement, the Company paid $300,000 in placement agent fees to Broker for securing $2,500,000 in commitments for the Private Placement. This fee was paid when the funds were released from escrow and recorded as a reduction to additional paid-in capital on the condensed consolidated statement of shareholders' deficit as of March 31, 2025.

Advisory Services

On October 3, 2024, as amended on January 23, 2025, the Company entered into an agreement with Broker, for financial advisory and investment banking services in connection with a direct listing of the Company's common stock on the Nasdaq Global Market or other major US market. The agreement provides for a one-time fee of $250,000 payable three days after the direct listing and the issuance of 30,000 shares of common stock (which are restricted until the shares are registered by filing a resale S-1 within 30 days after the effective date of the direct listing). In addition, the Company agreed to pay up to $100,000 for fees and expenses of legal counsel and other out-of-pocket expenses plus the costs associated with the use of a third-party electronic road show service. Such fees were included in accounts payable and deferred offering costs in the accompanying consolidated balance sheets as of December 31, 2024. The fair value of the 30,000 shares issued in March 2025, amounting to $363,300, was determined using the closing day price of $12.11. This amount was recorded as an advisory fee on the condensed consolidated statement of operations as of March 31, 2025. The agreement expired on January 3, 2025 and was amended and restated on January 23, 2025 to extend the term for another six months through July 23, 2025. No additional fees are expected under this agreement.

Deferred Offering Costs

Deferred offering costs relating to the Private Placement and direct listing at December 31, 2024 totaled $1,071,947. At March 31, 2025, this amount plus $319,561 incurred in the quarter ended March 31, 2025 was reclassified against the common stock issued in the condensed consolidated statement of changes in shareholder's deficit.

Equity Purchase Agreement

On October 22, 2024, we entered into an equity purchase agreement (the "Equity Purchase Agreement") with Mast Hill Fund, LP ("Mast Hill") pursuant to which the Company may sell and issue to Mast Hill, and the investor may purchase from the Company, up to $50,000,000 of Company's common shares. Under the Equity Purchase Agreement, the Company has the right, but not the obligation, to direct Mast Hill, by its delivery to the Mast Hill of a Put Notice from time to time, to purchase Put Shares (i) in a minimum amount not less than $50,000 and (ii) in a maximum amount up to the lesser of (a) $750,000 or (b) 150% of the average trading volume of the Company's common stock during the five trading days immediately preceding the Put Date. The Company could draw down any funds under the Equity Purchase Agreement until the Company has an effective registration statement.

The actual amount of proceeds we receive pursuant to each Put Notice (each, the "Put Amount") is determined by multiplying the Put Amount requested by the applicable purchase price. The purchase price for each of the Put Shares equals 95% of the Market Price, (as defined below) less the Clearing Costs (as defined below). Market Price is the lowest volume weighted average prices of the Company's common shares on its principal market on any trading day during the Valuation Period (as defined below). The Valuation Period is the five trading days immediately following the date on which Mast Hill receives the Put Shares in its brokerage account. Clearing Costs are all the fees incurred by Mast Hill with respect to its brokerage firm, clearing firm, Company transfer agent fees, and attorney fees, with respect to the Put Shares.

The term of the Equity Purchase Agreement will commence on the effective date of the direct listing and will terminate on the earlier of i) the date on which the Mast Hill shall have purchased Put Shares equal to the $50,000,000, (ii) twenty-four (24) months after the date of the Equity Purchase Agreement, (iii) written notice of termination by the Company to Mast Hill, (iv) this Registration Statement is no longer effective after the initial effective date of this Registration Statement, or (v) the date that, pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company, a receiver, trustee, assignee, liquidator or similar official is appointed for the Company or for all or substantially all of its property or the Company makes a general assignment for the benefit of its creditors. As of March 31, 2025, nothing has been transacted under this agreement.

In connection with this agreement, we issued 16,000 shares of common stock to Mast Hill. The fair value of the shares granted to Mast Hill upon issuance was determined by using the closing day price of $12.11. Such amount net of amortization was recorded as deferred offering cost on the condensed consolidated balance sheet as of March 31, 2025. For the period ended March 31, 2025, the Company reported $45,941 as amortization expense in the condensed consolidated statement of operations, and the remaining deferred offering costs of $147,819 at March 31, 2025 are to be amortized over the remaining term of the Equity Purchase Agreement.

NOTE 7 – SEGMENT REPORTING

The company manages our business activities on a consolidated basis and operates as a single operating segment: Biotechnology. The accounting policies of the Biotechnology segment are the same as those described in Note 1 – Summary of Significant Accounting Policies.

Our Chief Operating Decision Maker ("CODM") is our President and Chief Executive Officer, Dr. Chen. The CODM uses net loss, as reported on our condensed consolidated statement of operations, in evaluating the performance of the biotechnology segment and determining how to allocate resources of the Company as a whole, including investing in our research and development programs and acquisition/licensing strategy. The CODM does not review assets in evaluating the results of the biotechnology segment, and therefore, such information is not presented. The following supplemental information breaks down the research and development costs for the three months ended March 31, 2025 and 2024, respectively.

	For the Three Months ended March 31,	
	2024	**2023**
Revenues	$ 39,990	$ 43,000
Less: Significant and other segment expenses:		
NEO100	579,462	285,612
NEO100-02	108,461	27,064
NEO212	176,555	161,734
Pediatric	48,832	67,397
Laboratory	84,912	72,710
Total clinical trial expense	998,222	614,517
Advisory fee	11,737,806	-
Legal and accounting	957,545	564,354
Travel	170,273	156,500
Debt issuance and deferred offering costs amortization	167,951	-
Investor relations	544,307	121,812
Share based compensation	23,073,745	-
General and administrative expense	134,905	137,299
Interest expense - related parties' loans	308,922	1,387,493
Interest income	(51,699)	-
Net loss	$ (38,001,987)	$ (2,938,976)

NOTE 8 – STOCK-BASED COMPENSATION

On April 12, 2023, the Company adopted the 2023 Equity Incentive Plan (the "2023 Plan"), which allows the issuance of up to 3,440,000 shares of the Company's authorized and unissued common stock in the form of incentive stock options, non-qualified stock options, restricted stock units, performance share units, or other forms of equity as may be added in the future to employees, directors and consultants of the Company and its affiliates. The allowable number of shares that can be issued under the 2023 Plan increased upon the completion of the listing to 4,764,507 which represents the 20% of the fully diluted capitalization of the Company on the closing of Company's initial public price.

In January and February 2024, 2,460,000 and 200,000, respectively, restricted stock units ("RSUs") were granted to the executive officers and members of the Board of Directors further to the 2023 Plan as described above. Of the total RSUs granted (tranche 1) 1,686,667 vest 100% seven months from the date that the Company lists on a national exchange, (tranche 2) 486,667 will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of the listing on a national exchange and (tranche 3) 486,666 are performance-based, the vesting of which will be predicated on certain financial and operational performance metrics being met after the effective date of the listing on a national exchange as set forth the grant agreements. Since tranche 3 is performance based, it is not yet probable that all of the performance vesting conditions will be met and as such no expense has been recognized for tranche 3 as of March 31, 2025.

On October 23, 2024, 200,000 RSUs were granted to each of the CEO and the Executive Chairman, for a total of 400,000, and 100,000 granted to two members of the Board of Directors were canceled. These RSUs vest 100% seven months from the date the Company lists on a national exchange.

On March 26, 2025, 150,000 RSUs were granted to the three board members, in the amount of 50,000 each. These RSUs vest 100% seven months from the date the Company lists on a national exchange.

Prior to March 26, 2025, the Company determined that no expense should be recognized for the RSUs since the contingency related to the commencement of vesting (i.e., the listing) of the RSUs had not been met. On March 26, 2025, the listing occurred, satisfying the contingency required for vesting to begin and defining the service period.

The Company determined the fair value of the RSUs at their respective grant dates to be $37,336,500, based on the price of the most recent sale of common stock prior to each grant date. For the three months ended March 31, 2025, the company recognized $23,073,745 in share-based compensation of which $22,753,463 was amortization from the date of the grant until March 26, 2025, the listing date. As of March 31, 2025, there was unamortized stock-based compensation of approximately $14,262,755 which the Company expects to recognize over approximately 1.8 years.

The activity related to RSUs is summarized as follows:

Restricted Stock Units

Activity	RSUs Granted
2024	
January 1, 2024	-
Granted	3,060,000
Cancelled	(100,000)
December 31, 2024	2,960,000
2025	
Granted during quarter ended March 31, 2025	150,000
Balance at March 31, 2025	3,110,000
Released RSUs at March 31, 2025	-

As of March 31, 2025, 3,110,000 RSU's were granted, and 1,654,500 RSU's remain unissued in the 2023 Plan.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

Line of Credit Commitment – Related Party

On October 11, 2024, the Company entered into a Line of Credit Agreement ("the Agreement") with HCWG for borrowings of up to $10.0 million. Borrowings under the Line of Credit Agreement bear interest at 10.0% per annum and increases to 14% if the Agreement is extended. Interest payments are due on the first business day of each calendar month and unpaid principal is due on October 12, 2027. No amounts have been borrowed under the facility through March 31, 2025.

In connection with the agreement, the Company issued HCWG five-year warrants to purchase up to 312,500 shares of our common stock at an exercise price of $12.00 per share. These warrants expire on October 23, 2029. As of December 31, 2024, there were 312,500 warrants issued, outstanding and fully vested. In March 2025, 162,500 warrants were exercised in a cashless exercise, resulting in the issuance of 162,500 shares of common stock. At March 31, 2025, there are 150,000 shares of common stock remaining available to be purchased under the warrant.

The fair value of the warrants on the grant date was determined using the Black-Scholes valuation model, with the following key assumptions:

- Fair value of common stock: $12.00
- Expected volatility: 86%
- Risk-free interest rate: 4.82%
- Term: 2.5 years

The fair value of warrants at inception was $2,015,413, which was recorded as additional paid-in capital on the condensed consolidated statement of changes stockholders' deficit for the year ended December 31, 2024, and as debt issuance costs on the balance sheet. The debt issuance costs are being amortized over the term of the line of credit and amounted to $167,951 for the three months ended March 31, 2025. At March 31, 2025 and December 31, 2024, unamortized debt issuance costs total $1,030,561 and $1,870,316, respectively, which will be amortized over the remaining 22 months of the facility

Litigation

From time to time, the Company is involved in various disputes, claims, liens and litigation matters arising out of the normal course of business which could result in a material adverse effect on the Company's combined financial position, results of operations or cash flows. Liabilities for loss contingencies arising from claims, assessments, litigation, fines and penalties and other sources are recorded when it is probable that a liability has been incurred, and the amount of the assessment can be reasonably estimated. As of March 31, 2025 and December 31, 2024, the Company had no liabilities recorded for loss contingencies, except as below.

License Agreement - Orient EuroPharma Co., Ltd.

On November 8, 2013, the Company entered into a collaboration agreement ("Agreement") with Orient EuroPharma Co., Ltd. ("OEP"), pursuant to which the parties will develop certain licensed products defined in the Agreement. NeOnc will license OEP the right to commercialize the Company's drug NEO100, a highly purified form of *perillyl alcoho*l ("Licensed Product"), in the territories specified in the license agreement ("Territory").

In 2023, the Company sent notice to OEP indicating their intent to terminate the Agreement with OEP, after which OEP threatened litigation. On February 15, 2024, OEP and the Company entered into a settlement agreement whereas the Company and OEP terminated the Agreement in exchange for a payment in the amount of $4,000,000 payable by the Company to OEP within ten days of the date the Company completes its initial public offering. The Company has a litigation settlement payable of $4,000,000 in the accompanying condensed consolidated balance sheets as of March 31, 2025 and December 31, 2024. As of the date of this filing, the Company has not paid the litigation settlement amount.

On June 6, 2023, a vendor filed a complaint against the Company for breach of contract in the Central District of California. The vendor alleged that the Company improperly terminated an Intellectual Property License and Supply Agreement ("IPLSA") and that the Company also defrauded the vendor in connection with IPLSA. This matter was settled on October 16, 2023, and the Company agreed to pay the vendor $600,000 within 5 business days of the close of the date that the Company completes an IPO or March 31, 2024, whichever occurs first. The Company has a litigation settlement payable in the accompanying condensed consolidated balance sheet at March 31, 2025 and December 31, 2024. As of the date of this filing, the Company has not paid the litigation settlement amount.

On March 31, 2024, a vendor agreed to extend the payment until May 15, 2024 for payment of an additional $25,000, payable on demand. On July 25, 2024, the arbitrator granted the implementation of interest at the statutory rate on the unpaid balance commencing May 15, 2024 until paid, therefore an additional $7,500 of interest expense is recognized in the accompanying condensed consolidated statement of operations during the three months ended March 31, 2025. At March 31, 2025 and December 31, 2024, $48,750 and $41,250 of accrued interest is included in litigation settlement payable in the accompanying condensed consolidated balance sheet at March 31, 2025 and December 31, 2024.

NOTE 10 – SUBSEQUENT EVENTS

On April 7, 2025, the Company entered into a new lease agreement for office space, located in Calabasas, California. The lease term is 5 years and three months commencing on April 14, 2025, with monthly lease payments of approximately $6,778. The lease includes a security deposit of $47,176 and price increases of 3% each year.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from these forward-looking statements as a result of certain factors. For a complete discussion of such risk factors, see the section entitled "Risk Factors". Capitalized terms used herein, but not otherwise defined, shall have the meaning ascribed to those terms in the "Part I - Financial Information," including the related notes to the consolidated financial statements contained therein.

Overview

Our company (f/k/a NAS-ONC, Inc.) was formed in 2008, devoted to developing new drugs with new delivery modes. As a clinical-stage biopharmaceutical company, we have focused on establishing superior treatments for intracranial malignancies, i.e., aggressive cancers located in the brain. These cancer types include primary brain cancers, such as glioblastoma, and secondary brain cancers, that have arrived through metastatic spread from other cancers throughout the body, such as melanoma or breast and lung cancer. Brain-localized malignancies are particularly difficult to treat because the blood-brain barrier prevents efficient entry of most pharmacotherapeutic agents into the brain. As a result, these patients are faced with poor prognoses and shortened average life expectancy. NeOnc is developing novel drug delivery methods to be used in combination with novel drug candidates.

NeOnc's lead product candidate is NEO100. NEO100 is administered to patients via intranasal delivery. We have completed human safety testing in a Phase 1 clinical trial and are currently conducting preliminary efficacy testing in a Phase 2a trial with recurrent malignant glioma (Grade IV IDH1 mutant and Grade III Astrocytoma IDH1 mutant) patients. NeOnc is also developing a second product candidate, NEO212, which has completed preclinical testing, and an investigational new drug (IND) application has been filed and accepted with the United States Food and Drug Administration (FDA). The company has started Phase 1 clinical trials with patients harboring primary and secondary malignant brain cancer types. Several additional drug candidates are in the pipeline and are undergoing preclinical development.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates and undertaking preclinical and clinical studies and manufacturing. We do not have any products approved for sale and have not generated any revenue from product sales other than for humanitarian usage. From inception through March 31, 2025, we had raised an aggregate of approximately $29.3 million of gross proceeds through the sale and issuance of preferred stock and common stock, and approximately $11.7 million through the issuance of notes payable from HCWG, a related party (which was converted to common stock on June 30, 2024).

Since its inception, we have incurred significant operating losses. Our net loss was $38,001,987 and $2,938,976, for the three months ended March 31, 2025 and 2024, respectively. We had an accumulated deficit of $88,610,432 at March 31, 2025. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing, and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when needed, could have a material adverse effect on our business, results of operations and financial condition.

The report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2024 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. See Note 1 to our l financial statements for additional information on our assessment.

Components of Results of Operations

Revenue

We occasionally receive a fee from a patient for a "right to try" humanitarian program. Such revenues are not part of our core business.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) legal and professional expenses and (iii) general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research and development activities, including our product candidate discovery efforts and preclinical and clinical studies under our research programs, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense for our research and development personnel;
- costs of funding research performed by third parties that conduct research and development and preclinical and clinical activities on our behalf;
- costs of manufacturing drug products and drug supply related to our current or future product candidates;
- costs of conducting preclinical studies and clinical trials of our product candidates;
- consulting and professional fees related to research and development activities, including equity-based compensation to non-employees;
- costs of maintaining our laboratory, including purchasing laboratory supplies and non-capital equipment used in our preclinical studies;
- costs related to compliance with clinical regulatory requirements; and
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our preclinical and clinical studies or other services performed.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our product candidates, if they are approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress, and expenses of our ongoing research activities as well as any preclinical studies and clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates.

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 research and development costs to increase significantly for the foreseeable future as we commence clinical trials and continue the development of our current and future product candidates. However, we do not believe that it is possible at this time to accurately project expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Legal and Professional Expenses

Legal and professional expenses consist of costs related to corporate and intellectual property legal costs and accounting and auditing fees. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the Securities and Exchange Commission, or the SEC, and listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums, and investor relations costs.

General and Administrative Expenses

General and administrative expenses include salaries and other compensation-related costs, including stock-based compensation, for personnel in executive, finance and accounting, business development, operations and administrative roles. Other significant costs include insurance costs, travel costs, facility and office-related costs not included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as our business expands to support expected growth in research and development activities, including our future clinical programs. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside service providers, among other expenses. In addition, if we obtain regulatory approval for any of our product candidates and do not enter a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Share Based Compensation

Share based compensation expense result from the recognition of the fair value of restricted stock units (RSU) recorded on a straight-line basis from the date of grant to the date the RSU becomes fully vested.

Interest Expense

Interest expense primarily results from the bridge loan and a short-term loan both from related parties. Borrowings under these loans carry a 50% (or 1 times amounts borrowed) original issue discount ("OID") on principal. The OID to be earned under the bridge loan is recognized ratably over the term of each draw-down under the loan through the maturity date.

Amortization

Amortization on debt issuance costs resulted from the grant of warrants for a line of credit commitment. The fair value of the warrants was determined using the Black Scholes valuation method and the fair value is being amortized over the term of the line of credit commitment.

Amortization on deferred offering costs resulted from the issuance of common stock in connection with a private equity agreement

Comparison of the three months ended March 31, 2025 and 2024:

Results of Operations

The following table summarizes our results of operations for the periods presented:

	For the three months ended March 31,		
	2025	**2024**	**Change**
Revenues			
Revenue	$ 39,990	$ 43,000	$ (3,010)
Operating expenses:			
Research and development	998,222	614,517	383,705
Legal and professional	957,545	564,354	393,191
General and administrative	849,485	415,612	433,873
Share based compensation	23,073,745	-	23,073,745
Advisory fee	11,737,806	-	11,737,806
Total operating expenses	37,616,803	1,594,483	36,022,320
Loss from operations	(37,576,813)	(1,551,483)	(36,025,330)
Other expense:			
Interest income	51,699	-	51,699
Amortization on debt issuance	(167,951)	-	(167,951)
Interest expense	(308,922)	(1,387,493)	1,078,571
Net loss	$ (38,001,987)	$ (2,938,976)	$ (35,063,011)

Revenue

Revenue was generated for fees for a “right to try” humanitarian program during 2025 and 2024.

Research and Development Expenses

The following table summarizes the components of our research and development expenses for the periods presented:

	For the three months March 31,	
	2025	**2024**
Research and development costs by project:		
NEO100-01	$ 579,462	$ 285,612
NEO100-02	108,461	27,064
NEO212	176,555	161,734
Pediatric	48,832	67,397
Laboratory	84,912	72,710
Total	$ 998,222	$ 614,517

	For the three months ended March 31,		
	2025	2024	Change
Clinical trial expense	$ 913,310	$ 541,807	$ 371,503
Research and laboratory	84,912	72,710	12,202
Total research and development expense	$ 998,222	$ 614,517	$ 383,705

Research and development expenses were $998,222 and $614,517 for the three months ended March 31, 2025 and 2024, respectively. A portion of these expenses amounting to approximately $84,912 and $72,710 for the three months ended March 31, 2025 and 2024, respectively are from the University of Southern California (USC), where Dr. Chen is a member of the faculty. The total increase of $383,705 was primarily due to:

- The addition of clinical trial sites for NEO100's clinical trial.
- The recruitment for NEO212.
- The start of the clinical trial for NEO100-03 for a Pediatric Indication.
- Increased patient recruitment efforts.

Legal and Professional Expenses

Legal and professional expenses were $957,545 and $564,354 for the three months ended March 31, 2025 and 2024, respectively. The increase of $393,191 was primarily due to completion of the direct listing process.

General and Administrative Expenses

General and administrative expenses were $849,485 and $415,612 for the three months ended March 31, 2025 and 2024, respectively. The increase of $433,873 was primary due to a marketing campaign, rent and travel expenses.

Share Based Compensation

Share based compensation resulted from the granting of RSUs and is the recognition of the expense from the grant date to March 31, 2025.

Advisory Fee

The advisory fee was earned on the listing date March 26, 2025.

Interest Expense

Interest expense was $308,922 and $1,387,493 for the three months ended March 31, 2025 and 2024, respectively. The interest for the three months ended March 31, 2025 relates to the short-term loan in March from a related party in the amount of $301,422 and $7,500 accrued interest for a litigation matter. The OID interest for the three months ended March 31, 2024 relates to the OID for the related party bridge loan that was converted into common stock in June of 2024.

Amortization of Debt Issuance Costs

The debt issuance costs were $167,951 and $0 for the three months ended March 31, 2025 and 2024, respectively. This represents the amortization of the warrants issued for the HCWG line of credit.

Cash Flows

The following table summarizes our cash flow for the periods indicated:

	For the three months ended March 31,		
	2025	2024	Change
Net cash provided by (used in):			
Operating activities	$ (5,650,055)	$ 145,748	$ (5,795,803)
Financing activities	11,024,372	(172,595)	11,196,967
Net increase (decrease) in cash	$ 5,374,317	$ (26,848)	$ 5,401,165

Operating Activities

During the three months ended March 31, 2025, net cash used in operating activities was $5,650,055 consisting primarily of our net loss of $38,001,987, offset by share based compensation of $23,073,745, accretion of original issue discount of $300,000, amortization of costs of $577,192, the accrued advisory fee of $8,828,565 and increases in accounts payable in the amount of $628,276. These were offset by decreases in accrued compensation in the amount of $290,108, and prepaid expenses in the amount of $765,738. During the three months ended March 31, 2024, net cash used in operating activities was $145,748 consisting primarily of our net loss of $2,938,976 less the non-cash charge of the accretion of the original issue discount on the bridge loan in the amount $1,387,493, increase in the bridge loan – expenses paid by the bridge loan provider on behalf of the Company of $476,393 and an offset by an increase in accounts payable of $1,001,066.

Financing Activities

During the three months ended March 31, 2025, cash provided by financing activities was $11,024,372 consisting primarily of the sale of common stock of $11,644,005 offset by offering costs in the amount of $319,533, resulting in net offering costs of $11,324,372 and the repayment of related party loan of $600,000. During the three months March 31, 2024, cash used in financing activities was $172,595 consisting primarily of proceeds from related party loans, offset by repayment of the same related parties loans and the decrease in deferred offering costs.

Liquidity and Capital Resources

Sources of Liquidity/Going Concern

Since our inception, we have funded our operations through the sale and issuance of preferred and common stock and debt financing rounds from related and third parties.

In March 2025 prior to our direct listing we issued 625,000 shares of common stock in a private placement at a price of $16.00 per share for gross proceeds of approximately $10,000,000. In March 2025 after our direct listing we issued 102,750 shares of common stock in a private placement at a price of $16.00 per share for gross proceeds of approximately $1,644,000.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. Since our inception, we have not generated any revenue from product sales or any other sources, except humanitarian use, and we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for a number of years, if ever. As reflected in the accompanying consolidated financial statements, we have incurred recurring net losses since our inception. For the three months ended March 31, 2025, the Company incurred a net loss of $38,001,987 and has an accumulated deficit of $88,610,432 at March 31, 2025. At March 31, 2025, the Company had cash totalling $5,439,210. These factors raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional funds and implement our strategies, such as executing additional licensing contracts. The consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

The ability to continue as a going concern is dependent on us raising additional capital and attaining and maintaining profitable operations in the future to meet our obligations and repay our liabilities arising from normal business operations when they come due. Since inception, we have funded our operations primarily through equity and debt financings and licensing income and we expect to continue to rely on these sources of capital in the future.

No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to us. Even if we are able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our shareholders, in the case of equity financing, or grant unfavorable terms in licensing agreements.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our research and development, initiate and conduct preclinical studies and clinical trials, and seek marketing approval for our current and any of our future product candidates. In addition, if we obtain marketing approval for any of our current or our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution, which costs we may seek to offset through entry into collaboration agreements with third parties. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect to finance our operations over the next 12 months primarily through existing cash balances and the proceeds from the aforementioned private placements and supplemented as necessary by funds available through our Line of Credit Agreement with HCWG and sales under the Equity Purchase Agreement, each as described below.

Line of Credit Agreement

On October 11, 2024, we entered into a Line of Credit Agreement with HCWG for borrowings of up to $10.0 million. Borrowings under the Line of Credit Agreement bear interest at 10.0% per annum with interest payments due on the first business day of each calendar month, with unpaid principal due by October 12, 2027. This agreement may be extended by mutual agreement for a three year period and in the event of an extension of the maturity date the interest rate will increase to 14%. In connection therewith, we issued HCWG a five-year warrant to purchase up to 312,500 shares of our common stock at a per share exercise price of $12.00.

Equity Purchase Agreement

On October 22, 2024, we entered into an equity purchase agreement (the "Equity Purchase Agreement") and related registration rights agreement (the "ELOC RRA") with Mast Hill Fund, LP ("Mast Hill") pursuant to which the Company may sell and issue to the investor, and the investor may purchase from the Company, up to $50,000,000 of Company's common shares. Under the Equity Purchase Agreement, the Company has the right, but not the obligation, to direct Mast Hill, by its delivery to the Mast Hill of a Put Notice from time to time, to purchase Put Shares (i) in a minimum amount not less than $50,000.00 and (ii) in a maximum amount up to the lesser of (a) $750,000.00 or (b) 150% of the average trading volume of the Company's common stock during the five trading days immediately preceding the Put Date.

The actual amount of proceeds we receive pursuant to each Put Notice (each, the "Put Amount") is determined by multiplying the Put Amount requested by the applicable purchase price. The purchase price for each of the Put Shares equals 95% of the "Market Price," less the Clearing Costs. Market Price is the lowest volume weighted average prices of the Company's common shares on its principal market on any trading day during the Valuation Period. The Valuation Period is the five trading days immediately following the date on which Mast Hill receives the Put Shares in its brokerage account. Clearing Costs are all the fees incurred by Mast Hill with respect to its brokerage firm, clearing firm, Company transfer agent fees, and attorney fees, with respect to the Put Shares.

Because the purchase price per share to be paid by Mast Hill for the common shares that the Company may elect to sell to Mast Hill under the Equity Purchase Agreement, if any, will fluctuate based on the market prices of common shares prior to each sale made pursuant to the Equity Purchase Agreement, if any, it is not possible for us to predict, as of the date of this prospectus and prior to any such sales, the number of common shares that we will sell to Mast Hill under the Equity Purchase Agreement, the purchase price per share that Mast Hill will pay for shares purchased from us under the Equity Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Mast Hill under the Equity Purchase Agreement, if any.

Pursuant to the Equity Purchase Agreement, we will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold to Mast Hill. If and when we do elect to sell shares of our common shares to Mast Hill pursuant to the Equity Purchase Agreement, after it has acquired such shares, Mast Hill may resell all, some or none of such shares at any time or from time to time in its discretion and at different prices. As a result, the other investors who purchase shares from Mast Hill in this offering at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results.

The term of the Equity Purchase Agreement commenced on March 25, 2025 and will terminate on the earlier of (i) the date on which the Mast Hill shall have purchased Put Shares equal to the $50,000,000, (ii) twenty-four (24) months after the date of the Equity Purchase Agreement, (iii) written notice of termination by the Company to Mast Hill, (iv) the registration statement registering the Put Shares is no longer effective after the initial effective date of such registration statement, or (v) the date that, pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company, a receiver, trustee, assignee, liquidator or similar official is appointed for the Company or for all or substantially all of its property or the Company makes a general assignment for the benefit of its creditors.

We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on a number of factors, including:

- the costs of conducting preclinical studies and clinical trials;
- the costs of manufacturing;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing, and clinical trials for product candidates we may develop, if any;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through potential collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Advances – Executive Chairman of the Board

In February 2025, our Executive Chairman advanced the Company approximately $300,000. The advances carry a 50% (or 1 times amounts borrowed) original issue discount ("OID") on the principal. In the event of default, interest is payable at on any unpaid balance at a rate of 10% per annum. In March 2025, further to the terms of such advance, the Executive Chairman was paid a total of $600,000 upon repayment of such advances, including OID.

Critical Accounting Estimates

We account for stock-based compensation, including restricted stock units (RSUs), in accordance with ASC 718. RSUs are measured at fair value on the grant date based on our common stock price and expense over the vesting period. For awards with performance or market conditions, expense is recognized based on the probability of achievement and may be accelerated. We estimate forfeitures based on historical data and adjust these estimates periodically. Changes in forfeiture rates, stock price, or performance assumptions can materially affect stock-based compensation expenses. Management reviews these assumptions quarterly and updates estimates as necessary. We consider the accounting for RSUs a critical estimate due to the judgment involved and its material impact on our financial results.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with foreign vendors that are located in Europe and India. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2025 or the year ended December 31, 2024.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

We do not expect that our disclosure controls and procedures will prevent all errors and all instances of fraud. Disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Further, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and the benefits must be considered relative to their costs. Because of the inherent limitations in all disclosure controls and procedures, no evaluation of disclosure controls and procedures can provide absolute assurance that we have identified all of the information required to be disclosed, and that we have detected all our control deficiencies and instances of fraud, if any. The design of disclosure controls and procedures also is based partly on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2025. Based upon their evaluation, and due to material weaknesses in our internal control over financial reporting over the accounting for complex financial instruments, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective as of March 31, 2025.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the quarter ended March 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published consolidated financial statements. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal control over financial reporting will prevent all error and all fraud. Management conducted an evaluation of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission (the "2013 Framework"). Based on our evaluation under the 2013 Framework, management concluded that our internal control over financial reporting was not effective as of March 31, 2025, due to the material weakness in our internal control over duties separation, company-wide risk and communication processes, major financial transactions, related party dealings, and IT user access management. As a result, we performed additional analysis as deemed necessary to ensure that our consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles. Accordingly, management believes that the consolidated financial statements included in this Form 10-Q present fairly in all material respects our financial position, results of operations, and cash flows for the period presented.

Management has implemented remediation steps to improve our internal control over financial reporting. Specifically, we expanded and improved our review process for complex securities and related accounting standards. We plan to further improve this process by enhancing access to accounting literature, identification of third-party professionals with whom to consult regarding complex accounting applications and consideration of additional staff with the requisite experience and training to supplement existing accounting professionals. The Company can offer no assurance that these changes will ultimately have the intended effects.

This Quarterly Report on Form 10-Q does not include an attestation report on internal controls from our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On June 6, 2023, a vendor filed a complaint against the Company for breach of contract in the Central District of California. The vendor alleged that the Company improperly terminated an Intellectual Property License and Supply Agreement ("IPLSA") and that the Company also defrauded the vendor in connection with the IPLSA. This matter was settled on October 16, 2023, and the Company agreed to pay the vendor $600,000 within 5 business days of the close of the date that the Company completes an IPO or March 31, 2024, whichever occurs first. The Company recognized this as a litigation settlement expense in the accompanying consolidated statement of operations for the year ended December 31, 2023 and a litigation settlement payable in the accompany consolidated balance sheet at December 31, 2024 and December 31, 2023.

On March 31, 2024, the vendor agreed to extend the payment until May 15, 2024 for payment of an additional $25,000. The Company has not made the payment as of October 28, 2024 and the settlement is payable on demand. Such amount is included in litigation settlement payable in the accompanying consolidated balance sheet at December 31, 2024. On July 25, 2024 the arbitrator granted the implementation of interest at the statutory rate on the unpaid balance commencing May 15, 2024 until paid.

On July 1, 2022, NeOnc Technologies, Inc. and Fox Infused, LLC, a Delaware limited liability company ("Fox Infused"), entered into an Intellectual Property License and Supply Agreement effective July 1, 2022 (the "Agreement") whereby NeOnc agreed to supply certain products to Fox Infused and license certain of our patents. We terminated the Agreement with Fox Infused on April 25, 2023. On June 6, 2023, Fox Infused filed a complaint against NeOnc in the Central District of California alleging that the termination was improper (Civil Action No. 2:23-04431). Fox Infused also filed an ex parte application for a temporary restraining order and an order to show cause on a preliminary injunction against us seeking to have the court stop the termination of the contract. Fox Infused's temporary restraining order application was denied and the case dismissed without prejudice. Fox Infused refiled the case in arbitration before the American Arbitration Association (Case No. 01-23-0002-5020). The parties engaged in settlement discussions, and agreed to settle the dispute for a $600,000 payment by us to Fox Infused within 5 business days of the closing date of the Company's initial public offering or March 31, 2024. The Company is currently in default under the terms of such settlement agreement.

In addition to that set forth above, we are, from time to time, party to various claims and legal proceedings arising out of our ordinary course of business, but we do not believe that any of these claims or proceedings will have a material effect on our business, consolidated financial condition or results of operations.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, before deciding whether to invest in shares of our common stock. If any of the following risks actually occurs, our business, results of operations and financial condition could be materially adversely affected. In this case, the trading price of our common stock would likely decline, and you might lose part or all your investment in our common stock.

Summary of Risk Factors

An investment in our common stock involves a high degree of risk. You should carefully consider the risks summarized below. These risks are discussed more fully in the "Risk Factors" section immediately following this summary. These risks include, but are not limited to, the following:

Risks Related to our Financial Position and Need for Additional Capital

- We have incurred significant losses since our inception and anticipate that we will incur significant and increasing losses for the foreseeable future and we may never achieve or maintain profitability.
- Failure to obtain necessary capital could force us to delay, limit, reduce or terminate our product development programs, potential commercialization efforts or other operations.
- Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- The report of our independent registered public accounting firm included a "going concern" paragraph.

Risks Related to Product Discovery, Development and Regulatory Approval

- Our development of product candidates based on our technology platform is limited, and we do not know whether we will be able to develop any products of commercial value.
- Our product candidates are in preclinical and clinical stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable.
- Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.
- Announced or published data from our clinical trials may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Our efforts to expand our product candidates and develop marketable products may not be successful.
- We may expend our resources to pursue a product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- If we do not achieve our product development goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and as a result our share price may decline.
- The marketing approval process is expensive, time-consuming and uncertain and may prevent us or any of our existing or potential future collaboration partners from obtaining approvals for the commercialization of NEO100 and any other product candidate we develop.
- We will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Risks Related to Manufacturing and Reliance on Third Parties

- We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.
- We may face delays in the development and commercialization of, or be unable to meet demand for, any product candidates, and may lose potential revenues.
- We rely, and expect to continue to rely, on third parties to supply and quality-test the ingredients for our product candidates and components for our manufacturing process.
- If those third parties do not perform satisfactorily, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.
- We have and may in the future enter into collaboration agreements and strategic alliances to maximize the potential of our product candidates, and we may not realize the benefits of such collaborations or alliances.
- If we are not able to establish future collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans for one or more of our other development programs.
- Any future collaborations are not a guarantee of success, and all collaborations are as risky.

Risks Related to Commercialization

- If we, or our collaboration partners, are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience delays in doing so, our business will be materially harmed.
- We face significant competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us.
- If we are unable to establish effective marketing, sales and distribution capabilities, the revenues that we generate may be limited and we may never become profitable.
- Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by those in the medical community necessary for commercial success.
- The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.
- We may face competition for any of our product candidates for which we obtain regulatory approval.

Risks Related to Our Intellectual Property

- If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.
- If we fail to comply with our obligations in the 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 intellectual property rights that are important to our business.

- If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

- Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect NEO100, NEO212 and our other product candidates.

- We may become involved in lawsuits to protect or enforce our intellectual property, which could have a material adverse effect on the success of our business.

- If we obtain any issued patents covering our technology, such patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign regulatory authority.

- Patent terms may be inadequate to protect our position on our products for an adequate amount of time.

- Some intellectual property may be subject to federal regulations.

- If we fail to comply with our license obligations, we could lose rights that are important to our business.

Risks Related to Government Regulation

- If we fail to comply with federal and state laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

- If the government or third-party payors fail to provide adequate coverage, reimbursement and payment rates for our products, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.

- We are subject to legislation, regulatory proposals and third-party payor initiatives that may increase costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.

Risks Related to Our Business and Operations

- If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

- Our management team has limited public company experience.

- If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

- Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.

- Public health crises such as pandemics or similar future outbreaks could materially and adversely affect our preclinical studies and clinical trials, business, financial condition and results of operations.

- If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise.

- We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products or product candidates.

- Our employees, independent contractors, consultants, partners, investigators, CMOs, or CROs may engage in misconduct or other improper activities, which could have a material adverse effect on our business.

- Our ability to utilize our net operating loss carryforwards and research and development tax credits to reduce future tax payments may be limited or restricted.

Risks Related to Ownership of Our Common Stock

- An active trading market may not develop or continue to be liquid and the market price of shares of our common stock may be volatile.

- Tariff policies and potential countermeasures could disrupt our supply chain.

- Future sales of common stock by our stockholders could cause our share price to decline.

- Our shareholders may be diluted by future issuances of preferred stock or additional common stock.

- Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.

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

General Risk Factors

- We are involved in disputes with former licensees of our technology, which could result in direct and indirect costs to us in defending and responding to such proceedings and could result in operational disruptions that could harm our reputation, brand and result of operations.

- We will incur significantly increased costs as a result of operating as a public company.

- If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

- If we fail to establish and maintain effective internal controls over financial reporting, our operating results and our ability to operate our business could be harmed.

- Failure to build and improve our finance and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

- Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

* * *

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will incur significant and increasing losses for the foreseeable future and we may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company, and our operations to date have been focused substantially on organizing and staffing our company, business planning, raising capital, creating, assessing, and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates, undertaking preclinical studies, commencing clinical trials and manufacturing. Additionally, as an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful commercialization. We have never generated any significant revenue and have incurred significant operating losses. Our net loss was $38,001,987, $11,898,464 and $14,921,065, for the three months ended March 31, 2025 and the years ended December 31, 2024 and 2023, respectively. As of March 31, 2025, we had an accumulated deficit of $88,610,432. We expect to continue to incur significant and increasing operating losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' deficit and working capital.

We expect that it will be several years, if ever, before we have a commercialized product. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- advance the Phase II clinical trial for our lead product candidate, NEO100;
- initiate planned and future clinical trials of NEO100 or NEO212 in other cancer indications;
- discover and develop new product candidates, and conduct research and development activities, preclinical studies and clinical trials;
- manufacture preclinical, clinical and commercial supplies of our product candidates;
- broaden and strengthen our internal manufacturing capabilities, including the expansion and upgrade of our in-house manufacturing facility;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- hire additional research and development, clinical, scientific and management personnel;
- add operational, financial and management information systems and personnel;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval and we commercialize on our own or in collaboration with others; and
- incur additional legal, accounting and other expenses operating as a public company following our recent direct listing.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials, obtaining regulatory approval for product candidates and manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We are only in the development stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional financing to advance the development of our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, potential commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of, and seek regulatory approval for, our current and future product candidates. If we are able to gain marketing approval of any product candidate that we develop, including NEO100 and NEO212, we will require significant additional amounts of cash in order to launch and commercialize such product either alone or in collaboration with others. Because the design and outcome of our ongoing, anticipated and any future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing NEO100, NEO212 and our other product candidates and programs, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for NEO100, NEO212 and future product candidates we develop if clinical trials are successful;
- the success of any future collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost and timing of establishing, equipping, and operating our current and planned manufacturing activities;
- the cost of manufacturing NEO100, NEO212 and future product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of seeking FDA and any other regulatory approvals for any future product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation or other patent challenge costs and the outcome of such litigation or other patent challenges;
- our ability to establish and maintain healthcare coverage and adequate reimbursement for our future products, if any;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the emergence of competing cancer therapies and other adverse market developments;

- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;

- the costs associated with being a public company;

- our need and ability to retain key management and hire scientific, technical, medical and business personnel;

- the costs associated with expanding our facilities or building out our laboratory space; and

- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and the overall impact of the COVID-19 pandemic.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings and debt financings, or other capital sources such as potential collaborations, strategic alliances, licensing arrangements and other arrangements. We expect to finance our operations over the next 12 months primarily through existing cash balances and supplemented as necessary by funds available through our Line of Credit Agreement with HCWG and sales under the Equity Purchase Agreement, each as described below. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. In addition, because the design and outcome of our anticipated and any future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of NEO100, NEO212 or any future product candidates. Accordingly, we will be required to obtain further funding to achieve our business objectives.

We have never generated any revenue from product sales other than for humanitarian uses of less than $83,000 per year and may never become profitable.

The Company recognized point-in-time revenue of $39,990, $83,000 and $70,462, for the three months ended March 31, 2025 and the years ended December 31, 2024 and 2023, respectively. Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with future partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our development programs. We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends heavily on our success in achieving a number of goals, including:

- completing research regarding, and preclinical and clinical development of, product candidates and programs, including NEO100 and NEO212, and identifying and developing new product candidates;

- obtaining regulatory approval to use and sell products generated by our existing or future manufacturing processes for NEO100, NEO212 and future product candidates, including at our existing manufacturing facility and/or by establishing and maintaining supply and manufacturing relationships with third parties;

- launching and commercializing product candidates for which we obtain marketing approvals, either directly by establishing a sales force and marketing, medical affairs and distribution infrastructure or, alternatively, with a collaborator or distributor;

- establishing and maintaining healthcare coverage and adequate reimbursement for our future products, if any;

- obtaining market acceptance of product candidates that we develop as viable treatment options;

- addressing any competing technological and market developments;

- identifying, assessing, acquiring and developing new product candidates;

- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such collaborations;

- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trademarks, trade secrets, and know-how; and

- attracting, hiring, and retaining qualified personnel.

Even if NEO100, NEO212 or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate that we commercialize on our own or in collaboration with others. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market NEO100, NEO212 or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, 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 indications approved by regulatory authorities are narrower than we expect, the labels for our product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient populations for treatment are narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest may be diluted. Any future debt financings we undertake, if available, are likely to involve restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves.

Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations, stock price and prospects. Securing additional financing could also require a substantial amount of time from our management and may divert a disproportionate amount of their attention away from daily activities, which may adversely affect our management's ability to oversee the development of NEO100, NEO212 or any future product candidates.

The report of our independent registered public accounting firm included a "going concern" explanatory paragraph.

The report of our independent registered public accounting firm on our consolidated financial statements for the years ended December 31, 2024 and 2023 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. If we are unable to raise additional capital as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and we may be forced to delay our development efforts, limit our activities and reduce research and development costs. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. The inclusion of a going concern explanatory paragraph by our independent registered public accounting firm, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into licensing and collaboration arrangements or other contractual relationships with third parties and otherwise execute our development strategy.

Risks Related to Product Discovery, Development and Regulatory Approval

Our development of product candidates based on our technology platform is limited, and we do not know whether we will be able to develop any products of commercial value.

The success of our business depends primarily upon our ability to identify novel product candidates and to successfully develop and commercialize those product candidates. While we have had preclinical and clinical study results for NEO100 and preclinical results for NEO212, to date, these remain our only product candidates that have moved into clinical trials. We have not yet succeeded and may not succeed in demonstrating efficacy and safety in order to be able to commercialize NEO100 or NEO212. We also may be unsuccessful in identifying additional product candidates beyond NEO100 and NEO212, and any of our product candidates may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. Similarly, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value and potential of our discovery platform and resulting product candidates.

If any of these events occur, our ability to successfully discover, develop and commercialize any product candidates may be impaired and the value of our company could decline significantly.

Our product candidates are in preclinical and clinical stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable.

All of our product candidates are in research, preclinical or clinical development. We have not completed the development of any product candidates, we currently generate no revenue, and we may never be able to develop a marketable product. Enrollment in NEO100 Phase I was completed in September 2019, and we reported multiple data readouts in 2020. Our Phase I clinical trial – an open-label, single-arm study, of our lead product candidate, NEO100, in patients with recurrent malignant glioma (Grade IV, IDH1 mutation) – has been completed. Our Phase IIa trial of NEO100 is currently enrolling patients. We plan to enroll a total of 30 patients; 5 patients are currently enrolled. We plan to have a total of 12 sites for enrollment.

Our operating plan may change due to many unknown factors, and we may need to seek additional funds sooner than planned through equity and debt financing. We may consider new collaborations or selectively partner with our technology or programs. Even if we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or have specific strategic considerations.

The success of our current and future product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials and to pursue the necessary regulatory approval processes;
- acceptance of INDs/IND amendments for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- generating successful data from our clinical trials that support FDA conclusion of an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- obtaining regulatory approval to use our existing or future manufacturing processes for the clinical and commercial manufacture of our product candidates at our existing or future manufacturing facilities or at the facilities of one or more third-party manufacturers with whom we would need to establish supply arrangements;

- successfully launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- maintaining a continued acceptable safety profile of the products following approval; and
- maintaining compliance with all pre-approval and post-approval regulatory requirements.

If we do not achieve 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.

We currently have two clinical development product candidates, both of which rely in whole or in part on perillyl acid (NEO100 and NEO212). The failure of one of these two product candidates in clinical development would adversely affect our business. It may require us to discontinue developing other product candidates based on the same therapeutic approach.

Our business and future success substantially depend on our ability to obtain regulatory approval and license our lead product candidates successfully. Both NEO100 and NEO212 are in the early stages of clinical development. Our product candidates will require additional clinical and nonclinical development, regulatory review, and approval in one or more jurisdictions, a substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate revenue from product sales. In addition, because NEO100 and NEO212, our most advanced product candidates are both perillyl acid-based products and because all of our other future product candidates will likely be based on similar technology, if either encounters safety or efficacy problems, developmental delays, regulatory issues, or other problems, our development plans and business for our other product candidates would be significantly harmed.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

We are currently advancing our lead product candidates, NEO100, and NEO212, through clinical development and other product candidates through preclinical development. We are still recruiting for NEO100 Phase IIa and aim to finish that trial in 2 years. After Phase IIa is completed, Phase IIb or Phase III may still have to be performed depending on the results of the studies. Oral NEO212 has been submitted for an IND for a Phase I trial in patients with primary brain cancer and brain metastasis. Twelve patients will be recruited for the Phase I trial. Afterward, a Phase IIa trial is planned to be performed for primary gliomas and metastatic brain cancer. Intranasal NEO212 is still in development and an IND will be submitted for a Phase I trial for brain metastasis. We are also working on an intranasal delivery of a chemotherapeutic agent for midline primary pediatric intracranial tumor. This development is still preliminary but is in development with multi-center pediatric neuro-oncology consortiums. Any development problems we experience in the future may cause significant delays or unanticipated costs, and we may not be able to solve any such development problems. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA or foreign regulatory authorities may place all, or part, of our clinical development on hold or refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing and obtaining regulatory approval for a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. We may need to devote significant time and resources to satisfy these requirements.

Clinical development involves a lengthy and expensive process with an uncertain outcome and stringent regulations, and delays can occur for a variety of reasons.

In order to obtain FDA approval to market a new small molecule drug product, we must demonstrate proof of safety and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We cannot be certain of the timely completion or outcome of our clinical trials and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our clinical trials will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin and we cannot be sure that our planned clinical trials will begin on time, that our ongoing clinical trials will be completed on schedule, or that the results of any of our clinical trials will be sufficient to support regulatory approval.

Conducting clinical development is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any ongoing or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize NEO100 or any future product candidates, including:

- regulators or institutional review boards (IRBs), may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or contract research organizations (CROs);
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the unsuccessful development of nasal inhaler devices used to deliver NEO100;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates;
- delays or failures related to the COVID-19 pandemic or similar future pandemics, which may result in clinical site closures, delays to patient enrollment, patients withdrawing prior to receiving treatment (e.g., catheter implantation failure), patients discontinuing their treatment or follow up visits or changes to trial protocols;
- third-party clinical trial sites or individual clinical investigators may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- manufacturing delays;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, emergent drug-drug interactions between NEO100 and any of the other therapeutic agents given to the clinical trial subjects or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a pharmacologically, chemically or mechanistically similar therapeutic or therapeutic candidate;

- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;

- statutes or regulations could be amended, or new ones could be adopted;

- changes could be adopted in the regulatory review process for submitted product applications;

- the cost of clinical trials of our product candidates may be greater than we anticipate, or we may have insufficient funds for a clinical trial or product manufacture or to pay the substantial user fees required by the FDA upon the submission of a NDA or equivalent authorizations from comparable foreign regulatory authorities;

- 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;

- 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;

- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs;

- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent;

- regulators may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;

- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;

- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;

- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;

- the FDA or comparable foreign regulatory authorities may disagree with our trial design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;

- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;

- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our contract manufacturing facilities for clinical and future commercial supplies;

- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a New Drug Application or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates; and

- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development, including, for example due to a longer-and/or-higher-than-expected response rate determination in the active comparator group or a shorter-and/or-lower-than-expected response rate determination in the experimental drug group.

Our product development costs will also increase if we experience delays in clinical testing or marketing approvals, and we may not have sufficient funding to complete the testing and approval process for any of our current or future product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant delays relating to any preclinical studies or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. 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 receipt of necessary regulatory approvals could be delayed or prevented.

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 or foreign regulatory authorities.

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 proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, 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 that may be approved for the indications we are investigating.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment or retention in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- availability and efficacy of approved therapies for the disease under investigation;

- patient eligibility criteria for the trial in question;

- risks that enrolled subjects will drop out before completion of the trial, including as a result of emergent drug-drug interactions between NEO100 and any of the other therapeutic agents given to the clinical trial subjects, contracting COVID-19 or other health conditions or being forced to quarantine;

- perceived risks and benefits of the product candidate under study;

- efforts to facilitate timely enrollment in clinical trials;

- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- withdraw of consent for any reasons;
- unforeseen limitations of protocol design; and
- protocol amendment by the sponsor and/or as requested by applicable regulatory authorities.

In addition, our planned clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a competing clinical trial.

Our inability to enroll a sufficient number of patients for our anticipated and any future clinical trials would result in significant delays or may 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, which could have an adverse effect on our business, financial condition, results of operations, and prospects. In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter patient enrollment difficulties.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

For our lead product candidate, NEO100, we completed Phase I enrollment and reported multiple data readouts in 2021 and 2022. For our Phase IIa clinical trial, we expect the final readout by the end of 2024. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. NEO100 may not perform as we expect in clinical trials, particularly in our open label, randomized, and controlled Phase II clinical trial, may ultimately have a different or no impact on malignant gliomas, may have another mechanism of action than we expect, and may not ultimately prove to be safe and effective.

The results of previous clinical trials of NEO100 and NEO212 and results of preclinical studies or early clinical trials of any other product candidate we may develop, may not be predictive of the results of subsequent and later-stage clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We do not have experience in designing a registration-stage clinical trial and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, variations in conducting clinical trial at different sites, changes in medical practice, FDA requirements based on agency guidelines or precedence which may be more strict for a Phase II clinical trial, the rate of dropout among clinical trial participants and changes in the manufacturing process. Moreover, should there be an issue with the design of any of our clinical trials, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

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

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials, based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, topline, and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, such data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim, topline, and preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, interim or topline data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability, or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate, or our business. If the interim, topline, or preliminary 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 NEO100 and any future product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Serious adverse events, undesirable side effects (including emergent drug-drug interactions between NEO100 and any of the other therapeutic agents given to the clinical trial subjects) or other unexpected properties of our current or future product candidates may be identified during development or after approval, which could halt their development or lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

To date, NEO100 is the only product candidate we have tested in humans. As we continue our development of NEO100 and initiate clinical trials of any future product candidates, serious adverse events, undesirable side effects or unexpected characteristics may emerge or be reported, causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even if our product candidates initially show promise in early clinical trials, the side effects of therapies are frequently only detectable after they are tested in large, Phase II or Phase III clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidates, or the result of drug-drug interactions between our product candidate and any of the concomitant therapies given to the trial subjects, we, the FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, could interrupt, delay, or halt clinical trials and could result in a more restrictive label, a Risk Evaluation and Mitigation Strategy (REMS) or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may also require, or we may voluntarily develop strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. Any requests from the FDA or comparable foreign regulatory authority for additional data or information could also result in substantial delays in the approval of our product candidates.

Drug-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties;
- we could be sued and held liable for harm caused to patients; and
- the product may become less competitive, and our reputation may suffer.

The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations, stock price and prospects.

We anticipate that many of our product candidates may be tested and, if approved, used in combination with third-party drugs and/or devices, some of which may still be in development, and we have limited or no control over the supply, regulatory status or regulatory approval of such drugs and/or devices.

We anticipate developing our product candidates for use in combination with other oncology pharmaceutics, including chemotherapies and cellular and targeted therapies (e.g., immune checkpoint inhibitors). In particular, our development of NEO100 as a solvent (carrier) of other drugs and biologics to the brain will depend on our ability to access such drugs and devices on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs or devices on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing platinum-based and other chemotherapies, or any other combination products, or any devices in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For our product candidates that may be used in combination with platinum-based and other chemotherapies, or any other combination products or any devices, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that there are adverse events tied to the interaction of NEO100 with any of the other therapies, or that any positive previous trial results are attributable to the combination therapy and not our product candidates.

Moreover, following product approval, the FDA may require that products or devices used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product or device, this may require us to work with a third party to satisfy such a requirement. The ability to obtain cooperation from the third party may impact our ability to respond to the FDA's requests which could impact our ability to achieve regulatory approval. Moreover, developments related to the other product or device may impact our clinical trials as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the safety or efficacy profile of the other product or device, changes to the availability of the approved product or device, and changes to the standard of care.

In the event that any future collaborator or supplier of platinum-based and other chemotherapies, or any other products administered in combination, or any devices used, with our product candidates does not supply their products on commercially reasonable terms or in a timely fashion, we would need to identify alternatives for accessing these products. This could cause our clinical trials to be delayed and limit the commercial opportunities for our product candidates, in which case our business, financial condition, results of operations, stock price and prospects may be materially harmed.

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

We expect initially to develop our lead product candidate, NEO100. We anticipate pursuing clinical development of other product candidates, alone or in collaboration with our partners. Research programs to identify new product candidates require substantial technical, financial and human resources. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding and will be subject to the risks of failure inherent in medical product development. We cannot assure you that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of cancer, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications 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 prioritize our research programs and will need to focus our product candidates on the potential treatment of certain indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially-viable products.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring product candidates requires substantial technical, financial, and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

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

Drug development is inherently risky and uncertain. We cannot be certain that we will be able to:

- complete IND-enabling preclinical studies or develop manufacturing processes and associated analytical methods that meet current good manufacturing practice (cGMP) requirements in time to initiate or to complete our anticipated or future clinical trials in the timeframes we announce;
- obtain sufficient clinical supply of our product candidates to support our anticipated or future clinical trials;
- initiate clinical trials within the timeframes we announce;
- enroll and maintain a sufficient number of subjects to complete or timely complete any clinical trials; or
- collect and analyze the data from any completed clinical trials in the timeframes we announce.

The actual timing of our development milestones could vary significantly compared to our estimates, in some cases for reasons beyond our control. If we are unable to achieve our goals within the timeframes we announce, the commercialization of our product candidates may be delayed and, as a result, the stock price of our common stock could fall and you may lose all of your investment.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any of our existing or potential future collaboration partners from obtaining approvals for the commercialization of NEO100 and any other product candidate we develop.

Any current or future product candidate we may develop, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of our product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing our product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- contain significant safety warnings, including boxed warnings;
- contain significant contraindications, and precautions which could reduce the size of the patient population;
- not be approved with label statements necessary or desirable for successful commercialization;

- contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a REMS to monitor the safety or efficacy of the products; or

- be withdrawn from the market because of a serious safety issue becomes know after approval is granted.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, takes many years even if successful, and can vary substantially in and among jurisdictions based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries 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 studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. It is possible that our product candidates will never obtain the appropriate regulatory approvals necessary for us to commence product sales, or any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any current or future product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of any products for unapproved or "off-label" uses, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to pharmaceuticals are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for any products we develop, including claims comparing our products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

Because regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine, physicians may in their independent medical judgment choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities. Regulatory authorities do, however, limit communications by biopharmaceutical companies concerning off-label use. Therefore, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA.

If we are found to have impermissibly promoted any products that we may develop, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The federal government has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our product candidates obtains marketing approval the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Engaging in the impermissible promotion of our products, in the United States, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act (FCA) lawsuits against manufacturers of drugs and small molecule products have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to $3.0 billion, pertaining to certain sales practices and promoting off-label uses. In addition, FCA lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Obtaining and maintaining marketing approval for our product candidates in one jurisdiction would not mean that we will be successful in obtaining marketing approval of that product candidate in other jurisdictions, which could prevent us from marketing our products internationally.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction would not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. In cases where data from foreign clinical trials 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 the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. If we obtain approval for any product candidate and ultimately commercialize that product in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA or comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and GCPs for any clinical trials that we conduct post-approval.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or of the product being less effective than previously thought or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as New Drug Application boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product candidate is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;

- warning letters or untitled letters alleging violations;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidate(s), if approved, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

The FDA's policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.

If we are slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and be subject to regulatory enforcement action.

Should any of the above actions take place, we could be prevented from or significantly delayed in achieving profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

Risks Related to Manufacturing

We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The manufacture of active pharmaceutical ingredients (API) and finished dosage form (FDF) drug products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturing must strictly comply with regulatory requirements governing current Good Manufacturing Practices (cGMP). The process of manufacturing API and FDF products, including our product candidates, is complex, time-consuming, highly-regulated and costly.

Manufacturers of small molecule API and FDFs often encounter difficulties in production, particularly in scaling up initial production, with such risks including:

- quality control, including stability of the product candidate and quality assurance testing;
- shortages of qualified personnel or key raw materials or components;
- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;
- the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidate batches that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

As product candidates are developed through preclinical studies to later-stage clinical trials towards 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 effort to optimize processes and results. Such manufacturing changes may require separate regulatory approvals before being implemented.

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

We anticipate relying on contract manufacturing organizations (CMOs) to conduct large-scale manufacture of NEO100 and NEO212 API and FDF in the future. The inability to identify and contract with suitable CMOs or their failure to meet their obligations to us could affect our ability to develop or commercialize NEO100 in a timely manner.

If the FDA, state or a comparable foreign regulatory authority does not approve our manufacturing facility for the manufacture of our product candidates or if it withdraws any such approval in the future, or our current facility is unable to meet our volume requirements to fail to comply with cGMP regulations, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any alternative manufacturing facility would require obtaining the necessary equipment and materials and, if a third-party manufacturer, the necessary manufacturing know-how, which may take substantial time and investment. We must also receive FDA approval to use any manufacturing facility for commercial supply.

In such an instance, we may need to enter into an appropriate third-party relationship. We may fail to establish manufacturing relationships or alternative arrangements for our product candidates or programs. Any product candidates we develop compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers operating under cGMP regulations capable of manufacturing and filling our viral product for us and willing to do so.

If we are unable to have manufactured and release any product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, any product candidates, and may lose potential revenues.

We do not own or operate manufacturing facilities for the production of NEO100 nor do we plan to develop our own manufacturing operations in the foreseeable future. We currently depend on third party contract manufacturers for all of our required raw materials, active pharmaceutical ingredient and finished products for our preclinical and clinical trials.

Our clinical product supply may be limited, interrupted, or of unsatisfactory quality or not continue to be available at acceptable prices. Any delays in obtaining adequate supplies of our product candidates that meet the necessary quality standards may delay our development or commercialization.

We or our contract manufacturer(s) may be unable to comply with our specifications, applicable cGMP requirements or other FDA, state or foreign regulatory requirements of our product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our contract manufacturers' manufacturing equipment and processes. We may not be able to develop, retain or acquire the internal expertise and resources necessary for managing our ongoing contract manufacturing operations and complying with these requirements. 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 a product candidate that may not be detectable in final product testing. If we cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure or maintain regulatory approval for our manufacturing facility. Any such deviations may also require remedial measures that may be costly and/or time-consuming for us to implement, particularly in areas relating to operations, quality, regulatory, facilities and information technology. Any such remedial measures imposed upon us may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of our facility and could materially harm our business.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against us or our raw material and component suppliers (including fines and civil and criminal penalties, including imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our failure or our raw material and component suppliers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any problems or delays we experience in commercial-scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of any product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

Risks Related to Reliance on Third Parties

We rely, and expect to continue to rely, on third parties to supply and quality-test the ingredients for our product candidates and components for our manufacturing process.

While we are responsible for the manufacturing of our product candidates, drug substance and drug product, reliance on raw material and component suppliers entails risks, including:

- reduced control for certain aspects of our contracted manufacturing activities;
- termination or nonrenewal of the applicable supplier and service agreements in a manner or at a time that is costly or damaging to us;
- the possible breach by our third-party suppliers and service providers of our agreements with them;
- the failure of our third-party suppliers and service providers to comply with applicable regulatory requirements;
- disruptions to the operations of our third-party suppliers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Any failure or refusal to supply our product candidates or components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. In addition, we do not have any long-term commitments or guaranteed prices from our suppliers of raw materials, manufacturing equipment components or devices or combination products. In particular, any change in our suppliers could require significant effort and expertise because there may be a limited number of qualified replacements. Further, the terms of any new arrangement could be less favorable and transfer costs relating to technology and processes could be significant.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, impact our ability to successfully commercialize any of our product candidates or otherwise harm our business, financial condition, results of operations, stock price and prospects. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.

We rely, and will rely, on third-party CROs, study sites and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with the FDA's Good Laboratory Practice (GLP) regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCP guidelines, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions. For example, the data generated in our trials may not have been appropriately collected or documented, and thereby be deemed unreliable and the FDA or comparable foreign regulatory authorities may conclude the study findings are not adequate and require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on one or more government-sponsored databases, e.g., ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

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

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.

We have entered into, and may in the future enter into, certain collaboration agreements and strategic alliances to maximize the potential of our product candidates, and we may not realize the anticipated benefits of such collaborations or alliances. We expect to continue to form collaborations in the future with respect to our product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

We may form or seek other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop. These transactions can 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. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or other anticipated benefits that led us to enter into the arrangement. Additionally, the success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

If we are not able to establish future collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans for one or more of our other development programs.

We face significant competition in seeking appropriate additional collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

Any future collaborations are not a guarantee of success, and all collaborations are as risky, or more risky, than undertaking the activities ourselves.

Any potential future collaborations we might enter into for NEO100, NEO212 or our other product candidates, may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create 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 fail to make timely regulatory submissions for a product candidate;

- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or 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;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;

- 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 potential litigation; and

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

In addition, all of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of any of our current or future collaborators.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

If any collaborations we have entered into or might enter into do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

Additionally, if any collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, delay their ability to review and act on our regulatory submissions, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, the FDA and regulatory authorities outside the United States have and may adopt restrictions or other policy measures in response to the COVID-19 pandemic or similar future pandemics that divert resources and delay their attention to any submissions we may make. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it 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.

Risks Related to Commercialization

If we, or our collaboration partners, are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we, or our collaboration partners, are successful in obtaining marketing approval from applicable regulatory authorities for NEO100 or any other product candidate, our ability to generate revenues from any such products will depend on our success in:

- launching commercial sales of such products, whether alone or in collaboration with others;
- receiving approved labels with claims that are necessary or desirable for successful marketing, and that do not contain safety or other limitations that would impede our ability to market such products;
- creating market demand for such products through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize such products in the United States;
- creating partnerships with, or offering licenses to, third parties to promote and sell such products in foreign markets where we receive marketing approval;
- manufacturing such products in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- maintaining patent and trade secret protection and regulatory exclusivity for such products;
- achieving market acceptance of such products by patients, the medical community, and third-party payors;
- achieving coverage and adequate reimbursement from third-party payors for such products;
- achieving patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- competing with other therapies; and
- maintaining a continued acceptable safety profile of such products following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including viral immunotherapy and cancer vaccine approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

While certain of our product candidates may be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authorities' approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by third-party payors' coverage and reimbursement decisions.

Many of the companies with which we are competing or may compete 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 biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of any products that we may develop. If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own or in collaboration with others and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of the FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our product candidates, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing our product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training personnel, including sales and marketing personnel, on compliance matters and monitoring their actions;
- an inability to secure coverage and adequate reimbursement by third-party payors, including government and private health plans;
- the unwillingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement from third-party payors;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for our personnel, including sales or marketing personnel, who fail to comply with applicable law;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success. The revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval does not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any product for which we receive marketing approval will depend on a number of factors, including:

- the efficacy of our product, including in combination with other cancer therapies;
- the commercial success of any cancer therapies with which our product may be co-administered;
- the prevalence and severity of adverse events associated with our product or those products with which it is co-administered;
- the clinical indications for which our product is approved and the approved claims that we may make with respect to the product;
- limitations or warnings contained in the FDA-approved labeling of the product or the labeling approved by comparable foreign regulatory authorities, including potential limitations or warnings for our product that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our product, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our product and any products with which it is co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of coverage and adequate reimbursement by third-party payors, such as private insurance companies and government healthcare programs, including Medicare and Medicaid;
- the ability to have our product placed on approved formularies;
- patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- the price concessions required by third-party payors to obtain coverage and adequate reimbursement;
- the extent and strength of our marketing and distribution of our product;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our product or to which we agree as part of a REMS or voluntary risk management plan;

- the timing of market introduction of our product, as well as competitive products;
- our ability to offer our product for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our raw material supplier and service provider support;
- the actions of companies that market any products with which our product is co-administered;
- the approval of other new products;
- adverse publicity about our product or any products with which it is co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates. If the market opportunities for any product candidates we develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer.

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities. Additionally, because of the potential that any product candidates we develop could cure a target disease, we may not receive recurring revenues from patients and may deplete the patient population prevalence through curative therapy.

We may face early and aggressive generic competition for any of our product candidates for which we obtain regulatory approval.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") established a streamlined and expedited regulatory approval pathway, known as an Abbreviated New Drug Application or ANDA, for identical generic versions of drug products initially approved pursuant to full clinical trials and the New Drug Application (NDA) process. This process is explained in more detail later in this document. Using this pathway, generic drug companies aggressively seek to market approved generic versions of small molecule drug products, including by challenging patents covering the original drug product. Generic drugs approved under an ANDA usually are deemed by FDA to be "therapeutically equivalent" to the original version of the drug that they copy, and accordingly, such generic products may be automatically substituted by pharmacies for patients who present a prescription for the original brand-name version of the drug.

If a generic drug company files an ANDA that includes a challenge to one or more of our patents covering any of our approved drugs, a specialized type of patent litigation may ensue, which may result in a court ruling that our patent(s) are invalid, unenforceable, or would not be infringed by the proposed generic version of our product. In such cases, we may face direct competition from equivalent generic versions of our product before the expiration date of our patents. Moreover, because patent litigation is inherently uncertain, many such patent cases are settled with the patent holder agreeing to allow market entry of the generic product at some point prior to expiration of the patent.

The market entry of generic versions of approved drugs generally has a rapid and dramatic adverse impact on the pricing that can be realized by the maker of the original drug product. If we are unable to obtain and enforce patents and regulatory exclusivities on our drug candidates, earlier than expected market entry of generic competitors could significantly adversely affect our business.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology, including NEO100, NEO212 and our other product candidates. We also rely in part on trade secret, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our technology and product candidates.

The patent positions of biotechnology and pharmaceutical companies generally are uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation or patent challenges in the United States Patent and Trademark Office or in corresponding patent offices. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we may own are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States.

Further, the examination process may require us to narrow the claims for our pending patent applications, which may significantly limit the scope of patent protection that may be obtained if these applications issue. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. In addition, the scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. If we are unable to obtain and maintain patent protection for our technology or for NEO100, NEO212 or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours in a non-infringing manner, and our ability to successfully commercialize NEO100, NEO212 or our other product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify any 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.

In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. It is also possible that we will fail to identify patentable aspects of our research and development efforts in time to obtain any patent protection.

Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications with a claim that covers infringing third-party activity. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we license from third parties or own in the future may be challenged in the courts or patent offices in the United States and abroad, including through opposition proceedings, derivation proceedings, post-grant review, *inter partes* review, post-grant review, derivation proceedings, interference proceedings or litigation. Such proceedings may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection for our technology. Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we fail to comply with our obligations in the 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 intellectual property rights that are important to our business.

We may need to obtain licenses from others to advance our research and development activities or allow the commercialization of our current or future product candidates. We expect any such license agreements will impose various development, diligence, commercialization, and other obligations on us. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by the intellectual property under any such license agreements. If such in-licenses were to be terminated, or if the underlying patents were to fail to provide the intended exclusivity, 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 our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues and our respective compliance therewith;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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 have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and other proprietary information. To maintain the confidentiality of our trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators, contractors, and other third parties who have access to our trade secrets. Our agreements with employees and consultants also provide that any inventions conceived by the individual employee or consultant in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property or that of our licensor. In addition, we cannot be certain 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. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information including a breach of our confidentiality agreements. 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 in and outside of the United States are 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 or other third party, we would have no right to prevent them from using that technology or information to compete with us. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends on our ability and the ability of any future collaborators to develop, manufacture, market and sell NEO100, NEO212 and our other product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any other future product candidates, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the USPTO (or similar proceedings in foreign jurisdictions). Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be granted in the future. Numerous U.S. and foreign-issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing and commercializing NEO100, NEO212 and our other product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing NEO100, NEO212 or our other product candidates. In addition, in any such proceeding or litigation, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material adverse effect on our business. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Furthermore, we plan to develop our product candidates in combination with products developed by companies that may be covered by patents or licenses held by those entities to which we do not have a license or a sublicense. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with NEO100, NEO212 or our other product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

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

Filing, prosecuting and defending patents on our technology throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices 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 may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and/or manufacture 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 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 certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the granting or enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to obtain patent rights or stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally in those countries. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to protect and enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

In addition, the laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and those foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries. Furthermore, competitors may challenge the scope, validity and enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or proceedings.

Moreover, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and results of operations may be adversely affected.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, 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.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and to maintain patents after they are issued. For example, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications often must be paid to the USPTO and foreign patent agencies over the lifetime of our licensed patents or any patents we own. In certain circumstances, we may rely on future licensing partners to take the necessary action to comply with these requirements with respect to licensed intellectual property. Although an unintentional lapse may be curable, depending on the jurisdiction, for a period of time 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 fail to obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to NEO100, NEO212 or our other product candidates, which could have a material adverse effect on our business.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect NEO100, NEO212 and our other product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or other jurisdictions in which we have or seek patent protection could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law in the United States on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and 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, financial condition, results of operations, stock price and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our licensed patents or any patent we own, or misappropriate or otherwise violate our intellectual property rights. Litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets, or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Our licensed patents and any patents we own in the future may become involved in priority or other intellectual property related disputes. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of our owned or licensed intellectual property rights. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigations or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation and other intellectual property related proceedings could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or 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. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock, and could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. Any of the foregoing may have a material adverse effect our business, financial condition, results of operations, stock price and prospects.

We may be subject to claims by third parties asserting that we, our employees or any future collaborators have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management team, were previously employed at, or consulted for, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these people, including each member of our senior management team, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment or consulting agreements, that assigned ownership of intellectual property relating to work performed under such agreements to the contracting third party. Although we try to ensure that our employees, as well as those of our licensor and contractors, do not use, claim as theirs, or misappropriate the intellectual property, proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used, claimed as theirs, misappropriated or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of third parties or are in breach of non-competition or non-solicitation agreements with our competitors.

We could be subject to claims that we or our employees, including senior management, have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors or others. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we caused an employee to breach the terms of their 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 or other party. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, 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 NEO100, NEO212 and our other 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, competitors or other parties. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing NEO100, NEO212 and our other product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or consultants. A loss of key personnel or their work product could hamper or prevent our ability to develop and commercialize NEO100, NEO212 and our other product candidates, which could have an adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we obtain any issued patents covering our technology, such patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign regulatory authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect NEO100, NEO212 and our other product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. For example, with respect to the validity of our licensed patents or any patents we obtain in the future, we cannot be certain that there is no invalidating prior art of which we, our patent counsel or our licensing partner's patent counsel(s), and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on NEO100, NEO212 and our other product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as pharmacological products may face competition sooner than anticipated.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, such as NEO100 and our other 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.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent for the patent term lost during the FDA regulatory review process. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents that we believe are eligible for such extension. We also intend to seek patent term extensions in other jurisdictions where these are available. However, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. 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 products earlier than might otherwise be the case, which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Some intellectual property which we have 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 United States industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

The intellectual property rights we licensed from USC has been generated through the use of United States government funding and is therefore be subject to certain federal regulations. As a result, the United States government may have certain rights to intellectual property embodied in our future products and product candidates pursuant to the Bayh-Dole Act of 1980. These United States 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 United States government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of 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 public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The United States government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the United States government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the 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 United States manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

Our license agreement with USC, under which we license all of our current patent rights and a significant portion of our technology for our product candidates, imposes royalty and other financial obligations on us and other substantial performance obligations. We also may enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or product candidate that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of our products or product candidates. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

In addition, it is possible that USC may conclude that we have materially breached the USC licensing agreement and might therefore terminate the agreement, thereby removing our ability to market products covered by our license agreement with USC. If the USC licensing agreement is terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our license agreement with USC is terminated, USC may be able to prevent us from utilizing the technology covered by the licensed patents and patent applications. If we breach the agreement (including by failing to meet our payment obligations) and do not adequately cure such breach, the rights in the technology licensed to us under the USC license agreement will revert to USC at no cost to USC. This could have a material adverse effect on our competitive business position, our financial condition, our results of operations and our business prospects.

In addition, the agreement under which we currently license intellectual property is 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 have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected products or product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names, and evaluation of whether the proposed name implies an unapproved use or a level of safety or efficacy that is not supported by relevant data. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have 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 this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Government Regulation

If we fail to comply with federal and state healthcare laws, including fraud and abuse laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable healthcare fraud and abuse, and other healthcare laws, which may constrain the business or financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, 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 the Medicare and Medicaid programs.

- The federal civil and criminal false claims laws, including, without limitation, the civil FCA, and the federal Civil Monetary Penalties Law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or 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), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

- The U.S. Federal Food, Drug and Cosmetic Act, and its implementing regulations, which prohibits, among other things, the adulteration or misbranding of drugs, small molecule products and medical devices.

- The federal physician payment transparency requirements, sometimes referred to as the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) and its implementing regulations, which require certain manufacturers of drugs, devices, small molecule products 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 the Centers for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members.

- Analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; and state and local laws requiring the registration of pharmaceutical sales representatives.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that apply to us, we may be subject to penalties, including significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, imprisonment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, additional reporting requirements and/or oversight if we become subject to corporate integrity agreements or similar agreement to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in U.S. federal or state healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with such laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If the government or third-party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and adequate reimbursement from third-party payors or placement on approved product formularies. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new therapeutic products when more established or lower cost therapeutic alternatives are already available or subsequently become available, even if our products are alone in a class. Third-party payors establish reimbursement levels. Therefore, even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we may not be able to successfully commercialize our product candidates. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Our failure to obtain or maintain timely or adequate pricing or formulary placement of our products, or failure to obtain such formulary placement at favorable pricing may negatively impact our revenue.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved small molecule products. Marketing approvals, pricing, and reimbursement for new therapeutic products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a therapeutic 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 biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that 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. Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors.

A significant trend within the healthcare industry is cost containment, both in the United States and elsewhere. Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs, including use of formularies. Exclusion of a product from a formulary or other restrictions can significantly impact drug usage in the patient population and beyond. Consequently, pharmaceutical companies compete to gain access to formularies for their products, typically on the basis of unique product features, such as greater efficacy, better patient ease of use, or fewer side effects, as well as the overall cost of the therapy. Certain third-party payors are requiring that companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, are challenging the prices charged for therapeutics, and are negotiating price concessions based on performance goals. In addition, third-party payors are increasingly requiring higher levels of evidence of the benefits and clinical outcomes of new technologies, seeking performance-based discounts, and challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. If payors subject our product candidates to Maximum payment amounts, or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, stock price and prospects.

There may also be delays in obtaining coverage and reimbursement for newly approved therapeutics, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Such delays have made it increasingly common for manufacturers to provide newly approved drugs to patients experiencing coverage delays or disruption at no cost for a limited period in order to ensure that patients are able to access the drug. Moreover, eligibility for reimbursement does not imply that any therapeutic will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new therapeutics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

An inability to promptly obtain coverage and adequate reimbursement from third-party payors for any of our product candidates for which we obtain marketing approval 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 are subject to new legislation, regulatory proposals and third-party payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.

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 product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products.

For example, the ACA was passed in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the United States pharmaceutical industry.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 (the Tax Act), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, re-examining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2018 (BBA) and the Infrastructure Investment and Jobs Act, will remain in effect until 2031 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biopharmaceutical industry. For instance, the Drug Quality and Security Act of 2013 imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Further, manufacturers have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA concurrently released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services (HHS) finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed until 2032. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA directs the Secretary of HHS to establish a Drug Price Negotiation Program (the Program) to lower prices for certain single-source prescription drugs and biologics covered under Medicare Parts B and D, based on criteria established under the IRA. Under the Program, the Secretary of HHS will publish a list of "selected drugs," and will then negotiate maximum fair prices (MFP) with their manufacturers. Beginning in 2026, the first year of the Program, the number will be limited to 10 Part D drugs and biologics. By 2029, and in subsequent years thereafter, the number will increase to 20 drugs and biologics covered under Part D and Part B. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and the potential of civil monetary penalties. In August 2023, HHS released the first list of 10 drugs subject to this negotiation process. Several pharmaceutical companies had previously filed lawsuits challenging the legality of the program, but subsequently, many of those lawsuits were withdrawn as the companies decided to, at least initially, participate in the negotiation process. The possibility of renewed lawsuits could create further uncertainty about this program in the future. Further, the IRA imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Any new laws or regulations, including those that may result in additional reductions in Medicare and other healthcare funding, could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

We expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved product. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, and other consequences, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (FCPA) and other anti-corruption laws that apply in countries where we do business. The FCPA and these other anti-corruption laws generally prohibit us and our employees and intermediaries from authorizing, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. We can be held liable for the corrupt or other illegal activities of our personnel or intermediaries, even if we do not explicitly authorize or have prior knowledge of such activities.

We are also subject to other laws and regulations governing our international operations, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. An investigation of any potential violations of anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

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

We may be subject to or affected by evolving federal, state and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws (e.g. Section 5 of the Federal Trade Commission Act). For example, HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information or other personal information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions if it knowingly receives individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information under aiding-and-abetting or conspiracy principles.

Certain states have also adopted data privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018 (CCPA) imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, it is anticipated that the California Privacy Rights Act of 2020 (CPRA), which became effective January 1, 2023, will expand the CCPA. The CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR), and the Swiss Federal Act on Data Protection impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals or consumer protection organizations authorized at law to represent their interests may initiate litigation related to processing of individuals' personal data.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, in addition to direct compliance obligations under those laws. We may be directly or contractually subject to data privacy and security obligations, including industry standards adopted by industry groups and may become subject to new data privacy and security obligations in the future. For example, certain privacy laws, such as the EU GDPR and the CCPA, require companies to impose specific contractual restrictions on their service providers. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, Europe has significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from Europe to the United States in compliance with law, such as the EU and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from Europe or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, which could limit our ability to conduct clinical trial activities in Europe or elsewhere, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of Europe for allegedly violating the GDPR and EU's cross-border data transfer limitations.

Obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. We may also be bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Additionally, we publish privacy policies, self-certifications, and other documentation regarding our collection, use and disclosure of personal information and/or other confidential information. Although we endeavor to comply with our published policies, certifications, and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations. Such failures can subject us to potential international, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.

We are subject to numerous federal, state and local environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the controlled production, storage, use and disposal of hazardous and flammable materials, including chemicals. We would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties, as well as our curtailment of the use of these materials or even shutting down our facilities and operations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

Risks Related to Our Business and Operations

We are highly dependent on our key personnel, including our Chief Executive Officer and President. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and particularly on the services of our personnel including Dr. Thomas C. Chen, our Chief Executive Officer and President. We believe that his drug discovery and development experience and overall biopharmaceutical company management experience, would be difficult to replace. Any of our executive officers could leave our employment at any time, as all of our employees are "at-will" employees. We currently do not have "key person" insurance on any of our employees. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in our research and development objectives and harm our business.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. We conduct our operations at our facilities in Southern California, a region that is home to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employee agreements with our key employees, these agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of all of these individuals or the lives of any of our other employees.

Our management team has limited public company experience.

Our management team has limited public company experience. Our entire management team, as well as other of our personnel, will need to devote substantial time to compliance, and may not effectively or efficiently manage our transition into a public company. If we are unable to effectively comply with the regulations applicable to public companies or if we are unable to produce accurate and timely financial statements, which may result in misstatements that may be material in our financial statements or possible restatement of financial results, our stock price may be materially adversely affected. Any such failures could also result in litigation or regulatory actions by the SEC or other regulatory authorities, loss of investor confidence, delisting of our securities, harm to our reputation and diversion of financial and management resources from the operation of our business, any of which could materially adversely affect our business, financial condition, results of operations, and growth prospects. Additionally, the failure of a key employee to perform in his or her current position could result in our inability to continue to grow our business or to implement our business strategy.

We will need to continue to expand the size of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and comparable foreign regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize NEO100, NEO212 and any other product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of NEO100and our other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize NEO100, NEO212 and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations, stock price and prospects.

Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Public health crises such as pandemics, including the ongoing COVID-19 pandemic, or similar future outbreaks could materially and adversely affect our preclinical studies and clinical trials, business, financial condition and results of operations.

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, a number of governmental orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our office, clinical trial sites and third parties on whom we rely. As the COVID-19 pandemic started to spread in the first half of 2020, our clinical trial sites reported it had the most impact on patient care as facilities were generally ill prepared to conduct business as usual; adequate clinical evaluations, physical exams and tests were either absent or drastically reduced. Our clinical trial sites further reported that their institutions better adjusted to pandemic conditions beginning in the second half of 2020. Additionally, we have experienced disruption to our manufacturing supply chain which has delayed receipt of ordered materials and delayed our manufacturing timeline; while we now have received all ordered materials, we do not have insight into whether, or to what extent, there may be future delays.

Any further negative impact on our clinical development timelines could materially and adversely affect our business, financial condition and results of operations. Further, we have implemented a work-from-home policy allowing employees who can work from home to do so, while those needing to work in laboratory and manufacturing facilities work in shifts to reduce the number of people gathered together at one time. Business travel has been suspended, and online and teleconference technology is used to meet virtually rather than in person. We have taken measures to secure our research and development project activities, while work in laboratories has been organized to reduce risk of COVID-19 transmission. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business. For example, with our personnel working from home, some of our research activities that require our personnel to be in our laboratories could be delayed.

As a result of the COVID-19 pandemic, or similar pandemics, and related governmental orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our preclinical studies, clinical trials, business, financial condition and results of operations. Potential disruptions might include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from third-party providers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; and
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel.

The extent to which the ongoing COVID-19 global pandemic may affect our preclinical activities, clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs or vaccine rollout in the United States, business closures or business disruptions and the effectiveness of actions taken in the United States to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we may process, collect, store, and transmit proprietary, confidential, and sensitive data, including de-identified personal data (such as health-related data), intellectual property, proprietary business information and trade secrets (collectively, sensitive information). We may rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of information technology infrastructure, cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. 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. We may share or receive sensitive information with or from third parties.

Cyber-attacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," "hacktivists," threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, disruption of clinical trials, loss of data (including data related to clinical trials), and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past 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.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have established physical, electronic and organizational security measures to safeguard and secure our systems against security incidents, and rely on commercially-available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information, 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. Despite our efforts to identify and address vulnerabilities, if any, in our information technology systems, our efforts may not be successful. 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 of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, 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, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products and/or our product candidates.

The use of our product candidates in clinical trials, and the sale of any product for which we obtain regulatory approval, exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials, including liability relating to the actions and negligence of our investigators, and will face an even greater risk if we commercially sell any product candidates that we may develop. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;

- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decreases in our stock price;
- initiation of investigations and enforcement actions by regulators; and
- product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.

We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include clinical trials and the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.

Our employees, independent contractors, consultants, commercial partners, principal investigators, contract manufacturing organizations (CMOs), or contract research organizations (CROs) may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners or principal investigators could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a FCA case against us even if the government considers the claim unmeritorious and/or declines to intervene, which could require us to incur costs defending against such a claim. In addition, 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, financial condition, results of operations, stock price and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in U.S. federal healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We have generated significant net operating loss (NOL) carryforwards and research and development tax credits, and our ability to utilize our net operating loss carryforwards and research and development tax credits to reduce future tax payments may be limited or restricted.

We have generated significant NOL carryforwards and research and development tax credits (R&D credits) due to our incurrence of losses and our conduct of research activities since inception. As of December 31, 2024 we had federal NOL carryforwards of approximately $30,000,000. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. Our U.S. federal NOL carryforwards developed in taxable years beginning before January 1, 2018, can be carried forward to each of the 20 taxable years following the year of the loss. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, U.S. federal NOLs incurred in tax years beginning after December 31, 2017, totaling approximately $22,800,000, may be carried forward indefinitely, but the utilization of U.S. federal NOLs generated in tax years beginning after December 31, 2020, is limited. Our U.S. federal R&D credit carryforwards can be carried forward for 20 taxable years. If not utilized in that period, these R&D credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, the California state R&D credits carry forward indefinitely until utilized. These R&D credit carryforwards could expire unused and be unavailable to offset future income tax liabilities.

Under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and R&D credits to offset its post-change income and taxes, respectively, may be limited. For purposes of these rules, an "ownership change" generally occurs if one or more shareholders or groups of shareholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The application of these rules could limit the amount of NOLs or R&D credit carryforwards that we can utilize annually to offset future taxable income or tax liabilities. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Although the Company has not undertaken a formal analysis, an ownership change may have occurred prior to December 31, 2023, which would reduce the NOL available for use in future periods.

Our NOL and R&D credit carryforwards are subject to review and possible adjustment by U.S. and state tax authorities.

Risks Related to Ownership of Our Common Stock

An active trading market may not develop or continue to be liquid and the market price of shares of our common stock may be volatile.

Prior to the listing of our common stock on Nasdaq, there was no public market for any of our securities, and an active market for our common stock may not develop or be sustained after our recent listing, which could depress the market price of shares of our common stock and could affect the ability of our stockholders to sell our common stock. In the absence of an active public trading market, investors may not be able to liquidate their investments in our common stock. An inactive market may also impair our ability to raise capital by selling shares of our common stock, our ability to motivate our employees through equity incentive awards and our ability to acquire other companies, products or technologies by using shares of our common stock as consideration.

The public price of our common stock could be subject to wide fluctuations in response to the risk factors described in this prospectus and others beyond our control, including:

- changes in the industries in which we operate;
- variations in our operating performance and the performance of our competitors in general;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale; and
- general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism.

In addition, securities exchanges have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. Stock prices of many companies have fluctuated in a manner often unrelated to the operating performance of those companies. These fluctuations may be even more pronounced in the trading market for our common stock shortly following the listing of our common stock on Nasdaq as a result of the supply and demand forces described above. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations and financial condition.

Tariff policies and potential countermeasures could disrupt our supply chain, which could negatively impact the results of our operations.

U.S. President Trump has increased, and has indicated his willingness to continue to increase, the use of tariffs by the United States to accomplish certain United States policy goals. Such tariffs and any countermeasures could increase the cost of raw materials and components necessary for our products and create additional operational challenges. Further, it is possible that government policy changes and related uncertainty about policy changes could increase market volatility. Because of these dynamics, we cannot predict the impact of any future changes to the United States' or other countries' trading relationships or the impact of new laws or regulations adopted by the United States or other countries on our business. Such changes in tariffs and trade regulations could have a material adverse effect on our financial condition and results of operations.

Future sales of common stock by our stockholders could cause our share price to decline.

Prior to listing our common stock on Nasdaq, there was no public market for our common stock and there has not been a sustained history of trading in our common stock in "over-the-counter" markets. In the case of a lack of supply of our common stock, the trading price of our common stock may rise to an unsustainable level. Further, institutional investors may be discouraged from purchasing our common stock if they are unable to purchase a block of our common stock in the open market due to a potential unwillingness of our existing stockholders to sell a sufficient amount of common stock at the price offered by such institutional investors and the greater influence individual investors have in setting the trading price. If institutional investors are unable to purchase our common stock, the market for our common stock may be more volatile without the influence of long-term institutional investors holding significant amounts of our common stock. In the case of a lack of market demand for our common stock, the trading price of our common stock could decline significantly and rapidly after our listing. Therefore, an active, liquid and orderly trading market for our common stock may not initially develop or be sustained, which could significantly depress the public price of our common stock and/or result in significant volatility.

Our shareholders may be diluted by future issuances of preferred stock or additional common stock in connection with our incentive plans, acquisitions or otherwise; future sales of such shares in the public market, or the expectations that such sales may occur, could lower our stock price.

Our amended and restated certificate of incorporation authorizes us to issue shares of common stock and options, rights, warrants and appreciation rights relating to our common stock for the consideration and on the terms and conditions established by our board of directors in its sole discretion. We could issue a significant number of shares of common stock in the future in connection with investments or acquisitions. Any of these issuances could dilute our existing stockholders, and such dilution could be significant. Moreover, such dilution could have a material adverse effect on the market price for the shares of our common stock.

The future issuance of shares of preferred stock with voting rights may adversely affect the voting power of the holders of shares of our common stock, either by diluting the voting power of our common stock if the preferred stock votes together with the common stock as a single class, or by giving the holders of any such preferred stock the right to block an action on which they have a separate class vote, even if the action were approved by the holders of our shares of our common stock.

The future issuance of shares of preferred stock with dividend or conversion rights, liquidation preferences or other economic terms favorable to the holders of preferred stock could adversely affect the market price for our common stock by making an investment in the common stock less attractive.

Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.

We currently intend to retain all available funds and any future earnings to fund the development, commercialization and growth of our business, and therefore we do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Our future ability to pay cash dividends on our common stock may also be limited by the terms of any future debt securities or credit facility**.** As a result, capital appreciation, if any, of the common stock you purchase of the Company will be your sole source of gain for the foreseeable future.

We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) having the option of delaying the adoption of certain new or revised financial accounting standards, (iii) reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and (iv) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until such time that we are no longer an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. Further, pursuant to Section 107 of the JOBS Act, we have elected to take advantage of the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards.

We will remain an emerging growth company until the earliest of (i) December 31, 2028, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates was $700.0 million or more as of the last business day of the second fiscal quarter of such year or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is $250 million or more measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is $700 million or more measured on the last business day of our second fiscal quarter.

It is possible that some investors will find our common stock less attractive as a result of the foregoing, which may result in a less active trading market for our common stock and higher volatility in our stock price.

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

As of December 31, 2024, our executive officers, directors and five percent or greater stockholders and their respective affiliates, beneficially own, in the aggregate, approximately 60.64% of our outstanding common stock. To the extent that the same group continue to own a significant percentage of our common stock, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors, amendments of our organizational documents and approval of any merger, sale of substantially all our assets or other significant corporate transactions. This concentration of ownership may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you or other stockholders may feel are in your or their best interest as one of our stockholders.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, in each case, may delay or prevent a take-over that may not be in the best interests of our stockholders.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, in each case, may be deemed to have anti-takeover effects, which include, among others, (a classified board of directors serving staggered three-year terms

In addition, our amended and restated certificate of incorporation authorizes the issuance of shares of preferred stock which will have such rights and preferences determined from time to time by our board of directors. Pursuant to the amended and restated certificate of incorporation, our board of directors may, without stockholder approval (except as may be required under Nasdaq rules), issue additional preferred shares with dividends, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws, in each case, provide for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws, in each case, provide that, unless we consent in writing to the selection of an alternative forum, (i) the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on our behalf, (b) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (c) any action arising pursuant to any provision of the General Corporation Law of the State of Delaware, or the DGCL, our certificate of incorporation or our bylaws or (d) any action asserting a claim governed by the internal affairs doctrine and (ii) to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. Pursuant to our amended and restated certificate of incorporation, any person or entity purchasing or otherwise acquiring or holding any interest in shares of our common stock will be deemed to have had notice of and consented to the forum selection clause in our planned amended and restated certificate of incorporation described in this paragraph.

The foregoing provision would not preclude stockholders that assert claims under the Exchange Act from bringing such claims in federal court, to the extent that the Exchange Act confers exclusive federal jurisdiction over such claims, subject to applicable law.

We believe our choice of forum provision may benefit us by providing increased consistency in the application of Delaware law by chancellors and judges particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, our choice of forum provision may impose additional litigation costs on stockholders in pursuing claims and may limit a stockholder's ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or any of our directors, officers or other employees, which may discourage lawsuits with respect to such claims. In addition, while the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the choice of forum provision, and there can be no assurance that such provision will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

We are involved in disputes with former licensees of our technology, which could result in direct and indirect costs to us in defending and responding to such proceedings and could result in operational disruptions that could harm our reputation, brand and result of operations.

On July 1, 2022, NeOnc Technologies, Inc. and Fox Infused, LLC, a Delaware limited liability company ("Fox Infused"), entered into an Intellectual Property License and Supply Agreement effective July 1, 2022 (the "Agreement") whereby NeOnc agreed to supply certain products to Fox Infused and license certain of our patents. We terminated the Agreement with Fox Infused on April 25, 2023. On June 6, 2023, Fox Infused filed a complaint against NeOnc in the Central District of California alleging that the termination was improper (Civil Action No. 2:23-04431). Fox Infused also filed an ex parte application for a temporary restraining order and an order to show cause on a preliminary injunction against us seeking to have the court stop the termination of the contract. Fox Infused's temporary restraining order application was denied and the case dismissed without prejudice. Fox Infused refiled the case in arbitration before the American Arbitration Association (Case No. 01-23-0002-5020). The parties engaged in settlement discussions, and agreed to settle the dispute for a $600,000 payment by us to Fox Infused within 5 business days of the closing date of the Company's initial public offering or March 31, 2024. The Company is currently in default under the terms of such settlement agreement. The Company intends to satisfy this obligation in 2025 from sales of its securities or draws off of its line of credit. Prior to such payment, there is a risk that Fox Infused could institute default proceedings against us which could result in direct and indirect costs to us in defending and responding to such proceedings and could result in operational disruptions that could harm our reputation, brand and results of operations, any of which may affect our ability to raise additional proceeds from the sale of our securities.

On June 14, 2023, the Company terminated its collaboration agreement with Orient EuroPharma Co., Ltd. ("OEP"). OEP retained counsel, who informed the Company that it believed that the collaboration agreement was improperly terminated by the Company and intended to take legal action in connection therewith. The parties engaged in a mediation on August 29, 2023. The Company withdrew its termination notice on October 31, 2023. The Company believed this would resolve the matter. However, on February 5, 2024, OEP initiated an arbitration claiming that the Company's termination notice was invalid, the collaboration agreement remained binding and the Company breached representations in that agreement. The Company was prepared to defend the claims and assert counterclaims. Instead, the Company and OEP negotiated a settlement that resulted in the termination of the collaboration agreement and all of OEP's license rights and resolved all disputes between the parties. Pursuant to the settlement agreement, the Company agreed to pay OEP $4.0 million within ten days of the closing date of the Company's initial public offering. As the Company believes its direct listing was not an initial public offering, the Company does not intend to make payment to OEP. OEP recently informed the Company that it believes we are currently obligated to pay such amount; while we do not agree with this assertion, there is a risk that OEP could institute additional proceedings against us which could result in direct and indirect costs to us in defending and responding to such proceedings and could result in operational disruptions that could harm our reputation, brand and result of operations, any of which may affect our ability to raise additional proceeds from the sale of our securities.

We will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to maintain internal controls over financial reporting. Commencing with our fiscal year ending in 2025, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our direct listing, we were never required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities.

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

We have identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. If we fail to establish and maintain effective internal controls over financial reporting, our operating results and our ability to operate our business could be harmed.

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

In connection with the audit of NeOnc Technologies, Inc. for the years ended December 31, 2024 and 2023, our company and its independent registered public accounting firm identified material weaknesses in its internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses that NeOnc Technologies, Inc. and its independent registered public accounting firm identified in NeOnc Technologies, Inc.'s financial statements for the years ended December 31, 2024 and 2023 occurred because our company was a private company that had not previously been audited and had maintained a complement of resources with various levels of accounting knowledge, experience, and expertise that are not commensurate with our prospective financial reporting needs. These material weaknesses relate to the fact that we do not maintain a comprehensive policies and procedures manual designed to establish internal controls over financial reporting to reduce the risk of publishing materially misstated financial statements, as well as defined responsibilities and segregated incompatible duties to reduce the risk of unauthorized transactions. Collectively, this could result in difficulties in meeting our internal reporting needs and our external reporting requirements and assessing the appropriate accounting treatment for various events and/or transactions.

In addition, with respect to the three months ended March 31, 2025, management concluded that our internal control over financial reporting was not effective as of March 31, 2025, due to the material weakness in our internal control over duties separation, company-wide risk and communication processes, major financial transactions, related party dealings, and IT user access management.

We have initiated various remediation efforts, including the hiring of additional financial personnel/consultants with the appropriate public company and technical accounting expertise. We cannot reasonably estimate the cost of such remediation plan at this time. We can give no assurance that such efforts will remediate these material weaknesses internal control over financial reporting or that additional material weaknesses in its internal control over financial reporting will not be identified in the future.

We may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

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

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we will operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act, the regulations of the Nasdaq Capital Market, the rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with our fiscal year ending in 2025, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. Prior to the direct listing, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. For example, we expect that we will need to implement new systems to enhance and streamline the management of our financial, accounting, human resources and other functions.

However, such systems will likely require us to complete many processes and procedures for the effective use of the systems, which may result in substantial costs. Any disruptions or difficulties in implementing or using these systems could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting 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 met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to implement proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

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

Recent Sales of Unregistered Securities

During the three months ended March 31, 2025, the Company issued the following unregistered securities:

In February 2025, 50,000 restricted stock units were granted to each of Dr. Steven L. Giannotta, Jim Delshad and Dr. Ming-Fu Chiang. The forgoing restricted stock units vest one hundred percent (100%) seven months following March 25, 2025.

In March 2025, we issued 625,000 shares of common stock to various unaffiliated third parties in a private placement at a price of $16.00 per share for gross proceeds of approximately $10,000,000.

In March 2025, we issued to Dawson James Securities, Inc. 30,000 shares of common stock upon the time of our direct listing.

In March 2025, we issued 102,750 shares of common stock to various unaffiliated third parties in a private placement at a price of $16.00 per share for gross proceeds of approximately $1,644,000.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Use of Proceeds

Not applicable.

Repurchases

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed on Form 8-K filed by the Registrant on March 27, 2025)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 filed on Form 8-K filed by the Registrant on March 27, 2025)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
4.2	Fourth Amended & Restated Promissory Note, dated December 4, 2023, by NeOnc Technologies Holdings, Inc. and Holders (incorporated by reference to Exhibit 4.2 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
4.3	Promissory Note, dated October 11, 2024, by NeOnc Technologies Holdings, Inc. and HCWG LLC (incorporated by reference to Exhibit 4.3 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
4.4	Common Stock Purchase Warrant, dated October 11, 2024, by NeOnc Technologies Holdings, Inc. and HCWG LLC (incorporated by reference to Exhibit 4.4 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
4.5	Promissory Note, dated February 25, 2025, by NeOnc Technologies Holdings, Inc. and Amir Heshmatpour (incorporated by reference to Exhibit 4.5 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)
10.1#	NeOnc Technologies Holdings, Inc. 2023 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 filed with the Form S-8 filed by the Registrant on March 25, 2025)
10.2#	First Amendment to the NeOnc Technologies Holdings, Inc. 2023 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 filed with the Form S-8 filed by the Registrant on March 25, 2025)
10.3#	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.3 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
10.4#	Form of Option Exercise Agreement (incorporated by reference to Exhibit 10.4 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
10.5#	Form of Option Exercise Agreement (incorporated by reference to Exhibit 10.5 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
10.6#	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.6 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
10.7#	Form of Restricted Share Unit Agreement (incorporated by reference to Exhibit 10.7 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
10.8#	Form of Indemnity Agreement between NeOnc Technologies Holdings, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.8 filed with the Registration Statement on Form S-1 filed by the Registrant on January 3, 2025)
10.9	Direct Listing Engagement Letter dated January 23, 2025, between NeOnc Technologies Holdings, Inc., RBW Capital Partners LLC, and Dawson James Securities, Inc. (incorporated by reference to Exhibit 10.40 filed with the Registration Statement on Form S-1 filed by the Registrant on January 31, 2025)
10.10	Private Placement Engagement Letter dated January 29, 2025, between NeOnc Technologies Holdings, Inc., RBW Capital Partners LLC, and Dawson James Securities, Inc. (incorporated by reference to Exhibit 10.41 filed with the Registration Statement on Form S-1 filed by the Registrant on January 31, 2025)
10.11	Restricted Stock Award Agreement dated February 7, 2025, between NeOnc Technologies Holdings, Inc. and Dr. Ming-Fu Chiang (incorporated by reference to Exhibit 10.48 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)

10.12	Restricted Stock Award Agreement dated February 7, 2025, between NeOnc Technologies Holdings, Inc. and Dr. Steven L. Giannotta (incorporated by reference to Exhibit 10.49 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)
10.13	Restricted Stock Award Agreement dated February 7, 2025, between NeOnc Technologies Holdings, Inc. and Jim Delshad (incorporated by reference to Exhibit 10.50 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)
10.14	Amendment to Amended and Restated Restricted Stock Award Agreement dated February 7, 2025, between NeOnc Technologies Holdings, Inc. and Amir Heshmatpour (incorporated by reference to Exhibit 10.51 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)
10.15	Amendment to Amended and Restated Restricted Stock Award Agreement dated February 7, 2025, between NeOnc Technologies Holdings, Inc. and Dr. Thomas Chen (incorporated by reference to Exhibit 10.52 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)
10.16	Amendment to Amended and Restated Restricted Stock Award Agreement dated February 7, 2025, between NeOnc Technologies Holdings, Inc. and Bader Almonawer (incorporated by reference to Exhibit 10.53 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)
10.17	Amendment to Amended and Restated Restricted Stock Award Agreement dated February 7, 2025, between NeOnc Technologies Holdings, Inc. and Patrick Walters (incorporated by reference to Exhibit 10.54 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)
10.18	Amendment to Amended and Restated Restricted Stock Award Agreement dated February 7, 2025, between NeOnc Technologies Holdings, Inc. and Keithly Garnett (incorporated by reference to Exhibit 10.55 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)
10.19	Amendment to Second Amended and Restated Restricted Stock Award Agreement dated February 7, 2025, between NeOnc Technologies Holdings, Inc. and Victoria Medvec (incorporated by reference to Exhibit 10.56 filed with the Registration Statement on Form S-1 filed by the Registrant on February 26, 2025)
10.20	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 filed with the Form 8-K filed by the Registrant on April 1, 2025)
10.21	Office Lease, dated April 7, 2025, by and between the Company and RREF II Calabasas Park Center LLC (incorporated by reference to Exhibit 10.1 filed with the Form 8-K filed by the Registrant on April 11, 2025)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a)
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a)
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350

* Filed herewith.

** Furnished herewith.

# Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized, in Los Angeles, California, on May 9, 2025.

By: /s/ Dr. Thomas Chen
Name: Dr. Thomas Chen
Title: Chief Executive Officer (Principal Executive Officer)

By: /s/ Keithly Garnett
Name: Keithly Garnett
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Dr. Thomas Chen certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended March 31, 2025 of NeOnc Technologies Holdings, Inc; and

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 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 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: May 9, 2025

/s/ Dr. Thomas Chen

Dr. Thomas Chen
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Robert Steinberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended March 31, 2025 of NeOnc Technologies Holdings, 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 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 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: May 9, 2025

/s/ Keithly Garnett
Keithly Garnett
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Dr. Thomas Chen, Chief Executive Officer of NeOnc Technologies Holdings, Inc., certify that:

The quarterly report on Form 10-Q of NeOnc Technologies Holdings, Inc. for the period ended March 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

The information contained in such report fairly presents, in all material respects, the financial condition and results of operations of NeOnc Technologies Holdings, Inc.

/s/ Dr Thomas Chen
Dr Thomas Chen
Chief Executive Officer
(Principal Executive Officer)
Date: May 9, 2025

A signed original of this written statement required by Section 906 has been provided to NeOnc Technologies Holdings, Inc. and will be retained by NeOnc Technologies Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Keithly Garnett, Chief Financial Officer of NeOnc Technologies Holdings, Inc., certify that:

The quarterly report on Form 10-Q of NeOnc Technologies Holdings, Inc. for the period ended March 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

The information contained in such report fairly presents, in all material respects, the financial condition and results of operations of NeOnc Technologies Holdings, Inc.

/s/ Keithly Garnett
Keithly Garnett
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: May 9, 2025

A signed original of this written statement required by Section 906 has been provided to NeOnc Technologies Holdings, Inc. and will be retained by NeOnc Technologies Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.