Filed Pursuant to Rule 424(b)(4)
Registration No. 333-284115

2,101,313 Shares

NeOnc Technologies Holdings, Inc.

This prospectus relates to the registration of the resale of up to 2,101,313 shares of our common stock by our stockholders identified in this prospectus, or the Registered Stockholders, in connection with our direct listing, or the Direct Listing, on the Nasdaq Global Market, or Nasdaq. Unlike an initial public offering, the resale by the Registered Stockholders is not being underwritten on a firm-commitment basis by any investment bank. The Registered Stockholders may, or may not, elect to sell their shares of common stock covered by this prospectus, as and to the extent they may determine. The Registered Stockholders may offer, sell or distribute all or a portion of the shares of common stock hereby registered publicly or through private transactions at prevailing market prices or at negotiated prices. If the Registered Stockholders choose to sell their shares of common stock, we will not receive any proceeds from the sale of shares of common stock by the Registered Stockholders. We have engaged RBW Capital Partners LLC, as our financial advisor (the "Advisor"), to advise and assist us with respect to certain matters relating to the Direct Listing.

No public market for our common stock currently exists, and our shares of common stock have a limited history of trading in private transactions. From inception through December 31, 2023, we raised an aggregate of approximately $13,117,000 in gross proceeds from the sales of our stock at an average price of $1.25 per share. In June and July 2024, we issued an aggregate of 1,145,880 shares of common stock in private placements upon the conversion of an aggregate of approximately $13,750,439 of indebtedness at a price of $12.00 per share. Between June and October 2024, we issued an aggregate of 384,646 shares of common stock in private placements at a price of $12.00 per share for gross proceeds of approximately $4,616,000.

We have also engaged RBW Capital Partners LLC as a placement agent, all securities offered through Dawson James Securities, Inc., for the sale of shares of our common stock to unaffiliated third parties in a private placement at a price of $16.00 per share, such issuance to occur prior to the date of this Prospectus. We will pay RBW Capital Partners LLC a placement fee equal to 12% of the total gross dollar amount of the capital that is raised in the private placement by RBW Capital Partners LLC. To date, we have agreements with investors to sell 624,999 shares of common stock at the private placement price of $16.00 per share for gross proceeds of approximately $10,000,000. All 624,999 shares of common stock are being registered by means of this registration statement and unless otherwise indicated, all information regarding the number of shares of our common stock outstanding as of the date of this prospectus, the Registered Holders and the number of shares of our common stock to be sold pursuant to this prospectus gives effect to such issuance.

Recent purchase prices of our common stock in private transactions may have little or no relation to the opening public price of our shares of common stock on Nasdaq or the subsequent trading price of our shares of common stock on Nasdaq. For more information, see "*Sale Price History of Our Capital Stock.*" Further, the listing of our common stock on Nasdaq, without a firm-commitment underwritten offering, is a novel method for commencing public trading in shares of our common stock and, consequently, the trading volume and price of shares of our common stock may be more volatile than if shares of our common stock were initially listed in connection with an initial public offering underwritten on a firm-commitment basis.

On the day that our shares of common stock are initially listed on Nasdaq, Nasdaq will begin accepting, but not executing, pre-opening buy and sell orders and will begin to continuously generate the indicative Current Reference Price (as defined below) on the basis of such accepted orders. The Current Reference Price is calculated each second and, during a 10-minute "Display Only" period, is disseminated, along with other indicative imbalance information, to market participants by Nasdaq on its NOII and BookViewer tools. Following the "Display Only" period, a "Pre-Launch" period begins, during which, or the Advisor, in its capacity as our financial advisor, must notify Nasdaq that our shares are "ready to trade." Once the Advisor has notified Nasdaq that our shares of common stock are ready to trade, Nasdaq will confirm the Current Reference Price for our shares of common stock, in accordance with Nasdaq rules. If the Advisor then approves proceeding at the Current Reference Price, the applicable orders that have been entered will be executed at such price and regular trading of our shares of common stock on Nasdaq will commence, subject to Nasdaq conducting validation checks in accordance with Nasdaq rules. Under Nasdaq rules, the "Current Reference Price" means: (i) the single price at which the maximum number of orders to buy or sell can be matched; (ii) if there is more than one price at which the maximum number of orders to buy or sell can be matched, then it is the price that minimizes the imbalance between orders to buy or sell (i.e. minimizes the number of shares that would remain unmatched at such price); (iii) if more than one price exists under (ii), then it is the entered price (i.e. the specified price entered in an order by a customer to buy or sell) at which our shares of common stock will remain unmatched (i.e. will not be bought or sold); and (iv) if more than one price exists under (iii), a price determined by Nasdaq in consultation with the Advisor in its capacity as our financial advisor. In the event that more than one price exists under (iii), the Advisor will exercise any consultation rights only to the extent that it can do so consistent with the anti-manipulation provisions of the federal securities laws, including Regulation M, or applicable relief granted thereunder; in connection therewith. The Registered Stockholders will not be involved in Nasdaq's price-setting mechanism, including any decision to delay or proceed with trading, nor will they control or influence the Advisor in carrying out its role as a financial adviser; the Advisor will be issued 30,000 shares of our common stock in connection with and at the time of the Direct Listing but such shares are not registered further to this prospectus and the Advisor is not a Registered Stockholder. The Advisor will determine when our shares of common stock are ready to trade and approve proceeding at the Current Reference Price primarily based on considerations of volume, timing and price. In particular, the Advisor will determine, based primarily on pre-opening buy and sell orders, when a reasonable amount of volume will cross on the opening trade such that sufficient price discovery has been made to open trading at the Current Reference Price. For more information, see "*Plan of Distribution*" beginning on page 196 of this prospectus.

We have been approved to list our common stock on the Nasdaq Global Market under the symbol "NTHI." We expect our common stock to begin trading on Nasdaq on or about March 26, 2025.

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings. See "*Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company*."

Investing in our common stock involves a high degree of risk. See the "*Risk Factors*" section beginning on page 11 of this prospectus for the risks and uncertainties you should consider before investing in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Prospectus dated March 25, 2025

Table of Contents

You should rely only on the information contained in this prospectus or contained in any free writing prospectus filed with the Securities and Exchange Commission. Neither we nor any of the Registered Stockholders have authorized anyone to provide any information different from, or in addition to, the information contained in this prospectus and in any free writing prospectuses we have prepared or that have been prepared on our behalf or to which we have referred you. Neither we nor any of the Registered Stockholders take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The Registered Stockholders are offering to sell, and seeking offers to buy, shares of their common stock only under the circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or of any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since such date.

For investors outside the United States: Neither we nor any of the Registered Stockholders have done anything that would permit the use of or possession or distribution of this prospectus or any related free writing prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock by the Registered Stockholders and the distribution of this prospectus outside the United States.

ABOUT THIS PROSPECTUS

This prospectus is a part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration or continuous offering process. Under this process, the Registered Stockholders may, from time to time, sell the common stock covered by this prospectus in the manner described in the section titled "*Plan of Distribution*." Additionally, we may provide a prospectus supplement to add information to, or update or change information contained in, this prospectus, including the section titled "*Plan of Distribution*". You may obtain this information without charge by following the instructions under the "*Where You Can Find Additional Information*" section of this prospectus. You should read this prospectus and any prospectus supplement before deciding to invest in our common stock.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed or will be filed as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described under "*Where You Can Find Additional Information*."

PROSPECTUS SUMMARY

This summary highlights certain significant aspects of our business and is a summary of information contained elsewhere in this prospectus. This summary does not contain all the information that you should consider before deciding to invest in our common stock. You should read the entire prospectus carefully, including "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and our consolidated financial statements and related notes thereto included in this prospectus, before making an investment decision.

Unless otherwise indicated, all share and per share information in this prospectus has been retroactively restated to give effect to a 1.222 for-1 forward split of our outstanding shares of common stock in April 2023 and the subsequent issuance of 10,500,000 shares of our common stock to shareholders of NeOnc Technologies, Inc. in April 2023 in a share exchange.

We have engaged RBW Capital Partners LLC as a placement agent, all securities offered through Dawson James Securities, Inc., for the sale of shares of our common stock to unaffiliated third parties in a private placement at a price of $16.00 per share, such issuance to occur prior to the date of this Prospectus. To date, we have agreements with investors to sell 624,999 shares of common stock at the private placement price of $16.00 per share for gross proceeds of approximately $10,000,000. All 624,999 shares of common stock are being registered by means of this registration statement and unless otherwise indicated, all information regarding the number of shares of our common stock outstanding as of the date of this prospectus, the Registered Holders and the number of shares of our common stock to be sold pursuant to this prospectus gives effect to such issuance.

Unless the context otherwise requires, the terms "NeOnc", "Company", "we", "us" and "our" refer to NeOnc Technologies Holdings, Inc., a Delaware corporation, and its wholly-owned subsidiary NeOnc Technologies, Inc., and "this prospectus" refers to the offering contemplated this prospectus.

General

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 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 has two lead products in development: NEO100 and NEO212. NEO100 is a purified form of perillyl acid ("POH") which is administered to brain cancer patients via intranasal delivery. Ongoing activities for intranasal delivery of NEO100:

- We have completed human testing in a Phase I clinical trial and are currently conducting a Phase IIa trial with recurrent malignant glioma (Grade IV, IDH1 mutant and Grade III Astrocytoma, IDH1 mutant) patients.

- A similar Phase IIa trial of intranasal NEO100 (NEO 100-02) for patients with malignant skull-based meningioma is also ongoing. Meningiomas are slow-growing tumors originating in the meninges, the membranous layers surrounding the brain and spinal cord. We initiated this because these patients lack effective treatment options. These tumors are notoriously difficult to access, and conventional methods like surgery often lead to significant neurological deficits. Additionally, radiation therapy has shown limited effectiveness. The trial was officially launched in July 2023. As NEO100 uses the same treatment platform as the malignant gliomas, we bypassed the Phase I trial and received FDA approval for a Phase II trial within just 30 days.

- Separate from this single-drug application, NEO100 is further being investigated as a drug delivery vehicle, where the results of NeOnc's preclinical studies suggest evidence that the combination of NEO100 with other drugs may enable a patient's improved brain tumor delivery via the intranasal route. Intranasal NEO100, mixed with levodopa (L-DOPA), is in the planning stages for a clinical trial in patients with Parkinson's disease (PD). NeOnc's laboratory experiments showed that intranasal NEO100 mixed with levodopa was able to reverse PD symptoms in mice. A Phase I clinical trial is planned to study the impact on human patients.

Our initial application for the Phase I/IIa trial for NEO 100 focused on an enrollment population with recurrent glioblastoma. Based on our Phase I results, NEO 100 showed more promise in patients with IDH1,2 mutant Grade IV astrocytomas. However, this patient population represented less than 5-10 percent of all patients with recurrent glioblastoma. As we planned for a total of 31 patients for Phase IIa in our initial analysis, enrollment of recurrent Grade IV, IDH1,2 mutants was limited due to the fact that only 5-10 percent of Grade IV astrocytomas have IDH1,2 mutations. Independent biostatistical review of clinical progression patterns of recurrent IDH1,2 mutated Grade III astrocytomas compared to recurrent IDH1,2 mutated Grade IV astrocytomas revealed that these two tumors have the same prognosis. As a result, in June 2023 we requested that the FDA not object to the inclusion of patients with recurrent Grade III IDH1,2 mutant astrocytomas in the Phase IIa trial. The FDA did not object and, as a result, the population of patients available to be enrolled is now much larger. Because the prognosis of recurrent Grade III IDH1,2 mutants is similar to recurrent IDH1,2 Grade IV astrocytomas, the number of patients needed to be enrolled in the Phase IIa trial to assess the clinical efficacy of NEO100 in the population of high grade astrocytomas did not change. The expanded patient population means that there are a significant number of additional patients that can be targeted for potential enrollment in the Phase IIa study; in an initial review, we have identified approximately 80 grade III IDH1,2 mutation-positive candidates. Patients with residual measurable disease are now followed via MRI scans to determine if there is progression, (recurrent disease), making them eligible for enrollment. We believe this targeted enrollment of both Grade III and IV IDH1,2 mutants may significantly expedite our trial process and we project that the readout for our Phase II studies with respect to NEO100 could now be feasibly delivered by the end of 2024, advancing our original timeline by a full year from 2025.

Our second lead product, NEO212, a covalently conjugated molecule combining the chemotherapeutic drug temozolomide with perillyl alcohol, has completed preclinical testing and has received investigational new drug (IND) approval from the United States Food and Drug Administration (FDA), i.e., it has been authorized to proceed to clinical testing in cancer patients. We have designed a Phase I/II trial for oral NEO212, which began in the fourth quarter of 2023. In this trial, NEO212 will be administered orally to patients with primary brain tumors (i.e., malignant gliomas) and secondary brain tumors (i.e., brain metastases derived from peripheral tumors, such as tumors of the lung, breast, skin/melanoma, etc.). Furthermore, NEO212 is undergoing development towards intranasal application specifically for patients with uncontrolled brain metastases derived from peripheral tumors (lung, breast, skin, etc.), but has not yet been studied in human patients.

Currently, none of our product candidates have been approved for sale in the United States or elsewhere. We have no commercial products nor do we have a sales or marketing infrastructure. In order to market and sell our products we must conduct clinical trials on patients and obtain regulatory approvals from appropriate regulatory agencies, like the FDA in the United States, and similar organizations elsewhere in the world.

We have not generated any revenue from product sales and from January 1, 2023 to December 31, 2024 have only generated revenue of $153,462. We do not anticipate generating significant revenues for the foreseeable future. We had net loss of $11,898,464 and $14,921,065 for the years ended December 31, 2024 and 2023, respectively. At December, 2024, we had an accumulated deficit of $50,608,445.

Market Opportunity

The World Health Organization (WHO) has estimated that CNS diseases affect nearly 2 billion people globally, making up approximately 40%of total disease burden (based on disability adjusted life years),compared with 13% for cancer and 12% for cardiovascular disease. According to Fortune Business Insights, the CNS treatment market is estimated to grow at 9.4% CAGR to $166.5 billion by 2028 and the global brain tumor drug market to grow at CAGR of 9.0% to $4.4 billion by 2029.

iHeathcareAnalys has reported that the malignant Glioblastoma Multiforme (GBM) drug market is expected to grow at 12.7% CAGR to $2.3 billion by 2029. According to the book, *Glioblastoma* by Ahmad Faleh Tamimi and Malik Juweid (2017), GBM accounts for up to 54% of gliomas and 16% of all primary brain cancers.

Business Strategy

Our strategy is to leverage our considerable industry experience, understanding of the CNS and GBM markets and development expertise to identify, develop and commercialize product candidates with significant market potential that can fulfill unmet medical needs in the treatment of brain cancers and CNS diseases. We have assembled a management team along with both scientific and business advisors, including recognized experts in the fields of neuro-oncology, with significant industry and regulatory experience to lead and execute the development and commercialization of our NEO platform.

We plan to further develop NEO100 and NEO212 as our priority programs. We have generated and plan to continue to generate intellectual property (IP) that will further protect our products from competition. We will continue to prioritize our product development activities after considering the resources we have available, market dynamics and potential for adding value.

Intellectual Property Portfolio and Market Exclusivity

We have exclusively licensed a large worldwide patent portfolio from the University of Southern California (USC) consisting of both issued patents and pending patent applications related to NEO100, NEO212 and other products from the NeOnc patent family for multiple uses, including oncological and neurological conditions.

Key Strengths

We believe that the key elements for our market success include:

- Compelling lead product opportunity, with NEO100 currently in Phase II trials;
- Licensed large patent portfolio for NEO100 with currently issued patents expiring between 2030-2038; and
- Potential in additional multiple indications in underserved markets with large patient populations.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As an emerging growth company, we are eligible to take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies and may elect to take advantage of other exemptions from reporting requirements in our future filings with the Securities Exchange Commission ("SEC"). In particular, in this prospectus, these exemptions include:

- presenting only two years of audited consolidated financial statements and only two years of related selected financial data and Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in our registration statement of which this prospectus forms a part;
- reduced disclosure about our executive compensation arrangements;
- exemption from the requirements to hold non-binding advisory votes on executive compensation ("Say on Pay");
- extended transition periods for complying with new or revised accounting standards;
- exemption from the auditor attestation requirement in the assessment of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"); and

- the auditor not being required to comply with the requirement in Public Company Accounting Oversight Board Auditing Standard 3101, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion*, to communicate critical audit matters in the auditor's report.

We may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.235 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1 billion of non-convertible debt securities over a three-year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of certain reduced reporting obligations in this prospectus. Further, pursuant to Section 107 of the JOBS Act, as an emerging growth company, we have elected to use the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock, and our consolidated financial statements may not be comparable to the consolidated financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. See "*Risk Factors—Risks Related to this offering and Ownership or Our Common Stock*" which describes that we are an emerging growth company, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

Summary of Risks Related to Our the Direct Listing and Volatility of Our Common Stock Following the Offering

We cannot predict the prices at which our common stock may trade on Nasdaq following the listing of our common stock, and the market price of our common stock may fluctuate significantly in response to various factors, some of which are beyond our control. In particular, prior to the opening trade, there will not be a price at which underwriters initially sold shares of common stock to the public as there would be in a firm-commitment underwritten initial public offering. The absence of a predetermined initial public offering price could impact the range of buy and sell orders collected by Nasdaq from various broker-dealers. Consequently, upon listing on Nasdaq, the public price of our common stock may be more volatile than in a firm-commitment underwritten initial public offering and could decline significantly and rapidly.

In addition, because of our novel listing process, individual investors, retail or otherwise, may have greater influence in setting the opening public price and subsequent public prices of our common stock on Nasdaq and may participate more in our initial trading than is typical for a firm-commitment underwritten initial public offering. These factors could result in a public price of our common stock that is higher than other investors (such as institutional investors) are willing to pay, which could cause volatility in the trading price of our common stock and an unsustainable trading price if the price of our common stock significantly rises upon listing and institutional investors believe our common stock is worth less than retail investors, in which case the price of our common stock may decline over time. Further, if the public price of our common stock is above the level that investors determine is reasonable for our common stock, some investors may attempt to short our common stock after trading begins, which would create additional downward pressure on the public price of our common stock.

Finally, there can be no assurance that the Registered Stockholders and other existing stockholders will not sell all of their shares of common stock, resulting in an oversupply of our common stock on Nasdaq. 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, which could affect your ability to sell your shares of common stock.

Summary of Risks Relating to Our Business

Our business is subject to numerous risks and uncertainties, including those described in "*Risk Factors*" and elsewhere in this prospectus. You should carefully consider these risks before making an investment. These risks include, among others, 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.
- 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.
- We have never generated any revenue from product sales and may never become profitable. Raising additional capital may cause dilution to our shareholders, including purchasers of common stock in this offering, 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" explanatory 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.
- We currently have two clinical development product candidates (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 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.
- Clinical development involves a lengthy and expensive process with an uncertain outcome and stringent regulations, and delays can occur for a variety of reasons.

- If we experience delays or difficulties in the enrolment 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.
- 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.
- 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.
- We anticipate that many of our product candidates, if approved, may be 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 may not be successful in our efforts to expand our pipeline of product candidates and develop marketable products.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.

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.
- Changes in product candidate manufacturing or formulation may result in additional costs or delay, including due to requirements for additional regulatory approvals.
- If we or our contract manufacturing partner(s) are unable to manufacture product candidates in the volumes that we require on a timely basis, or fail to comply with 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.

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.
- 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 competing 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.
- 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.
- 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.
- 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.

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.
- 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.

- We may not be able to protect our intellectual property and proprietary rights throughout the world.
- 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 be expensive, time-consuming and unsuccessful and 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 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.
- 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.

Risks Related to Our Business and Operations

- We are highly dependent on our key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- 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 and/or our product candidates.
- 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 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.

Risks Related to This Offering and Ownership of Our Common Stock

- The direct listing process differs from an initial public offering underwritten on a firm-commitment basis.
- Our common stock currently has no public market. 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.
- Future sales of common stock by our Registered Stockholders and other existing stockholders could cause our share price to decline.

- You 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.

- 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 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.

- 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.

- Our amended and restated certificate of incorporation, in each case, which will become effective in connection with the effectiveness of the registration statement, of which this prospectus forms a part, will 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.

General Risk Factors

- 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.

- 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 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.

- 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.

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

Corporate Information

NeOnc Technologies, Inc. was incorporated in Delaware in 2008 as NAS-ONC, Inc. In April 2023, shareholders of NeOnc Technologies, Inc. completed a share exchange (the "Share Exchange") with NeOnc Technologies Holdings, Inc. pursuant to which all shareholders of NeOnc Technologies, Inc. became shareholders of NeOnc Technologies Holdings, Inc. and NeOnc Technologies, Inc. became a wholly-owned subsidiary of NeOnc Technologies Holdings, Inc. Our executive offices are located at 2 Dole Drive, Westlake Village, CA 91362 and our telephone number is (310) 633-7831. Our corporate website is www.neonctech.com. Information appearing on our corporate website is not incorporated as part of this prospectus.

SUMMARY FINANCIAL DATA

The summary financial data set forth below should be read together with our financial statements and the related notes to those statements, as well as the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. The consolidated statements of operations data for the years ended December 31, 2024 and 2023, and the consolidated balance sheet data as of December31, 2024, have been derived from our audited financial statements included elsewhere in this prospectus.

Consolidated Statements of Operations Data

	Year ended December 31,	
	2024	**2023**
Revenue		
Revenue	$ 83,000	$ 70,462
Operating expenses:		
Research and development	3,045,239	1,534,114
Legal and professional	2,000,623	1,907,687
General and administrative	1,638,410	1,488,557
Advisory fee	500,000	500,000
Litigation settlement expense, net	41,250	4,100,000
License expense	-	2,737,773
Total operating expenses	7,225,522	12,268,131
Loss from operations	(7,142,522)	(12,197,669)
Other income (expense):		
Interest income	16,133	-
Amortization on debt issuance costs	(145,097)	-
Interest expense - related parties	(2,557,055)	(2,723,396)
Loss on extinguishment of Bridge loan	(2,069,923)	-
Total other expense	(4,755,942)	(2,723,396)
Net loss	$ (11,898,464)	$ (14,921,065)
Diluted net loss per share	$ (0.69)	$ (1.02)
Weighted average shares outstanding	17,342,755	14,681,111

Consolidated Balance Sheet Data

	As of December 31, 2024
Cash	$ 64,893
Deferred offering costs	$ 1,071,947
Accounts payable	$ 2,893,079
Accounts payable related - parties	$ 628,277
Litigation settlement payable	$ 4,641,250
Accrued compensation	$ 734,874
Paid-in capital	$ 45,101,675
Accumulated deficit	$ (50,608,445)
Shareholders' (deficit) equity	$ (5,504,961)

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 prospectus, 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.

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 $11,898,464 and $14,921,065, for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $50,608,445. 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 the completion of this offering.

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. As of December 31, 2024, we had $64,893 in cash. 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 $ 83,000 and $70,462, for 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 Chairman. 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 Chairman. 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 million. 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 million, 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 This Offering and Ownership of Our Common Stock

The direct listing process differs from an initial public offering underwritten on a firm-commitment basis.

This is not an underwritten initial public offering of common stock. This listing of our common stock on Nasdaq differs from an underwritten initial public offering in several significant ways, which include, but are not limited to, the following:

- There are no underwriters engaged on a firm-commitment basis. Consequently, prior to the opening of trading on Nasdaq, there will be no traditional book building process and no price at which underwriters initially sold shares to the public to help inform efficient and sufficient price discovery with respect to the opening trades on Nasdaq. Therefore, buy and sell orders submitted prior to and at the opening of trading of our common stock on Nasdaq will not have the benefit of being informed by a published price range or a price at which the underwriters initially sold shares to the public, as would be the case in an initial public offering underwritten on a firm-commitment basis. Moreover, there will be no underwriters engaged on a firm-commitment underwritten basis assuming risk in connection with the initial resale of shares of our common stock. In an initial public offering underwritten on a firm-commitment basis, the underwriters may engage in "covered" short sales in an amount of shares representing the underwriters' option to purchase additional shares. To close a covered short position, the underwriters purchase shares in the open market or exercise the underwriters' option to purchase additional shares. In determining the source of shares to close the covered short position, the underwriters typically consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the underwriters' option to purchase additional shares. Purchases in the open market to cover short positions, as well as other purchases underwriters may undertake for their own accounts, may have the effect of preventing a decline in the market price of shares. Given that there will be no underwriters' option to purchase additional shares and no underwriters engaging in stabilizing transactions, there could be greater volatility in the public price of our common stock during the period immediately following the listing. See also "— *Our shares of common stock have no prior public market. An active trading market may not develop or continue to be liquid and the market price of our shares of common stock may be volatile*."

- There is not a fixed number of shares of common stock available for sale. Therefore, there can be no assurance that any Registered Stockholders or other existing stockholders will sell any or all of their common stock and there may initially be a lack of supply of, or demand for, our common stock on Nasdaq. Alternatively, we may have a large number of Registered Stockholders or other existing stockholders who choose to sell their common stock in the near term resulting in an oversupply of our common stock, which could adversely impact the public price of our common stock once listed on Nasdaq and thereafter.

- None of our Registered Stockholders or other existing stockholders have entered into contractual lock-up agreements or other contractual restrictions on transfer. In a firm-commitment underwritten initial public offering, it is customary for an issuer's officers, directors, and most of its other stockholders to enter into a 180-day contractual lock-up arrangement with the underwriters to help promote orderly trading immediately after such initial public offering. Consequently, any of our stockholders, including our directors and officers who own our common stock and other significant stockholders, may sell any or all of their common stock at any time (subject to any restrictions under applicable law), including immediately upon listing. If such sales were to occur in a significant volume in a short period of time following our listing, it may result in an oversupply of our common stock in the market, which could adversely impact the public price of our common stock.

- We did not conduct a traditional "roadshow" with underwriters prior to the opening of trading on Nasdaq. Instead, we hosted an investor day, as well as engaged in certain other investor education meetings. In advance of the investor day, we announced the date for such day over financial news outlets in a manner consistent with typical corporate outreach to investors. We prepared an electronic presentation for this investor day, which included content similar to a traditional roadshow presentation, and made one version of the presentation publicly available, without restriction, on a website. There can be no guarantees that the investor day and other investor education meetings had the same impact on investor education as a traditional "roadshow" conducted in connection with a firm-commitment underwritten initial public offering. As a result, there may not be efficient price discovery with respect to our common stock or sufficient demand among investors immediately after our listing, which could result in a more volatile public price of our common stock.

Such differences from a firm-commitment underwritten initial public offering could result in a volatile trading price for our common stock and uncertain trading volume, which may adversely affect your ability to sell any common stock that you may purchase.

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 has not been a public market for any of our securities, and an active market for our common stock may not develop or be sustained after the 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.

In addition, we cannot predict the prices at which our common stock may trade on Nasdaq following the listing of our common stock. The opening trading price of our common stock may be unrelated to historical sales prices of our common stock and the market price of our common stock may fluctuate significantly in response to various factors, some of which are beyond our control. In particular, as this listing is taking place through a novel process that is not a firm-commitment underwritten initial public offering, there will be no traditional book building process and no price at which traditional underwriters initially sold shares to the public to help inform efficient price discovery with respect to the opening trades on Nasdaq. On the day that our shares of common stock are initially listed on Nasdaq, Nasdaq will begin accepting, but not executing, pre-opening buy and sell orders and will begin to continuously generate the indicative Current Reference Price on the basis of such accepted orders. The Current Reference Price is calculated each second and, during a 10-minute "Display Only" period, is disseminated, along with other indicative imbalance information, to market participants by Nasdaq on its NOII and BookViewer tools. Following the "Display Only" period, a "Pre-Launch" period begins, during which the Advisor, in its capacity as our financial advisor, must notify Nasdaq that our shares are "ready to trade." Once the Advisor has notified Nasdaq that our shares of common stock are ready to trade, Nasdaq will confirm the Current Reference Price for our shares of common stock, in accordance with Nasdaq rules. If the Advisor then approves proceeding at the Current Reference Price, the applicable orders that have been entered will be executed at such price and regular trading of shares of our common stock on Nasdaq will commence, subject to Nasdaq conducting validation checks in accordance with Nasdaq rules. The Advisor will determine when our shares of common stock are ready to trade and approve proceeding at the Current Reference Price primarily based on considerations of volume, timing and price. In particular, the Advisor will determine, based primarily on pre-opening buy and sell orders, when a reasonable amount of volume will cross on the opening trade such that sufficient price discovery has been made to open trading at the Current Reference Price. If the Advisor does not approve proceeding at the Current Reference Price (for example, due to the absence of adequate preopening buy and sell interest), the Advisor will request that Nasdaq delay the open until such a time that sufficient price discovery has been made to ensure a reasonable amount of volume crosses on the opening trade. For more information, see "*Plan of Distribution*."

Additionally, prior to the opening trade, there will not be a price at which underwriters initially sold shares of common stock to the public as there would be in a firm-commitment underwritten initial public offering. The absence of a predetermined initial public offering price could impact the range of buy and sell orders collected by Nasdaq from various broker-dealers. Consequently, upon listing on Nasdaq, the public price of our common stock may be more volatile than in a firm-commitment underwritten initial public offering and could decline significantly and rapidly.

Furthermore, because of our novel listing process on Nasdaq, Nasdaq's rules for ensuring compliance with its initial listing standards, such as those requiring a valuation or other compelling evidence of value, are untested. In the absence of a prior active public trading market for our common stock, if the price of our common stock or our market capitalization falls below those required by Nasdaq's eligibility standards, we may not be able to satisfy the ongoing listing criteria and may be required to delist.

In addition, because of our novel listing process, individual investors, retail or otherwise, may have greater influence in setting the opening public price and subsequent public prices of our common stock on Nasdaq and may participate more in our initial trading than is typical for a firm-commitment underwritten initial public offering. These factors could result in a public price of our common stock that is higher than other investors (such as institutional investors) are willing to pay, which could cause volatility in the trading price of our common stock and an unsustainable trading price if the price of our common stock significantly rises upon listing and institutional investors believe our common stock is worth less than retail investors, in which case the price of our common stock may decline over time. Further, if the public price of our common stock is above the level that investors determine is reasonable for our common stock, some investors may attempt to short our common stock after trading begins, which would create additional downward pressure on the public price of our common stock. To the extent that there is a lack of consumer awareness among retail investors, such a lack of consumer awareness could reduce the value of our common stock and cause volatility in the trading price of our common stock. In addition, demand for our common stock may be adversely affected by any actual or perceived damage to our public reputation or brand recognition.

The public price of our common stock following the listing also 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.

The Advisor, which will own 30,000 shares of our common stock on the date of the Direct Listing and is acting as placement agent in connection with the sale of shares of our common stock to unaffiliated third parties in a private placement at a price of $16.00 per share, may have a conflict of interest.

Given RBW Capital Partners' dual role as our financial advisor under Nasdaq direct listing rules and its status as a stockholder and placement agent may present a conflict of interest. A conflict of interest situation can arise when a person or an entity takes has interests that may make it difficult to perform their work objectively and effectively. Conflicts of interest may also arise if a person or entity receives personal benefits as a result of their position. Nasdaq will determine the Current Price of our common stock in the Direct listing price in consultation with the Advisor in its capacity as our financial advisor. The Advisor will determine when our shares of common stock are ready to trade and approve proceeding at the Current Reference Price primarily based on considerations of volume, timing and price. In particular, the Advisor will determine, based primarily on pre-opening buy and sell orders, when a reasonable amount of volume will cross on the opening trade such that sufficient price discovery has been made to open trading at the Current Reference Price. We have agreed to issue the Advisor 30,000 shares of our common stock at the time of the Direct Listing and retained the Advisor as placement agent in connection with the sale of shares of our common stock to unaffiliated third parties in a private placement at a price of $16.00 per share. As the Advisor will receive substantial personal benefit as a result of the Direct Listing, the existence of such financial and personal interests may result in a conflict of interest on the part of the Advisor between what it may believe is best for the Company and its shareholders and what it may believe is best for itself.

Future sales of common stock by our Registered Stockholders and other existing 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. While our common stock may be sold after our listing on Nasdaq by the Registered Stockholders pursuant to this prospectus or by our other existing stockholders in accordance with Rule 144 under the Securities Act, unlike a firm-commitment underwritten initial public offering, there can be no assurance that any Registered Stockholders or other existing stockholders will sell any of their shares of common stock and there may initially be a lack of supply of, or demand for, common stock on Nasdaq. As described herein, certain shares of our common stock outstanding as of the date hereof will be registered under this registration statement. There can be no assurance that the Registered Stockholders and other existing stockholders will not sell all of their shares of common stock, resulting in an oversupply of our common stock on Nasdaq. 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, which could affect your ability to sell your shares of common stock.

You 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.

Prior to the effectiveness of the registration statement of which this prospectus forms a part, we adopted an amended and restated certificate of incorporation which 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. For example, investors in the common stock may not wish to purchase common stock at a price above the conversion price of a series of convertible preferred stock because the holders of the preferred stock would effectively be entitled to purchase common stock at the lower conversion price, causing economic dilution to the holders of 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.

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 in this offering 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 bylaws, in each case, which become effective prior to the effectiveness of the registration statement, of which this prospectus forms a part, 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 bylaws, in each case, which become effective prior to the effectiveness of the registration statement, of which this prospectus forms a part, 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. Following the adoption of 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, in each case, which become effective prior to the effectiveness of the registration statement, of which this prospectus forms a part, provides 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, in each case, which become effective prior to the effectiveness of the registration statement, of which this prospectus forms a part, will 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 will pay OEP $4.0 million within ten days of the closing date of the Company's initial public offering. As the Company believes this offering is not the Company's initial public offering but rather only a Direct Listing of its common stock, the Company does not intend to make payment to OEP as a result of this offering. 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 the year after this offering is completed, 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 this offering, 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.

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 intern*al *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.

As a private company, our company has not been required to document and test its internal controls over financial reporting, nor has management been required to certify the effectiveness of its internal controls, and our auditors have not been required to opine on the effectiveness of its internal control over financial reporting. Similarly, our company has not been subject to the SEC's internal control reporting requirements. Upon the completion of this offering, we will become 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.

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 the year after this offering is completed, 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 this offering, 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the timing, progress and results of preclinical studies and clinical trials for our current and future product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing, scope or likelihood of regulatory submissions, filings, and approvals, including final regulatory approval of our product candidates;
- our ability to develop and advance product candidates into, and successfully complete, clinical trials;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- the implementation of our business model and our strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of our product candidates, in particular, and cell therapy, in general;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our competitive position;
- the scope of protection we and/or our licensors are able to establish and maintain for intellectual property rights covering our product candidates;
- developments and projections relating to our competitors and our industry;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements; and
- the impact of laws and regulations.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled "*Risk Factors*" and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

MARKET AND INDUSTRY DATA

This prospectus includes estimates regarding market and industry data. Unless otherwise indicated, information concerning our industry and the markets in which we operate, including our general expectations, market position, market opportunity, and market size, are based on our management's knowledge and experience in the markets in which we operate, together with currently available information obtained from various sources, including publicly available information, industry reports and publications, surveys, our customers, trade and business organizations, and other contacts in the markets in which we operate. Certain information is based on management estimates, which have been derived from third-party sources, as well as data from our internal research.

In presenting this information, we have made certain assumptions that we believe to be reasonable based on such data and other similar sources and on our knowledge of, and our experience to date in, the markets in which we operate. While we believe the estimated market and industry data included in this prospectus is generally reliable, such information is inherently uncertain and imprecise. Market and industry data is subject to change and may be limited by the availability of raw data, the voluntary nature of the data gathering process, and other limitations inherent in any statistical survey of such data. In addition, projections, assumptions, and estimates of the future performance of the markets in which we operate are necessarily subject to uncertainty and risk due to a variety of factors, including those described in "*Risk Factors*" and "*Cautionary Note Regarding Forward-Looking Statements*." These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us. Accordingly, you are cautioned not to place undue reliance on such market and industry data or any other such estimates.

TRADEMARKS, SERVICE MARKS AND TRADENAMES

We own or otherwise have rights to the trademarks, including those mentioned in this prospectus, used in conjunction with the operation of our business. This prospectus includes our own trademarks, which are protected under applicable intellectual property laws, as well as trademarks, service marks and tradenames of other entities, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, TM or SM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks, service marks and tradenames. We do not intend our use or display of other entities' trademarks, service marks or tradenames to imply a relationship with, or endorsement or sponsorship of us by, any other entities.

USE OF PROCEEDS

The Registered Stockholders may, or may not, elect to sell shares of our common stock covered by this prospectus. To the extent any Registered Stockholder chooses to sell shares of our common stock covered by this prospectus, we will not receive any proceeds from any such sales of our common stock. See "*Principal and Registered Stockholders.*"

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. 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 as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors. Any such determination will also depend upon our business prospects, operating results, financial condition, 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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2024, as follows.

This table should be read in conjunction with, and is qualified in its entirety by reference to, our financial statements and related notes appearing elsewhere in this prospectus.

	As of December 31, 2024
Cash	$ 64,893
Stockholders' equity/(deficit):	
Preferred Stock, $0.0001 par value per share; 10,000,000 total shares authorized, no shares issued and outstanding	-
Common Stock, $0.0001 par value per share; 100,000,000 shares authorized, 18,090,526 shares issued and outstanding	1,809
Additional paid-in capital	45,101,675
Accumulated deficit	(50,608,445)
Total stockholders' equity	$ (5,504,961)

The total number of shares of our common stock reflected in the discussion and table above excludes the following:

- 2,660,000 shares of common stock issuable upon the vesting of restricted stock units.
- 3,440,000 shares of common stock (which include the 2,660,000 shares issuable upon the vesting of the restricted stock units described above) currently reserved for future grant or issuance under our 2023 Plan of which, 780,000 shares would be available for grants.
- 312,500 shares of common stock issuable upon exercise of outstanding warrants at a per share exercise price of $12.00.
- 624,999 shares of common stock issuable in a private placement at a price of $16.00 per share for gross proceeds of approximately $10,000,000, such issuance to occur prior to the date of this Prospectus. All 624,999 shares of common stock are being registered by means of this registration statement.

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 financial statements and related notes thereto included elsewhere in this prospectus. 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. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this prospectus, including those set forth in the sections of this prospectus entitled "Risk Factors" and "Cautionary Statement Concerning Forward-Looking Statements". Financial information as of and for the year ended December 31, 2024 and 2023 is for NeOnc Technologies Holdings, Inc.

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 December 31, 2024, we had raised an aggregate of approximately $17.7 million of gross proceeds through the sale and issuance of preferred stock and common stock, and approximately $11.7 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 $11,898,464 and $14,921,065, for the years ended December 31, 2024 and 2023, respectively. We had an accumulated deficit of $50,608,445 at December 31, 2024. 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 into 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 and 2023 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. See Note 1 to our annual financial statements appearing at the end of this prospectus for additional information on our assessment.

In December 2022, the Company signed a Letter of Intent ("LOI") with an investment advisory firm AFH Holdings and Advisory, LLC ("AFH") to create a newly formed corporation called NeOnc Technologies Holding Company, Inc. ("NTHI") to facilitate future fundraising transactions. On April 7, 2023, the Company entered into share exchange agreements whereby all of the common shareholders of NTI exchanged all of their stock in NTI for a total of 10,500,000 shares of NTHI common stock in the share exchange ("Share Exchange"). At the consummation of the Share Exchange transaction, AFH and its affiliated entities, individuals, or assignees owned an aggregate of 34.4% (5,500,000 shares) of the fully diluted issued and outstanding common shares of the Company. For a period of two years after an initial public offering ("IPO") or a direct listing, AFH will also act as an investment advisor in future financing transactions.

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. During the year ended December 31, 2024, we entered into agreements with investors to sell 624,999 shares of common stock at the private placement price of $16.00 per share for gross proceeds of approximately $10,000,000 (the "Private Placement") which are currently being held in escrow until the Company has an effective registration statement on file with the SEC.

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. No amounts have been borrowed under the facility through December 31, 2024.

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 the investor, and the investor may purchase from the Company, up to $50,000,000 of Company's common shares. The Company cannot draw down any funds under the Equity Purchase Agreement until the Company has an effective registration statement.

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.

We have deferred payments received for the license of our products to third parties – See collaboration agreement accounting policy below.

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 product 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 profile 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 into 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.

Advisory Fee Expenses

The advisory fee expenses result from the advisory arrangement with AFH.

License Expense

The license expense results from the amendment of the license with USC whereby we agreed to issue USC 560,000 additional shares of our common stock such that USC's ownership of our company, when combined with the shares currently held by USC, equals three and one-half percent (3.5%) of our fully diluted capitalization just prior to the issuance. We have recorded license expense during the year ended December 31, 2023 equal to the estimated value of such shares, which were issued in October 2023.

Interest Expense

Interest expense results from the bridge loan from a related party. Borrowings under the note 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 on Debt Issuance Costs

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.

Comparison of the years ended December 31, 2024 and 2023:

Results of Operations

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

	For the years ended December 31,		
	2024	**2023**	**Change**
Revenues			
Revenue	$ 83,000	$ 70,462	$ 12,538
Operating expenses:			
Research and development	3,045,239	1,534,114	1,511,125
Legal and professional	2,000,623	1,907,687	92,936
General and administrative	1,638,410	1,488,557	149,853
Advisory fee	500,000	500,000	-
Litigation settlement expense, net	41,250	4,100,000	(4,058,750)
License expense	-	2,737,773	(2,737,773)
Total operating expenses	7,225,522	12,268,132	(5,042,610)
Loss from operations	(7,142,522)	(12,197,669)	5,055,147
Other expense:			
Interest income	16,133	-	16,133
Amortization on debt issuance costs	(145,097)	-	(145,097)
Interest expense	(2,557,055)	(2,723,396)	166,340
Loss on extinguishment of Bridge loan	(2,069,923)	-	(2,069,923)
Net loss	$ (11,898,464)	$ (14,921,065)	$ 3,022,601

Revenue

Revenue was generated for fees for a “right to try” humanitarian program during 2024 and 2023 and sale of product to a licensee.

Research and Development Expenses

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

	For the year ended December, 31,	
	2024	**2023**
Research and development costs by project:		
NEO100-01	$ 1,200,624	$ 702,226
NEO100-02	320,987	-
NEO212	870,634	279,859
Pediatric	191,593	169,777
Laboratory	460,559	326,272
Other	841	55,980
Total	$ 3,045,238	$ 1,534,114

	For the years ended December 31,		
	2024	2023	Change
Clinical trial expense	$ 2,583,838	$ 1,207,842	$ 1,375,996
Research and laboratory	461,400	326,272	135,128
Total research and development expense	$ 3,045,238	$ 1,534,114	$ 1,511,124

Research and development expenses were $3,045,238 and $1,534,114 for the years ended December 31, 2024 and 2023, respectively. A portion of these expenses amounting to approximately $460,559 and $326,272 for the years ended December 31, 2024 and 2023, respectively are from the University of Southern California (USC), where Dr. Chen is a member of the faculty. The total increase of $1,511,124 was primarily due to:

- The addition of clinical trial sites for NEO100's clinical trial.
- The completion of the IND for NEO212 and the start of the clinical trial.
- The completion and filing of the IND for NEO100-03 for a Pediatric Indication and preparation for the start of the clinical trial.
- The start of a new clinical trial NEO100-02 for Meningiomas.
- Increased patient recruitment efforts.

Legal and Professional Expenses

Legal and professional expenses were $2,000,623 and $1,907,687 for the years ended December 31, 2024 and 2023, respectively. The increase of $92,936 was primarily due to ending the IPO process and preparing a direct listing resulting in a writing off deferred professional fees in the amount of approximately $704,000, offset by legal expense related to litigation matters in the prior year, which were non-recurring in the current year.

General and Administrative Expenses

General and administrative expenses were $1,638,410 and $1,488,557 for the years ended December 31, 2024 and 2023, respectively. The increase of $149,853 was primary due to the rent expense related to a new lease and advertising and public relations costs. The Company did not have a lease in the prior year.

Advisory Fee

Advisory fee expenses resulting from the advisory arrangement with AFH for the years ended December 31, 2024 and 2023 were $500,000 and $500,000, respectively.

Litigation Settlement Expense

Litigation settlement expense of $4,100,000 for the year ended December 31, 2023 resulted from the settlement of legal matters with two former licensees in the amount of $4,100,000, in part offset by write off of $500,000 of deferred revenue related to one of the licenses. No such settlements were incurred during the year ended December 31, 2022.

License Expense

For the year ended December 31, 2023, the license expense of $2,737,773 is equal to the estimated fair value of the shares to be issued to USC in accordance with the USC amended license agreement. For the year ended December 31, 2024, no additional license expense has been incurred.

Cash Flows

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

	For the year ended December 31,		
	2024	**2023**	**Change**
Net cash provided by (used in):			
Operating activities	$ (4,213,916)	$ (1,880,012)	$ (2,333,904)
Financing activities	4,246,947	1,278,576	2,968,371
Net increase (decrease) in cash	$ 33,301	$ (601,436)	$ 634,467

Operating Activities

During the year ended December 31, 2024, net cash used in operating activities was $4,213,916 consisting primarily of our net loss of $11,898,464 less the non-cash charge of the accretion of the original issue discount on the bridge loan in the amount of $2,557,055, loss on the extinguishment of the bridge loan in the amount of $2,069,923 the write off of deferred offering costs in the amount of $703,796, and an increase in accounts payable of $1,798,583. We have primarily used the proceeds of the bridge loan to prepare the company for an offering of its securities and activities related thereto, while payment for operating activities has been deferred. During the year ended December 31, 2023, net cash used in operating activities was $1,880,012 consisting primarily of our net loss of $14,921,065 less the non-cash charge for license expense payable in stock of $2,507,773, increase in the bridge loan – expenses paid by the bridge loan provider on behalf of the Company of $1,997,775, and accretion of original issue discount of $2,721,747 and an offset by an increase in accounts payable of $1,059,789, accrued compensation of $678,743 and litigation settlement expense of $4,100,000.

Financing Activities

During the year ended December 31, 2024, cash provided by financing activities was $4,246,947 consisting primarily of net proceeds of $4,615,789 from the sale of common stock and $892,028 from the bridge loan, offset by the repayment of bridge loans of $791,077. During the year ended December 31, 2023, cash provided by financing activities was $1,278,576 consisting primarily of net proceeds of $3,507,972 from the bridge loans, offset by the repayment of bridge loans of $2,135,277.

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.

We have engaged RBW Capital Partners LLC as a placement agent, all securities offered through Dawson James Securities, Inc., for the sale of shares of our common stock to unaffiliated third parties in a private placement at a price of $16.00 per share, such issuance to occur prior to the date of this Prospectus. To date, we have agreements with investors to sell 624,999 shares of common stock at the private placement price of $16.00 per share for gross proceeds of approximately $10,000,000. All 624,999 shares of common stock are being registered by means of this registration statement. The Company is in the process of filing with the SEC for a registration statement, however no assurance can be given that the Company will complete the process.

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 year ended December 31, 2024, we incurred a net loss of $11,898,464 and used cash in operations of $4,213,916 and had a shareholders' deficit of $5,504,961 as of December 31, 2024. 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, upon the completion of this offering, 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 $10.0 million private placement 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. 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.

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 will commence on the effective date of this offering 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.

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 at December 31, 2023. The outstanding amounts under this Bridge Loan were payable at the earlier of the IPO date or December 4, 2024, (the "Maturity Date").

We had the option to prepay this note with no penalties at any time and prior to the Maturity Date in an amount equal to the sum of: (A) the then principal balance of this note plus (B) all other amounts, costs, and expenses then due in respect of this note.

On June 14, 2024**,** the Company reached an agreement with HCWG to convert the outstanding principal and interest on the Bridge Loan totaling $11,748,464 to 979,039 shares of common stock at $12 per share. The difference between the carrying value of the debt as of the date of the extinguishment of $9,678,541 and the fair value of the shares issued to settle to the debt as of the date of the extinguishment of $11,748,464 is recorded as a loss on extinguishment of Bridge Loan in the consolidated statement of operations in the amount of $2,069,923. As a result of this conversion, the Bridge Loan was terminated and is no longer available to the Company for borrowing.

Summary of the bridge loan activity through December 31, 2024 is summarized as follows:

	For the year ended December 31, 2024	For the year ended December 31, 2023
Bridge loan roll-forward		
Principal outstanding	$ 9,802,697	$ -
Borrowings	1,368,422	5,968,987
OID	1,368,422	5,968,987
Repayments	(791,077)	(2,135,277)
Total principal outstanding before conversion	11,748,464	9,802,697
Conversion to common stock	(11,748,464)	-
Principal; outstanding – December 31, 2024	$ -	$ 9,802,697

	For the year ended December 31, 2023
Bridge loan	
Principal Outstanding	$ 9,802,697
Less: Unrecognized OID	(3,247,240)
Total:	$ 6,555,457

Note Payable

In 2022, we issued $50,000 of convertible notes to a shareholder due August 30, 2023 (“Note”). The Note bears interest at 2% per annum. This Note and all accrued interest thereon is convertible, at the option of the noteholder, into the class and series of equity securities (“Conversion Stock”) that is sold by us in our next issuance of equity securities in a Financing Transaction (as defined below), consummated after the issuance date of the note. A Financing Transaction is a sale, other than in an initial public offering (“IPO”), of equity securities by the Company to investors for cash. The number of shares of Conversion Stock to be issued to the noteholder upon such conversion shall be equal to the quotient obtained by dividing (i) the entire principal amount of this Note plus accrued interest by (ii) the Financing Transaction Conversion Price (as defined below). The Financing Transaction Conversion Price shall be equal to seventy-five percent (75%) of the price paid for one share of Conversion Stock by the investors in the Financing Transaction. The entire principal amount of and accrued interest on this Note shall automatically be converted, without further action on the part of the noteholder or us, into the class and series of stock issued by us, at the closing of an IPO. The number of shares of stock to be issued to the holder upon such conversion shall be equal to the quotient obtained by dividing (i) the entire principal amount of this Note plus accrued interest by (ii) the IPO Conversion Price (as defined in the Note). On January 31, 2024, the Note was assigned to HCWG LLC (an entity owned by certain shareholders, directors, and officers of the Company). Additionally, as part of the assignment, the Note was amended to increase the principal balance to $62,500, amend the maturity date to the date that the Company completes its initial public offering, and the Note was subordinated to the Bridge Loan.

We have elected to account for the Note under the fair value option. The fair value of the Note approximated the face amount of $50,000 at both December 31, 2024 and 2023. As such, no adjustment was made to the carrying value of the Note.. On June 30, 2024, the Company and noteholder entered an agreement with HCWG LLC to assume the Note. As part of the agreement, an outstanding interest of $2,250 at the time of the assignment, plus an additional interest charge of $10,250 upon assignment of the loan, was converted to principal, for a total principal balance of $62,500. The additional interest of $10,250 is recorded as an interest expense in the accompanying consolidated statement of operations. On July 23, 2024, the note was converted into 5,208 shares of common stock.

Advances to Affiliates

As of December 31, 2023, advances to affiliates totaled $83,505 and was included in prepaids and other on the consolidated balance sheet. These advances were repaid in February 2024. As of December 31, 2024, there were no advances to affiliates.

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. The Executive Chairman is to receive a total of $600,000 upon repayment of such advances, including OID, absent default. The Company shall pay the Executive Chairman the entire unpaid principal balance on the earlier of one year following the date of the effective date of the agreement or the date of the direct listing on the Nasdaq Global Market.

Contractual Obligations and Commitments

We enter into agreements in the normal course of business for sponsored research, preclinical studies, contract manufacturing, and other services and products for operating purposes, which are generally cancellable upon written notice.

USC License

On March 9, 2009, Nas-Onc, Inc. (k/n/a NeOnc Technologies, Inc.) entered into an exclusive, worldwide license agreement with USC, pursuant to which USC granted us a license to use certain patents and patent applications for the treatment and therapies of disease symptoms in mammals (the "USC Agreement"). The license is exclusive except for the rights granted to the US government pursuant to the Bayh-Dole Act and the right of USC and other non-profit academic research institutions to practice and improve the licensed patents for educational and research purposes. Pursuant to the USC Agreement, we (1) paid USC an upfront royalty payment of $20,000, (2) granted USC 117,236 shares of common stock, (3) will pay USC an earned royalty of 2% of Net Sales (as that term is defined in the USC Agreement), and (4) have paid and will continue to pay annual maintenance royalties of: $5,000 due January 1, 2011, $5,000 due January 1, 2012, $10,000 due January 1, 2013, and $20,000 due January 1 yearly thereafter. Annual maintenance royalties paid to USC are creditable toward earned royalties. We are also responsible for paying all reasonable patent expenses incurred by USC for filing prosecution and maintaining the licensed patents.

In the event of suspected patent infringement, the parties may agree to jointly institute suit, wherein the parties will share equally all costs and any recovery, with control of such lawsuit being by agreement between us and USC. Absent an agreement to jointly institute a suit, USC has the sole right to institute suit, at its option, where USC will bear the cost of such litigation and retain all recovery. In the event that USC does not institute the lawsuit, we may bring suit, at its option, and bear all such costs. Any recovery obtain by us must be shared with USC, after litigation costs reimbursement, as royalties on Net Sales for the remaining recovery. These rights and obligations were changed pursuant to the Amended License Agreement discussed below.

The USC Agreement is sublicensable subject to the same terms, except that (1) sublicensees may not grant sublicenses, (2) the earned royalty may be increased as to sublicensees, (3) the sublicense reverts to USC in the event the USC Agreement is terminated as to us and, (4) additional issue and maintenance fees are owed to USC for each sublicense. These rights and obligations were changed pursuant to the Second Amendment and the Restated Agreement discussed below.

We may challenge the licensed patents upon 90 days' notice and payment of all royalties due. If we are unsuccessful in its challenge, the earned royalty will thereafter be increased by a factor of three. These rights and obligations were changed pursuant to the Restated Agreement discussed below.

The Term of the USC Agreement extends until the last to expire of the licensed patents. The Term of the USC Agreement was changed pursuant to the Restated Agreement discussed below.

The USC Agreement may be terminated by either party upon 30 days' notice or upon material breach, wherein the breaching party is permitted 30 days to remedy such breach. USC may terminate immediately if (1) we attempt to sublicense, transfer or assign its rights contrary to the terms of the agreement, (2) we do not maintain the required insurance coverage, or (3) we are determined to be insolvent. These rights and obligations were changed pursuant to the Restated Agreement discussed below.

The parties amended the USC Agreement on April 5, 2023 ("Amended License Agreement"). The Amended License Agreement added NeOnc Technologies Holdings, Inc., our parent company, as a licensee. The Amended License Agreement also added additional patents and patent applications to the prior license grant and requires us to obtain and record fully executed assignments of the added patents demonstrating USC's ownership in all relevant jurisdictions.

Pursuant to the Amended License Agreement, we agreed to issue USC 560,000 additional shares of our common stock. We issued such shares on October 11, 2023 at which time the estimated value of such shares; upon issuance, was recorded as a credit to additional paid in capital. For more information, see "*Business – Exclusive Patent License Agreement between USC and our Company*." In addition, the Amended License Agreement provides for an 4% earned royalty on Net Sales on licensed products protected by the newly added patents on a country by-country basis. In the event that a licensed product is protected by patents from both the USC Agreement and the Amended License Agreement, the higher royalty will apply. The Amended License Agreement also recognizes a Royalty Credit, in the event that we must obtain additional licenses from third parties in order to sell the licensed products. The Amended License Agreement also grants us control for the prosecution of any patent application and maintenance of any patent included within Licensed Patents. We continue to be responsible for all costs associated with the prosecution and maintenance of the licensed patents. The Amendment also changed the parties enforcement obligations. Specifically, we shall have the first right, following consultation with USC, at our sole expense, to file suit against any alleged infringer or in defense of any third party claim. Any recovery or settlement in excess of litigation costs paid to us will be shared with USC as if it were Sublicense Revenue as defined in the USC Agreement. USC must consent to any settlement that is detrimental to USC or USC's intellectual property rights. If we elect not to file suit against an alleged infringer, then upon such election, we will be deemed to have assigned to USC all rights, causes of action, and damages resulting from the alleged infringement. USC then has the sole right to institute suit, at its option.

The parties further amended the USC Agreement on May 30, 2023 ("Second Amendment"). The Second Amendment revised the license agreement to permit Sublicensees to sublicense the patents pursuant to specific terms.

On November 19, 2023, the Company and USC entered into an Amended and Restated Exclusive License Agreement (the "Restated Agreement"). The Restated Agreement addressed and clarified certain reporting obligations of the Company under the USC Agreement and addressed certain financial and other obligations, defaults, and deficiencies in connection with the Company's performance under the USC Agreement. In satisfaction of prior unpaid sublicense issue royalties and annual maintenance royalties due for sublicensees, the Company must pay USC $230,000 by June 1, 2025.

The Restated Agreement provides for the same annual maintenance royalties of $20,000 per year noted above as well as the earned royalty of 2% or 4% on Net Sales on Licensed Products based on patent coverage (with the higher royalty applied when the Licensed Product is protected by patents from both the USC Agreement and the Amended License Agreement) and on a country by-country basis. As above, the Restated Agreement recognizes the Royalty Credit.

In the event that we, or our sublicensee (other than Orient EuroPharma Co., Ltd. ("OEP") (discussed below), challenges a Licensed Patent the annual maintenance royalty, milestone payments and the earned royalty percentage rated will be doubled during the pendency of such challenge. At the conclusion of such challenge, if a Valid Claim that covers the Licensed Product, Licensed Service or Licensed Process is held valid and enforceable then such ongoing royalty payments will be tripled. We must also reimburse USC for all costs incurred in connection with such challenge. Further, we must provide USC at least 180 day's written notice prior to our, or our sublicensee (excluding OEP) challenging a Licensed Patent. The notice is required to contain the prior art and a description of the facts and arguments that support the invalidity or unenforceability contention. We are required to discuss same with USC in an attempt to resolve the issues.

As above, we may grant sublicenses and our sublicensees may further grant licenses through one tier. By way of reference, on November 8, 2013, we entered into a collaboration agreement ("OEP Agreement") with OEP, pursuant to which NeOnc licensed to OEP the right to commercialize NEO100 in those territories specified in the OEP Agreement. As to the OEP Agreement, the Restated Agreement waives any prior breach by us of the USC Agreement and permits the OEP sublicense despite inconsistencies with certain terms of the Restated Agreement. On February 15, 2024, OEP and the Company entered into a settlement agreement whereas the Company and OEP terminated the OEP Agreement in exchange for a payment in the amount of $4,000,000 payable by the Company to OEP within ten days of the close of an IPO.

As above, pursuant to the Restated Agreement we maintain sole control of the prosecution of any patent application and maintenance of any patent included within Licensed Patents. We continue to be responsible for all costs associated with the prosecution and maintenance of the Licensed Patents. In addition, the parties enforcement obligations as described in the Amended License Agreement remain unchanged. Specifically, we have the first right, following consultation with USC, at our sole expense, to file suit against any alleged infringer or in defense of any third party claim. Any recovery or settlement in excess of litigation costs paid to us will be shared with USC as if it were sublicense revenue. USC must consent to any settlement that is detrimental to USC or USC's intellectual property rights. If we elect not to file suit against an alleged infringer, then upon such election, we will be deemed to have assigned to USC all rights, causes of action, and damages resulting from the alleged infringement. USC then has the sole right to institute suit, at its option.

The Restated Agreement changes the Term of the license. Specifically, the term is now tied to our royalty obligations under the Restated Agreement. We are obligated to pay royalties as to each Licensed Product, Licensed Service or Licensed Process on a country-by-country basis until (a) the last to expire Licensed Patent covering such product/service/process or (b) for 15 years after the date of first commercial sale of such product/service/process where such product/service/process is not covered by a Valid Claim of a Licensed Patent but such product/service/process was developed or made using any Licensed Process. The Term of the license ends when no further royalty obligations are due.

Last, as to termination, the Restated Agreement provides that the parties may mutually agree to terminate. Further, USC may immediately terminate if (a) we do not make payments when due and fail to cure, (b) we default on our indemnification or insurance obligations, (c) we are determined to be insolvent, (d) if any of our officers, directors or employees are convicted of a felony related to the development, manufacture use, marketing, distribution or sale of the Licensed Product, (e) if an audit shows an underpayment by us or a sublicensee of 15% or more for any 12 month period, or (f) we default in the performance of our other obligations in the agreement, and in each case fail to cure. We may terminate the license by giving 180 days advance written notice.

Upon any termination of the license (other than expiration of the Term), then the Restated Agreement grants to USC a non-exclusive worldwide fully paid license, with the right to sublicense, to the Licensed Product Data, which includes all pre-clinical, clinical and other regulatory data generated by or on behalf of the Company relating to the Licensed Product and generated after the effective date of the USC Agreement.

Collaboration and license agreements

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").

Pursuant to the terms of the Agreement, OEP will bear the cost of, and be responsible for, among other things, developing pre-clinical materials, conducting the clinical studies and other developmental activities for the Licensed Products, and bear the cost of and be responsible for, among other things, preparing and filing applications for regulatory approval in the Territory and for commercializing Licensed Products in the Territory, and will use commercially reasonable efforts to commercialize Licensed Products and obtain pricing approval for Licensed Products in the Territory.

As part of the Agreement, OEP agreed to compensate the Company as follows:

- Reimbursement of the costs related to an Investigational New Drug Application filing with the FDA, which was received in 2014 and 2016.
- $200,000 paid upon signing the agreement in 2013, and
- Specified clinical milestone payments of up to $1,900,000. The Company received a milestone payment of $300,000 during the year ended December 31, 2020 upon completion of the first phase of clinical trials. The Company has received no other clinical milestone payments through December 31, 2024.

The Company has determined that the arrangement is within the scope of ASC 808, *Collaborative Arrangements,* as both NeOnc and OEP are active participants in the activity, and they are both exposed to significant risks and rewards dependent on the commercial success of the activity. The Company has determined two performance obligations under the arrangement – the scientific development phase and the clinical trial evaluation phase. The Company had deferred recognition of revenue on the $200,000 paid upon signing the agreement and the $300,000 milestone payment received in 2020 as the clinical trial evaluation phase had not yet been completed at that time.

If, after completion of Phase II clinical trials, the Company enters into one or more agreements to license any of the patent rights or Licensed Products to a party other than OEP, then the Company will reimburse specified amounts based upon amounts paid by OEP to the Company, not to exceed $3,000,000 to be paid as various milestones are met.

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. As part of the settlement, the license was terminated and all rights in the underlying licensed territories have been returned to the Company. The Company recognized $4,000,000 as a litigation settlement expense in the accompanying consolidated statement of operations in the year ended December 31, 2023, and had recorded an associated litigation settlement payable in the accompanying consolidated balance sheets as of December 31, 2024 and December 31, 2023.

License Agreement – Neucen Biomedical Co., Ltd.

On December 5, 2015, the Company entered into a license agreement with Neucen Biomedical Co., Ltd. ("NB"), a shareholder of NeOnc Technologies, Inc., in which NeOnc will license to NB the right to commercialize the Company's drug NEO212, a conjugate of perillyl alcohol and temozolomide ("NB Licensed Product") in the territories specified in the license agreement ("NB Territory").

Pursuant to the terms of the Agreement, NB will bear the cost of, and be responsible for, among other things, developing pre-clinical materials, conducting the clinical studies and other developmental activities for the NB Licensed Products, and bear the cost of, and be responsible for, among other things, preparing and filing applications for regulatory approval in the NB Territory and for commercializing NB Licensed Products in the NB Territory, and obtain pricing approval for NB Licensed Products in the NB Territory.

NB must pay the Company tiered royalties of 1-5% on net sales of NB Licensed Products in the NB Territory. The Company received no sales milestones or royalties through December 31, 2023, as no commercialized products are using such technology.

In June 2023, NB and NTHI mutually agreed to terminate this license agreement, and no consideration was paid or received related to such termination.

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 June 30, 2024 and December 31, 2023, the Company had no liabilities recorded for loss contingencies, except as below.

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.

Controls and Procedures

A company's internal control over financial reporting is a process designed by, or under the supervision of, that company's principal executive and principal financial officers, or persons performing similar functions, and effected by that company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness in future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with policies or procedures may deteriorate.

We have concluded that there were material weaknesses in internal control over financial reporting. Historically, we were 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 define responsibilities and segregate 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 circumstances.

We have initiated various remediation efforts, including the hiring of additional financial personnel/consultants with the appropriate public company and technical accounting expertise and other actions that are more fully described below. As such remediation efforts are still ongoing, we have concluded that the material weaknesses have not been fully remediated. Our remediation efforts to date have included the following:

We have assessed our current accounting personnel, financial reporting, and information system environments and capabilities. Based on our preliminary findings, we have found these resources and systems lacking and have concluded that these resources and systems will need to be supplemented and/or upgraded. We have hired a Chief Financial Officer and implemented accounting procedures and controls, such as a two-signature policy for all disbursements and vendor invoice/contract review processes. We have also instituted procedures to store and maintain vendor invoices, contracts and agreements for efficient retrieval, and analysis of financial reporting requirements.

We engaged external consultants with public company and technical accounting experience to facilitate accurate and timely accounting closes and to accurately prepare and review the financial statements of NeOnc Technologies Holdings, Inc. and related footnote disclosures. We plan to retain these financial consultants until such a time that our internal resources have been upgraded and the required financial controls have been fully implemented.

The actions that have been taken are subject to continued review, implementation, and testing by management, as well as audit committee oversight. While we have implemented a variety of steps to remediate these weaknesses, we cannot assure you that we will be able to fully remediate them, which could impair our ability to accurately and timely meet our public company reporting requirements.

Notwithstanding the assessment that our internal controls over financial reporting are not effective and that material weaknesses exist, we believe that we have employed supplementary procedures to ensure that the financial statements contained in this filing fairly present our financial position, results of operations, and cash flows for the reporting periods covered herein in all material respects.

Critical Accounting Estimates and Significant Judgments

Common Stock Issued for Debt Conversion

During the year ended December 31, 2024,we issued 1,145,880 shares of common stock for the conversion of the bridge loan, a vendor payable and for the settlement of accrued compensation. The fair value of the common stock issued for the conversions was valued based upon the pricing from a recent financing round which was $12.00 a share.

In addition, in April of 2023, the Company valued a license expense based upon the pricing of the share exchange discounted for the dilution from the share exchange. As the financing rounds occurred near the time of the aforementioned transactions, and there were no material changes in the Company or its operations between the transaction dates and the dates of the recent financing rounds, and that the financing round pricing provides the most observable and input in determining the fair value of the Company's equity, management determined that the recent financing rounds approximated fair value at the time of the aforementioned transactions.

Warrants Issued for Line of Credit

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 December 31, 2024.

In connection with the agreement, the Company issued HCWG five-year warrants to purchase up to 312,500 shares of our common stock at a per-share exercise price of $12.00. As of December 31, 2024, there were 312,500 warrants issued, outstanding and fully vested.

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

Off-Balance Sheet Arrangements

During the years ended December 31, 2024 and 2023, we did not have, and we do not currently have, any off-balance sheet arrangements (as defined under SEC rules).

Quantitative and Qualitative Disclosures about Market Risk

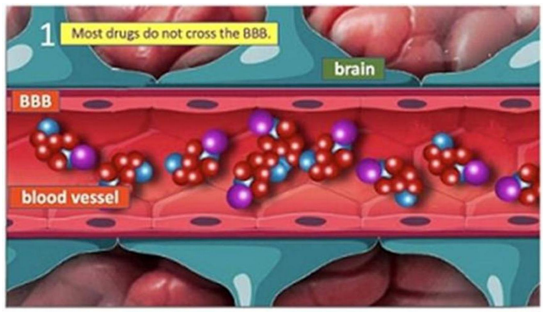
We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates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

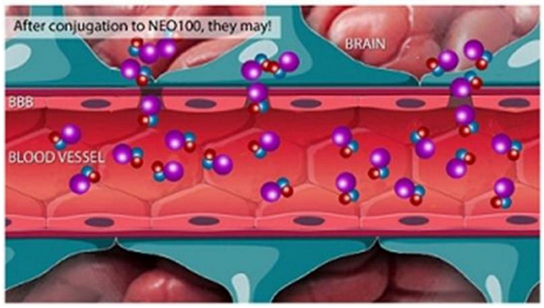
Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2024 or 2023.

BUSINESS

General

Our company was originally formed in Delaware in 2008 under the name NAS-ONC, Inc. and was renamed to NeOnc Technologies, Inc. in 2009. In 2015, the Delaware entity was merged with and into NeOnc Technologies California, Inc., a California corporation, and the surviving California corporation was renamed to NeOnc Technologies, Inc. Our company is devoted to developing new drugs with new delivery modes. As a clinical-stage biopharmaceutical company, we have focused on establishing 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 has two lead products in development: NEO100 and NEO212. NEO100, a purified form of perillyl alcohol ("POH"), is planned to be administered to brain cancer patients via intranasal delivery. Ongoing activities for intranasal delivery of NEO100:

- We have completed human testing in a Phase I clinical trial and are currently conducting a Phase IIa trial with recurrent malignant glioma (Grade IV, IDH1 mutant) patients (further details are provided below).

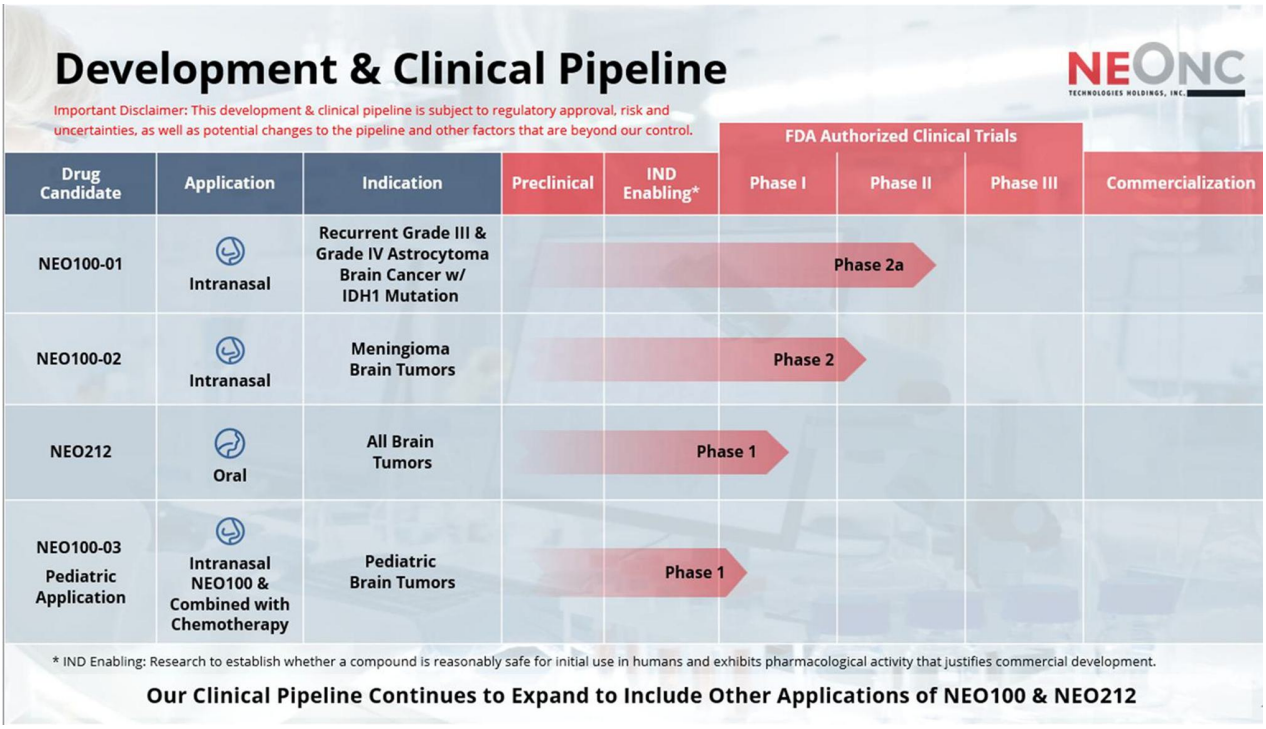
- A similar Phase IIa trial of intranasal NEO100 (NEO100-02) for patients with malignant skull based meningioma is also ongoing. Meningiomas are slow-growing tumors originating in the meninges, the membranous layers surrounding the brain and spinal cord. We initiated this because these patients lack effective treatment options. These tumors are notoriously difficult to access, and conventional methods like surgery often lead to significant neurological deficits. Additionally, radiation therapy has shown limited effectiveness. The trial was officially launched in July 2023. As NEO100 uses the same treatment platform as the malignant gliomas, we bypassed the Phase I trial and received FDA approval for a Phase II trial within just 30 days.

- Separate from this single-drug application, NEO100 is further being investigated as a drug delivery vehicle, where the results of NeOnc's preclinical studies suggest evidence that the combination of NEO100 with other drugs may enable a patient's improved brain tumor delivery via the intranasal route. Intranasal NEO100, mixed with levodopa (L-DOPA), is in the planning stages for a clinical trial in patients with Parkinson's disease (PD). NeOnc's laboratory experiments showed that intranasal NEO100 mixed with levodopa was able to reverse PD symptoms in mice. A Phase I clinical trial is planned to study the impact on human patients.

In our ongoing effort to streamline our clinical trials, we have identified approximately 80 grade III IDH1 mutation-positive patients as potential candidates for our clinical trial. We believe this targeted enrolment pool may significantly expedite our trial process. With this refined focus, we are revising our protocol inclusion criteria to include Residual Measurable Disease (RMD) grade III IDH1 mutant patients. We believe this amendment to our enrolment criteria may markedly accelerate patient accrual, enhance the efficiency of our trials and may lead to quicker results. As a result of these changes, we project that the readout for our Phase II studies with respect to NEO100 could now be feasibly delivered by the end of 2024, advancing our original timeline by a full year from 2025.

Separate from this single-drug application, NEO100 is further being investigated as a drug delivery vehicle, where the results of NeOnc's preclinical studies suggest that the combination of NEO100 with other drugs may enable a patient's improved brain tumor delivery via the intranasal route. Our second lead product, NEO212, a covalently conjugated molecule combining the chemotherapeutic drug temozolomide with perillyl alcohol, has completed preclinical testing and has received investigational new drug (IND) approval from the United States Food and Drug Administration (FDA), i.e., it has been authorized to proceed to clinical testing in cancer patients. We have designed a Phase I/II trial for oral NEO212, which began in the fourth quarter of 2023. In this trial, NEO212 will be administered orally to patients with primary brain tumors (i.e., malignant gliomas) and secondary brain tumors (i.e., brain metastases originating from peripheral tumors, such as tumors of the lung, breast, skin/melanoma, etc.). Furthermore, NEO212 is undergoing development towards intranasal application specifically for patients with uncontrolled brain metastases derived from peripheral tumors (lung, breast, skin, etc.), but has not yet been studied in human patients.

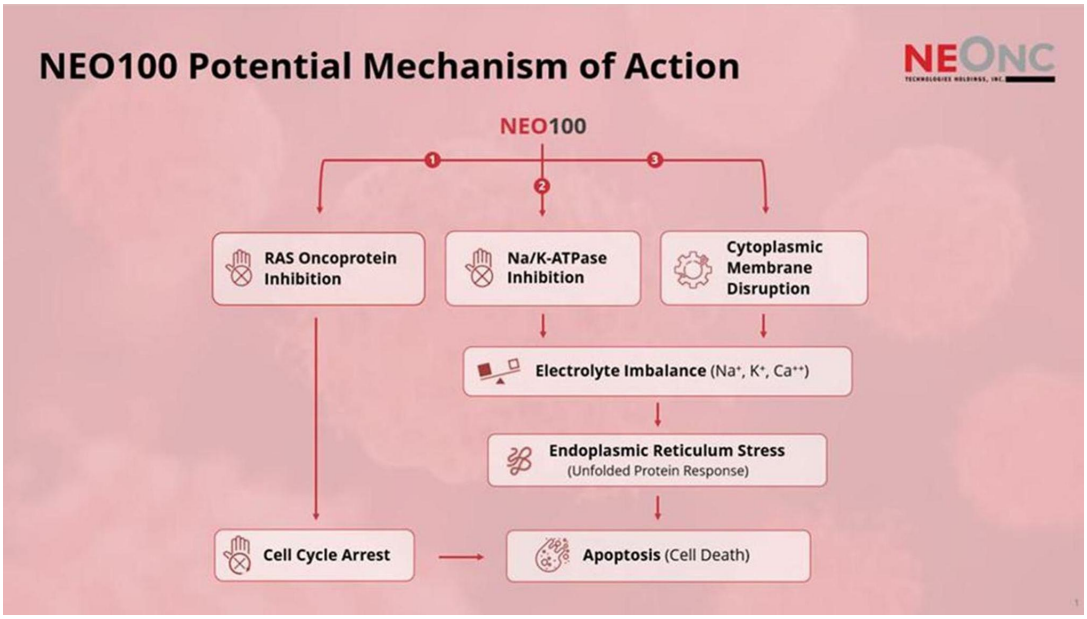
The Pipeline of NeOnc Drug



Lead Product: NEO100

NEO100 is our most advanced product candidate based on perillyl alcohol (POH). This naturally occurring monoterpenoid can be found as a constituent of essential oils from various botanicals, including peppermint, spearmint, lavender, bergamot, lemongrass, sage, thyme, cherries, and others. POH has been used in cosmetics, fragrances, and some cleaning products and as an ingredient in baked goods, frozen dairy, gelatine, puddings, beverages, and candies. However, clinical trials by other companies with an oral POH formulation administered to cancer patients were not successful for two presumed reasons: (i) after ingestion, not enough POH entered the bloodstream, because the liver (portal vein) quickly metabolized and thereby eliminated POH; in fact, it was not possible to demonstrate the presence of POH in the blood of these patients; and (ii) in an effort to overcome the rapid depletion of POH, physicians attempted to administer increasing amounts of oral POH, which resulted in significant gastrointestinal toxicity that became dose-limiting. As a result, efforts to introduce oral POH into the clinic were abandoned.

Under the direction of NeOnc, a novel manufacturing and delivery pathway was investigated which we believe may avoid the drawbacks of oral POH. Using derivatization of POH with a crystalline intermediate enabled the production of ultra-pure, pharmaceutical-grade NEO100. NEO100 received fast-track status in 2016 and orphan-drug designation in 2011 from the FDA. NeOnc's novel approach uses intranasal, rather than oral, delivery. Our completed Phase I trial of intranasal NEO100 suggested that when given via the intranasal route: (i) the drug appeared to be well tolerated with no severe adverse effects being observed, despite consistent treatment over several months; and (ii) patients' reported quality of life was unchanged. In one patient, we were able to obtain brain tumor tissue (based on surgery immediately following intranasal delivery of a dose of NEO100), which we analyzed for the presence of NEO100 (POH). The presence of NEO100 (POH) was confirmed in the tumor tissue, thus providing proof of principle that intranasal delivery of NEO100 reaches its tumor target in the brain. This is in contrast to the above-mentioned studies with oral POH, where the presence of drug could not be demonstrated in blood or tumor tissue of any patient. Among the group of 12 patients in our Phase I trial, there were several long-term survivors: At two years after start of intranasal NEO100 treatment, five patients (37%) were still alive, which is noteworthy, because recurrent glioblastoma patients (that is, patients where the tumor has returned after one or more rounds of traditional treatment) have an average life expectancy of about six months, and 24-month survival is rare. Another result from our Phase I trial is the fact that three patients (i.e., 25% of the original cohort of 12 patients), were still alive after 3 years. These outcomes will have to be investigated with a larger number of patients to establish statistical significance. This is currently being pursued in our Phase IIa trial, where we are planning to expand our clinical trial sites and potentially enrolling the remaining Phase IIa patients. A data read out for any patient enrolled in the clinical trial is expected beginning six months from the enrollment of such patient.



The above chart illustrates what is currently known about NEO100's mechanism of action. The manner by which NEO100 may block tumor growth is thought to result from its pleiotropic (multi-faceted) impact on tumor cells. In *in vitro* tests: (i) NEO100 has been shown to inhibit the activity of the Ras protein. Ras is a (proto)onco-protein that stimulates mitogenic (growth-stimulatory) pathways inside cells. In tumor cells, it is often mutated, resulting in its increased activity and uncontrolled cell growth. Inhibition of Ras by NEO100 is thought to remove this aberrant growth stimulus from tumor cells, causing cell cycle arrest. (ii) NEO100 has been shown to block the activity of sodium/potassium (Na/K) adenosine triphosphatase (ATPase). Na/K-ATPase is an ion pump that sits in the plasma membrane and regulates the flux of ions across the membrane. In cancer cells, it can have abnormal activity and not only helps cancer cells resist chemotherapy, but also stimulates them to spread to other locations in the body. We believe that NEO100 may stunt these advantages for cancer cells. (iii) NEO100 has been shown to intercalate into the plasma membrane to disturb membrane fluidity and the function of some proteins that are located at or near the plasma membrane (including Ras and Na/K-ATPase). Among the consequences is an electrolyte imbalance that triggers endoplasmic reticulum (ER) stress. Cancer cells in general are less resistant to withstand prolonged ER stress. As a result, in combination with cell cycle arrest, they undergo apoptosis (cell death).

Therapeutic applications of NEO100 that are under development by NeOnc:

- Intranasal delivery that we hypothesize may bypasses the blood-brain barrier (BBB), which could permit delivery of drugs to the brain via cranial nerves I and V, and possibly allow delivery of other pharmaceutics to the brain. Proof of this principle has been observed in animal models, but has not yet been tested in human patients.

- At high concentrations, we are investigating whether intranasal NEO100 may be used as a therapeutic for treating brain cancers. In a Phase I trial there were preliminary signs of activity, based on several (25%) patients who have survived for at least 4 years, but validation of activity will have to await results from the ongoing Phase IIa and possible additional clinical trials.

- At low concentrations, NEO100 might act as a solvent and delivery vehicle for traditional large-molecule pharmaceutics, which could potentially bypass the BBB and enter the brain. Proof of this principle has been observed in animal models but has not yet been tested in human patients.

- Intra-arterial delivery of NEO100 could possibly create a temporary opening in the BBB, which might allow traditional large-molecule pharmaceutics to pass through and enter the brain. Proof of this principle has been observed in animal models, but has not yet been tested in human patients.

- NEO100 could potentially be covalently conjugated with other pharmaceutics to create novel fusion compounds that might enable superior BBB penetration ability and, potentially higher activity against brain cancer. Proof of this principle has been observed in animal models but has not yet been tested in human patients.

Intranasal NEO100 for the treatment of malignant glioma:

The FDA granted NEO100 Orphan Drug Designation (ODD) for treating malignant glioma in 2011. Orphan drug designation qualifies sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees, and potential seven years of market exclusivity after approval. Upon approval, the exclusivity granted to orphan drugs provides seven years during which FDA may not approve any other sponsor's application for the same drug for the same designated orphan disease or condition, regardless of whether such other sponsor files an Abbreviated New Drug Application (ANDA) for a generic version of the drug, or if another sponsor files a "full" new drug application (NDA). Orphan Drug Exclusivity does not, however, prevent FDA approval of applications for the same drug for a different indication, nor applications for a different drug for the same orphan indication. In limited circumstances, such as showing clinical superiority to the product with orphan drug exclusivity, FDA may approve a competing application during the Orphan Drug Exclusivity period. However, the process of clinical development is inherently uncertain and there is no guarantee that orphan drug designation will accelerate the timeline for approval or make it more likely that NEO100 will be approved.

For clinical testing of NEO100, a combined Phase I/IIa trial was conducted, with the first patient enrolled in April 2017. NEO100 was administered intranasally 4-times a day to patients with recurrent glioblastoma. Patients enrolled in this trial had already undergone standard therapy, but the disease had returned and was deemed untreatable.

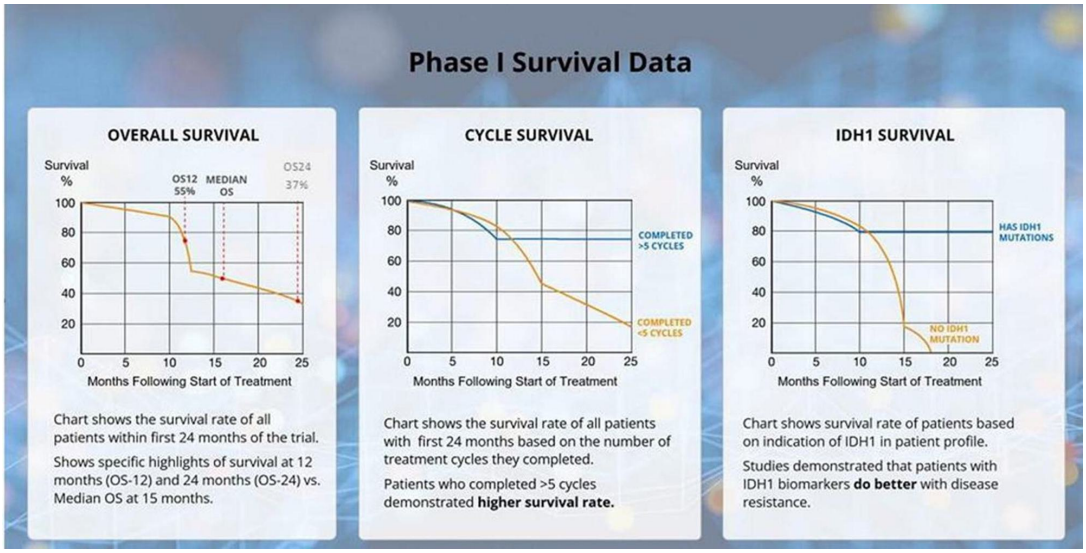
Among the inclusion criteria were the following: (i) Radiographically confirmed progression or recurrent grade IV glioma, and on a stable dose of steroid for at least 5 days; (ii) Patients must have failed previous radiation and temozolomide treatment; (iii) Age ≥ 18 years; (iv) ECOG performance status of 0-2, or KPS ≥ 60; (v) An expected survival of at least 3 months; (vi) Baseline MRI with gadolinium within two weeks of entry into the trial; and (vii) Seizures controlled on a stable dose of anti-epileptics for two weeks prior to enrollment. Furthermore, patients were screened with MR perfusion scan if there was a possibility that progression seen on a MRI scan represented pseudo-progression. Response assessment was performed by gadolinium-enhanced MRI and assessment by RANO (Response Assessment in Neuro-Oncology) criteria every two months. Adverse events were graded for severity using NCI Common Terminology Criteria for Adverse Events v.4.0.

The institutions that participated in the trial were Cleveland Clinic, University of Washington/Seattle, University of Wisconsin, and the University of Southern California. It was sponsored by NeOnc Technologies, Inc. (Los Angeles, CA) with ClinDatrix, Inc. (Irvine, CA), as the Clinical Data Management CRO (Contract Research Organization). A total of 12 patients were enrolled in Phase I, which was completed in 2020. The patients were divided into four cohorts, three patients per cohort in a dose escalating trial (384-1152 mg/day). Patients received the intranasal dosage using a nebulizer mask four times a day. The results suggested that intranasal NEO100, even at the highest dose given, appeared to be well tolerated, and there were no serious adverse events reported in any of the patients, i.e., there were only minor side effects, such as a runny nose or nasal discomfort.

Results from Phase I preliminarily suggested that intranasal NEO100 might have exerted therapeutic activity in some of these patients, although statistical analysis was limited by the small number of 12 patients, which means that statistically firm conclusions cannot be drawn. Most patients (55%) survived for more than one year, four patients (33%) survived for over two years, and three patients (25%) remained alive at the 3-year mark.

Primary endpoints for Phase I were to determine maximum tolerated dose (MTD) and progression free survival (PFS). NEO100 did not reach MTD, as results suggested that NEO100 was well tolerated by the cohort 4 patients. The recommended Phase II dose was therefore at 1152 mg/day. PFS at 6 months was 33%.

Survival Data from NeOnc's Phase I Clinical Trial with Intranasal NEO100



Patient Survival: NeOnc's Phase I Trial

Secondary endpoints were evaluated for: a) pharmacokinetic endpoints of POH and perillic acid (PA) metabolism, b) objective tumor response according to RANO criteria, and c) adverse events.

Pharmacokinetic measurements were performed in patients at the time of trial entry and used to measure the ability of patients to properly inhale NEO100. All patients had the expected rapid elimination of NEO100 within 30 minutes from serum, and elimination of its PA within 2 hours.

Objective tumor response to NEO100 was determined by RANO criteria. NEO100 performance by RANO criteria was reported as follows:

Table 3. Cohorts, Dosages, and Results

Patient ID	Cohort	Dosage (mg/day)	Completed Number of Cycles[a]	RANO[b]	Survival After Start of NEO100 (Months)	IDH1 Status	Current Status	NEO100Tx Ongoing
104	1	384	2	PD	18	Wild type	Deceased	N/A
105	1	384	2	PD	9	Mutated	Deceased	N/A
106	1	384	2	PD	33	Mutated	Deceased	N/A
202	2	576	33	SD	33	Mutated	Alive	Yes
203	2	576	2	PD	11	Wild type	Deceased	N/A
204	2	576	1	N/A	2	Wild type	Deceased	N/A
301	3	768	24	SD	24	Mutated	Alive	Yes
302	3	768	11	SD	27	Mutated	Alive	No
303	3	768	2	PD	10	Wild type	Deceased	N/A
401	4	1152	4	PD	>4	Wild type	Unknown	No
402	4	1152	2	PD	15	Wild type	Deceased	N/A
403	4	1152	8	SD	9	Wild type	Deceased	N/A

[a]Each cycle is 28 days.
[b]Performed at end of even-numbered cycles and 6 month final.

The third secondary endpoint was adverse events, as characterized by type, frequency, and severity (NCI common terminology for adverse events were reported as follows:

Table 2. Adverse Events Attributable to NEO100 Administration

Number of Events, According to Body System and Grade	NEO100 Dose Level (mg/day)				
	384	576	768	1152	Causality
General disorder or administration-site condition:					
Fatigue, grade 1	1	–	–	–	Possibly related
Nervous system disorder:					
Headache, grade 1	1	–	–	–	Probably related
Skin and subcutaneous tissue disorders:					
Piloerection, grade 1	1	–	–	–	Possibly related
Skin irritation around nose, grade 1	–	–	1	–	Definitely related
Respiratory, thoracic and mediastinal disorders:					
Rhinorrhea, grade 1	2	–	–	1	Definitely related
Nasal dryness, grade 1	1	–	1	–	Probably related
Nasal pruritus, grade 1	1	–	–	–	Probably related
Nasal discomfort, grade 1	1	1	–	–	Probably related
Cough, grade 1	–	–	–	1	Definitely related
Blood and lymphatic system disorders:					
Leukopenia, grade 2	–	2	–	–	Possibly related
Total no. of patients with an event:	**3**	**2**	**1**	**1**	

Moreover, our Phase I clinical trial indicated that patients harboring an IDH1 mutation in their tumor cells responded to treatment more favorably than those without the mutation. Among the 12 patients, five presented with IDH1 mutant status. Among these five, four patients (80%) survived longer than the seven patients without IDH1 mutation. As of February 12, 2021 three of them were still alive four years after the recurrence of their original tumor and initiation of NEO100 treatment.

A potential advantage of intranasal NEO100 is that intranasal delivery via a nebulizer device does not require surgeries, infusions, or other invasive procedures that would require medical visits. Rather, intranasal delivery could be done conveniently at home (or while traveling) by the patients themselves. Compared to the well-known toxicities of many chemotherapeutic agents, NEO100 appeared to be well tolerated at the doses tested in the limited Phase I trial, and none of the typical side effects of other cancer pharmaceutics (nausea, debilitating fatigue, anemia, infections, diarrhea, hair loss, etc.) were observed. It, therefore, suggests that NEO100 may not lead to deterioration of quality of life for patients (Schönthal AH et al., *Neuro-Oncol. Adv.* 3:1, 2021).

NeOnc Phase IIa studies describe the first time NEO100 is given to the intended treatment population. The studies are undertaken to confirm dosing requirements identified in Phase I testing (such as how much, how often and to whom the drug should be given) are correct. They are sufficiently powered (statistically) to determine how well the drug performs at the prescribed dose and for the intended outcome. Work in future trials may be needed to further understand results obtained in Phase IIa testing (i.e., dosing, effect on a patient sub-population) and randomized, controlled Phase III testing may be required prior to marketing authorization. Details regarding the ongoing Phase IIa trials of NEO100 and the ongoing Phase I/II trial of oral NEO212 are as follows:

1. ***"An Open-Label, Phase I/IIa Dose Escalation Study of Safety and Efficacy of NEO100 in Recurrent or Progressive Grade III or IV Gliomas with IDH1 Mutation" (NEO100-01)***

Enrollment

Number of Patients to be Treated: 25

Patient Sub-Populations Tested: Radiographically-confirmed progression of, or recurrent, primary or secondary Grade IV glioma (the original study population) and radiographically-confirmed progression of, or recurrent, primary or secondary Grade III astrocytoma.

Primary Endpoint:

1. Progression free survival at six months.

NEO100 Performance – Cannot be reported until completion of the Phase IIa portion of the study.

Secondary Endpoints:

1. Objective tumor response to NEO100 as determined by RANO criteria.

NEO100 Performance – Cannot be reported until completion of the Phase IIa portion of the study.

2. Progression free survival.

NEO100 Performance – Cannot be reported until completion of the Phase IIa portion of the study.

3. Overall survival.

NEO100 Performance – Cannot be reported until completion of the Phase IIa portion of the study.

4. Perillic acid measurement.

NEO100 Performance – Cannot be reported until completion of the Phase IIa portion of the study.

Safety Endpoint:

1. Adverse Events characterized by type, frequency, severity, as graded by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE v. 5.0), seriousness and relationship to study therapy NEO100.

NEO100 Performance – Cannot be reported until completion of the Phase IIa portion of the study.

2. Changes from baseline in vital signs and clinical laboratory parameters (hematology and chemistry), as well as ECOG performance status will be assessed.

NEO100 Performance – Cannot be reported until completion of the Phase IIa portion of the study.

Number of Patients Currently Enrolled: 6

2. ***"An Open-Label, Phase II Study of NEO100 in Participants with Residual, Progressive or Recurrent High-Grade Meningioma" (NEO100-02)***

Number of Patients to be Treated: 29

Patient Sub-Populations Tested: Radiographically-confirmed progression of, or recurrent, WHO Grade II or III meningioma

Primary and Secondary Endpoints:

Primary Endpoint: Progression free survival at 6 months

Secondary Endpoint:

1. Objective tumor response by RANO criteria

2. Progression free survival

3. Overall survival

4. Perillic acid measurement and level

Number of Patients Currently Enrolled: 2

3. ***"An Open-Label, Phase I/II Dose Finding, Safety and Efficacy Study of Oral NEO212 in Patients with Astrocytoma IDH-Mutant, Glioblastoma IDH-Wildtype or Uncontrolled Metastasis to the Brain in Patients with Select Solid Tumors (NEO212-01)***

Number of Patients to be Treated:

Phase I: Up to 36

Phase IIa: 12

Phase IIb: 27 per cohort

Patient Sub-Populations Tested:

Phase I: Radiographically-confirmed astrocytoma IDH-mutant, glioblastoma IDH-wildtype following previously radiation therapy or treatment with temozolomide and radiation or a select solid tumor with uncontrolled brain metastases (e.g., melanoma, NSCLC, SCLC, HNSCC, urothelial carcinoma, gastric cancer, renal cell cancer, colorectal cancer)

Phase IIa: Radiographically-confirmed astrocytoma IDH-mutant, glioblastoma IDH-wildtype following previously radiation therapy or treatment with temozolomide and radiation

Phase IIb: Select solid tumor with uncontrolled brain metastases (e.g., melanoma, NSCLC, SCLC, HNSCC, urothelial carcinoma, gastric cancer, renal cell cancer, colorectal cancer)

Primary and Secondary Endpoints

Primary Objectives ●

1. Assess the safety and tolerability of increasing dose levels of orally administered NEO212 in patients with Astrocytoma IDH-mutant, Glioblastoma IDH-wildtype and patients with select solid tumors with uncontrolled metastases to the brain.

2. Identify the maximum tolerated dose (MTD) of NEO212.

3. Determine the recommended Phase II dose (RP2D) of NEO212.

Secondary Objectives

1. Characterize the pharmacokinetics (PK) of NEO212.

2. Evaluate anti-tumor activity of NEO212 in patients with Astrocytoma IDH-mutant, Glioblastoma IDH-wildtype and patients with select solid tumors with uncontrolled brain metastases.

Number of Patients Currently Enrolled:

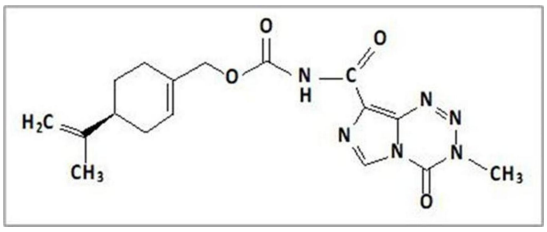
Phase I: 2

Phase IIa: Not Open to Accrual

Phase IIb: Not Open to Accrual

Pipeline Product Candidates

NEO212



NEO212 (chemical structure shown on the right) was designed as a hybrid compound where NEO100 was covalently conjugated to temozolomide (TMZ), an alkylating agent that represents the current standard of chemotherapeutic care for patients with glioblastoma. Based on the recognition that amphipathic NEO100 in research has suggested it may permeate biological barriers and cellular membranes, we hypothesized that this novel covalent molecule might penetrate the blood-brain barrier, possibly enabling a dual approach against malignant lesions in the brain. Our preclinical characterization of NEO212 in various mouse tumor models suggests that this multifunctional agent may show activity against a variety of cancer types. In preclinical studies, results suggested that NEO212 demonstrated activity against primary and secondary brain cancers as well as cancer types that were chemoresistant to other commonly used cancer therapeutics (Chen TC et al., *Molecular Cancer Therapeutics* 13:1181, 2014; Chen TC et al., *Cancer Letters* 358:144, 2015; Chen TC et al., *Journal of Biomedical Sciences* 22:71, 2015; Cho HY et al., *Molecular Cancer Therapeutics* 13:2004, 2014; Jhaveri N et al., *Cancer Letters* 371:240, 2016; Marin-Ramos NI et al., *Oncoscience* 5:148, 2018; Marin-Ramos NI et al., *Molecular Cancer Therapeutics* 17:625, 2018). So far, the activity of NEO212 has not yet been studied in humans.

NEO212 demonstrates an interesting feature that its demonstrated activity in preclinical studies may be greater than the sum of its parts. That is: merely applying its individual constituents, NEO100 and TMZ, as a mix of two independent compounds (akin to the conventional combination therapy mode) may not mimic the potential of the conjugated hybrid molecule. The toxicological studies in rodents and dogs suggest that NEO212 was tolerated. When administered at the same dosages as those that suggest activity in mouse cancer models, there were no detectable side effects in mice, rats, or dogs.

The demonstrated activity in preclinical studies of NEO212, along with its low toxicity profile, contributed to our IND application for oral administration that was approved by the FDA in 2023. FDA approval provides an opportunity for Phase I/IIa clinical trials, primarily focusing on patients with intracranial malignancies. We are designing clinical trials that evaluate two different modes of NEO212 delivery: oral and intranasal. Oral NEO212 during Phase I will be administered to patients with brain malignancies that include primary and secondary brain cancers (so-called “all comers”). Phase IIa will focus on newly diagnosed, primary glioblastoma. Intranasal NEO212 will be used in a Phase I/IIa trial in patients with metastatic brain cancer, i.e., where brain lesions originated from cells that were disseminated by tumors from outside the brain, such as lung cancer, breast cancer, or melanoma. All these patients represent a cohort in dire need of better therapies, and NEO212 may hold the potential that might improve their prognosis and survival.

The FDA granted NEO212 Orphan Drug Designation (ODD) for three different indications: (i) glioma (2014), (ii) brain metastases from breast cancer (2017), and (iii) nasopharyngeal carcinoma (2017). As stated above, if a product that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years (except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity). However, the process of clinical development is inherently uncertain and there is no guarantee that orphan drug designation will accelerate the timeline for approval or make it more likely that NEO212 will be approved.

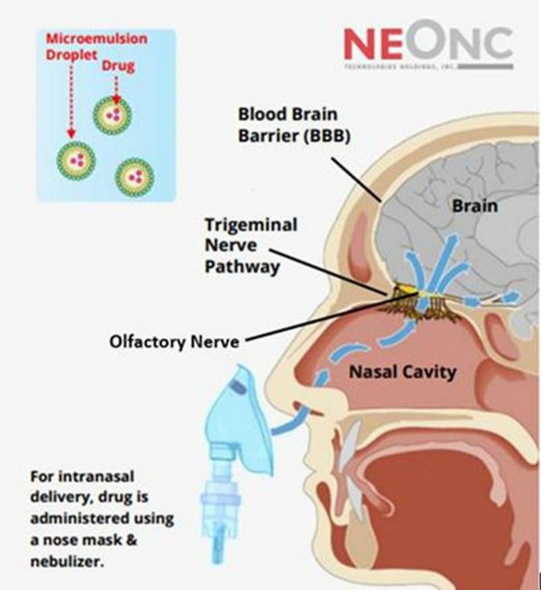
Three Drug Delivery Pathways Potentially Enabled by NEO100

Cancerous tissue in the brain is protected from systemically circulating drugs by the blood-brain barrier (BBB), which prevents the brain entry of most pharmaceutical agents. We are using NEO100 to develop three different methods of overcoming the obstacle placed by the BBB:

- *Intranasal delivery:* As part of a direct nose-to-brain route, this pathway could potentially allow direct brain access without interference from the BBB.
    - *Monotherapy with NEO100:* At higher dosages, intranasal delivery of NEO100 is in clinical testing for patients with glioblastoma.
    - *Combination therapy with NEO100:* At lower dosages, intranasal NEO100 might be used as a carrier for the co-delivery of established therapeutics to the brain. This has been observed in animal models, but it has not yet been studied in humans.
- *Conjugated delivery:* Stable conjugation of NEO100 to other therapeutic agents (such as temozolomide, creating NEO212) indicated a possible increase in the ability of the fused compound to penetrate the BBB and enter the brain. This has been observed in animal models, but it has not yet been studied in humans.
- *Permeable delivery:* Intra-arterial delivery of NEO100 may create temporary (up to 4 hours) openings in the BBB, that we believe could potentially enable drugs (Adriamycin®, Velcade®, etc.) and therapeutic antibodies (Herceptin®, Opdivo®, etc.) to enter the brain and reach the tumor bed. This has been observed in animal models, but it has not yet been studied in humans.

All three drug delivery pathways potentially enabled by NEO100 are being investigated by NeOnc and are at different stages of development. Only one of these pathways, monotherapy with intranasal NEO100, has moved into clinical testing, where Phase I studies have been completed and Phase IIa studies are ongoing. The other pathways, including combination therapy with NEO100, conjugated delivery (e.g., NEO212), and permeable delivery have not yet reached the clinical stage and have not yet been studied in humans. In these latter pathways, preclinical studies are currently ongoing to provide further results and IND-enabling data, so that in the future these principles can be studied in human cancer patients.

We believe these three delivery areas (details below) may be key to a potential shift in physicians' ability to treat brain diseases. They represent potential pathways for possible reliable delivery of pharma-therapeutics to the brain, potentially mitigating problems and side effects from current methodologies, and potentially providing an alternative treatment protocols to existing pharma manufacturers for their drugs.



Intranasal Delivery of NEO100: Administration of NEO100 into the nose is accomplished by a standard nebulizer that aerosolizes NEO100 into fine particles that reach the olfactory mucosa and its embedded nerve endings in the nasal cavity. Uptake by these and other nerve cells enables direct nose-to-brain transport of NEO100 so it can reach the tumor sites without interference from the BBB. This direct mode of brain-targeted drug administration is thought to deliver higher levels of the drug to the brain tumor site as compared to oral delivery of a given drug, also because this route of transport avoids drug breakdown in the liver. It also lowers total drug exposure to the rest of the body; therefore, it's hypothesized there may be fewer side effects. This principle was observed in the Phase I clinical trial with glioblastoma patients above-mentioned (Schönthal AH et al., *Neuro-Oncol. Adv.* 3:1, 2021). And the actual presence of NEO100 (perillyl alcohol), along with its major metabolite, perillic acid, has been observed in brain tumor tissue (Schönthal AH et al., *J. Neurosurg. Case Lessons* 4:case22215, 2022).

Ongoing activities for intranasal delivery of NEO100:

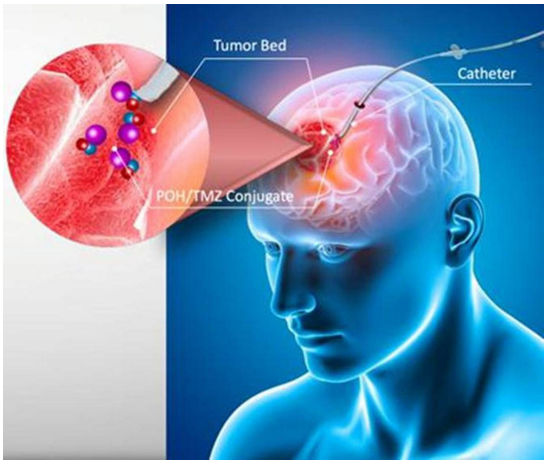
- The Phase IIa component of our clinical trial is ongoing in patients with recurrent Grade IV glioma (further details are provided below).

- A similar Phase IIa trial of intranasal NEO100 (NEO100-02) for patients with malignant skull based meningioma is also ongoing. Meningiomas are slow-growing tumors originating in the meninges, the membranous layers surrounding the brain and spinal cord. We initiated this because these patients lack effective treatment options. These tumors are notoriously difficult to access, and conventional methods like surgery often lead to significant neurological deficits. Additionally, radiation therapy has shown limited effectiveness. The trial was officially launched in July 2023. As NEO100 uses the same treatment platform as the malignant gliomas, we bypassed the Phase I trial and received FDA approval for a Phase II trial within just 30 days.

- Intranasal NEO100, mixed with levodopa (L-DOPA), is in the planning stages for a clinical trial in patients with Parkinson's disease (PD). NeOnc's laboratory experiments showed that intranasal NEO100 mixed with levodopa was able to reverse PD symptoms in mice. A Phase I clinical trial is planned to study the impact on human patients.

Stable Conjugation of NEO100 to Other Therapeutic Agents: Many drugs work quite well for diseases in the rest of the body but do not reach the brain due to the BBB obstacle. Our pre-clinical results suggested that stable conjugation of several such drugs to NEO100 may increase their ability to reach lesions located in the brain. Temozolomide (TMZ) is widely used to treat malignant glioma—even though it enters the brain sub-optimally, its modest therapeutic impact is an expression of this limitation. However, when conjugated to NEO100, creating NEO212, the molecule may cross the BBB, and in preclinical mouse models, various types of brain malignancies have shown therapeutic activity. NEO212's IND application was approved by the FDA in May 2023. (Further details on NEO212 are provided below.)

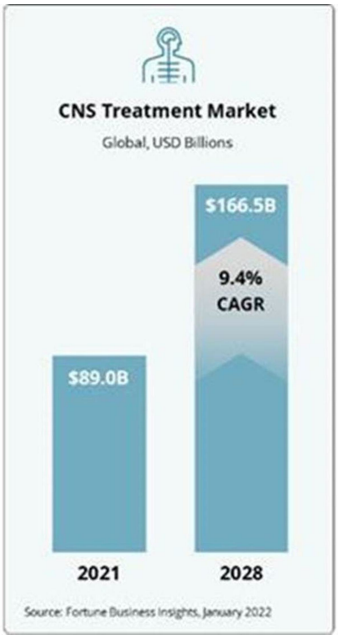
Intra-arterial Injection of NEO100: Our preclinical studies in mouse models with brain cancer suggest that intra-arterial delivery of NEO100 might open the BBB up to four hours, which could allow other therapeutic agents to enter the brain from the bloodstream or a catheter in those models. The mechanism appears to be via a transient opening of the tight junctions between the brain endothelial cells. Catheters can be used to deliver NEO100 to specific parts of the brain, particularly to the sites where the tumor bed is located, so that co-delivered pharmaceutics can immediately access the malignant tissue. In this manner, NEO100 and any other co-delivered therapeutic agent might impact the tumor. While this principle has been established in our preclinical studies, it has not yet been tested in human patients., Well-known side effects of the brain cancer agent temozolomide (TMZ) are bone marrow suppression and resulting infections. We believe these side effects may be reduced or possibly avoided if the bone marrow can be spared from whole-body exposure to TMZ, as is a consequence of the typical oral ingestion of TMZ. This catheter-based approach is based on the co-delivery of another agent (as a mix). It is distinct from the above described stable conjugation of NEO100 to another compound, such as TMZ, which creates a single fusion molecule (as in NEO212).

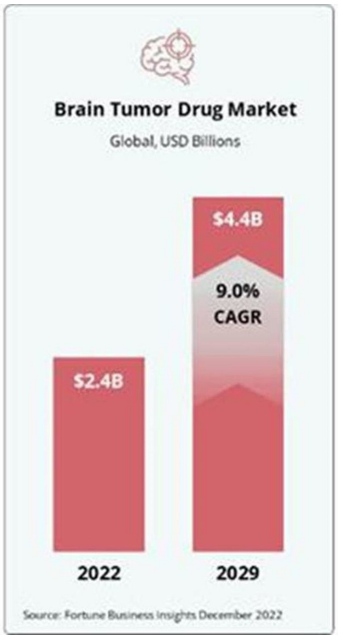


Our Markets

The global central nervous system (CNS) treatment market is expected to grow at 9.4% CAGR to reach $166.5 billion by 2028, and the global brain tumor drug market is expected to grow at CAGR of 9.0% reach $4.4 billion by 2029, according to Fortune Business Insights.

Radiation therapy still accounts for 38% of the brain cancer treatment market, while drug treatment remains second mostly due to current inefficiencies of drug delivery, according to Grandview Research.





We also address the malignant glioblastoma multiforme (GBM) treatment market. The GBM drug market is expected to grow at 12.7% CAGR to $2.3 billion by 2029, according to iHealthcare Analyst, with the market being driven by rising geriatric population, growing incidence cases, and a pipeline of new products.

GBM accounts for up to 54% of gliomas and 16% of all primary brain cancers, according to research published in the journal, *Glioblastoma*. By creating an alternative delivery mechanism for GBM drug therapy, we believe we can significantly impact market demand in this sector.

Our Strategy

Our goal is to change the cancer therapeutic landscape by developing novel therapeutic approaches leveraging dual approaches of novel drug delivery methods in combination with novel drug candidates that potentially lead to better therapeutic results with low side effects.

The following five clinical applications of our drugs are at different stages of preclinical or clinical development:

1. Intranasal delivery of NEO100 to patients with IDH mutant malignant glioma (Phase IIa clinical trial has started).
2. Intranasal delivery of NEO212 to patients with brain metastasis (IND approved).
3. Intranasal delivery of NEO100 alone, and in combination with doxorubicin for pediatric brain tumors (IND approved).
4. Intranasal co-delivery of NEO100 with levodopa for Parkinson's disease (preclinical stage).
5. Intra-arterial delivery of NEO100 to open the patient's blood-brain barrier, allowing brain entry of BBB-impermeable pharmaceuticals or biologics (preclinical stage).
6. Oral NEO212 for primary brain cancer, including glioblastoma (IND approved).

Details: **1.** Intranasal delivery of NEO100 to patients with IDH mutant malignant glioma (Phase IIa clinical trial has started).

NEO100 is our most advanced product candidate. Its chemical structure (**Figure 1**) is based on the natural compound perillyl alcohol (POH). We have investigated a novel manufacturing and delivery pathway that avoided the drawbacks of oral POH and capitalized on its recognized properties. The FDA granted NEO100 Orphan Drug Designation (ODD) for treating malignant glioma.

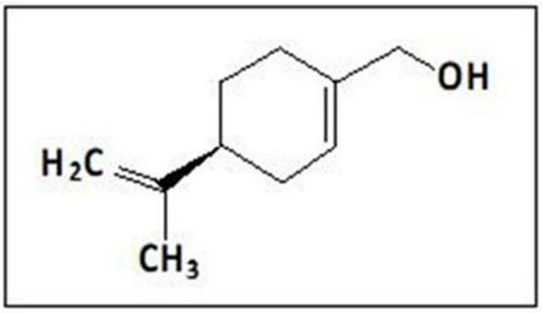


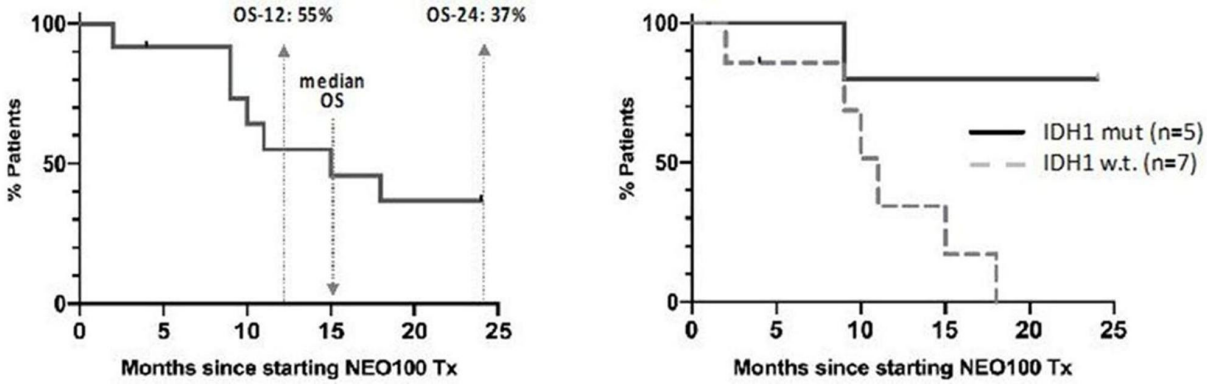
Figure 1: Chemical structure of NEO100

NeOnc sponsored a Phase I clinical trial, where NEO100 was administered to patients with recurrent glioblastoma. All enrolled patients had already undergone standard therapy for this disease, consisting of radiation treatment combined with chemotherapy. Still, this standard therapy had stopped working, and patients were no longer benefiting from it. At this stage of the re-emerging glioblastoma disease, there is no clear clinical recommendation for specific further treatment because effective treatments do not exist for this patient group. Rather, the prognosis is dismal, and the average median survival is only 6-9 months.

After enrollment in our study, patients received intranasal NEO100 four times daily, using a standard nebulizer and nasal mask. After initial instructions by a nurse, patients can self-administer this treatment at the convenience of their home. Four cohorts of 3 patients each received the following dosages: 96 mg/dose (384 mg/day), 144 mg/dose (576 mg/day), 192 mg/dose (768 mg/day), and 288 mg/dose (1152 mg/day). Completion of 28 consecutive days of treatment was recorded as one cycle. Adverse events were documented, and radiographic response *via* RANO criteria was evaluated every two months. Progression-free and overall survival were determined after 6 and 12 months, respectively (PFS-6, OS-12).

The trial was completed in 2020, and after peer review, the results obtained from these 12 patients were published in 2021 (Schönthal AH et al., *Neuro-Oncology Advances* 3(1):1-12, 2021). Data analysis suggested that intranasal NEO100 may be well tolerated at all four dose levels, and even at the highest dose levels, no severe adverse events were noted. Minor side effects included a runny nose or nasal discomfort. PFS-6 was 33%, OS-12 was 55%, and of the three cohorts' median survival was 15 months (**Figure 2**, left panel). Four patients (33%) survived >24 months. Thus, compared to historical controls and what is commonly observed in clinical practice, average patient survival in our clinical trial with these 12 patients might be improved (see further comparison details below). As important, there were none of the typically harsh side effects of many conventional chemotherapies, such as nausea, debilitating fatigue, anemia, infections, diarrhea, hair loss, etc.). Treatment with intranasal NEO100, therefore, did not lead to deterioration of quality of life for patients. However, further research is needed to confirm these results.

Figure 2: Survival of all 12 patients (left) and survival in relation to IDH status (right).



from: Schönthal AH et al., *Neuro-Oncology Advances* 3(1):1-12, 2021

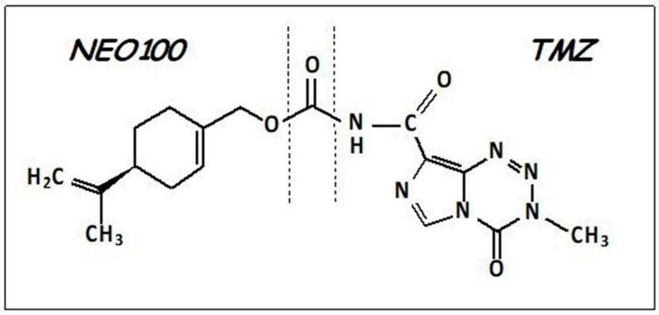
Detailed further analysis of our Phase I trial suggested that patients with the highest response to intranasal NEO100 were those whose tumor harbored a mutation in the gene for isocitrate dehydrogenase 1 (IDH1) (**Figure 2**, right panel). In the five patients with this mutation, 4 (80%) survived a minimum of 24 months while being treated with intranasal NEO100. In contrast, seven patients without this mutation succumbed to disease earlier—although their average median survival of 11 months was still longer than what might have been expected based on historical experience in the clinic.

Prompted by these observations from our Phase I clinical trial, a Phase IIa continuation of intranasal NEO100 was started in 2021 for high-grade glioma patients with IDH1 mutations. As with Phase I, the trial is being conducted as a multicenter study. A total of 12 institutions will be recruited to enroll 31 patients for our Phase IIa trial, of which five have been recruited. The potential mechanism by which these IDH1 mutant patients may have a specific survival advantage in response to NEO100 is the subject of our current laboratory investigations.

Details: **2.** Intranasal delivery of NEO212 to patients with brain metastasis (IND submission scheduled for late 2023).

NEO212 is a hybrid compound where NEO100 is covalently conjugated to temozolomide (TMZ) via a carbamate bridge (**Figure 3**). While TMZ has been widely used as the standard of care for the treatment of glioblastoma, it does not penetrate the BBB effectively; unsurprisingly, its clinical efficacy is relatively modest. Also, its activity could be further reduced when applied to tumors that are positive for O6-methylguanine methyltransferase (MGMT). This DNA repair protein protects tumor cells from killing by TMZ. Our preclinical studies suggest that NEO212 may potentially be able to overcome these drawbacks and exert its activity even against tumor cells that are positive for MGMT. The FDA granted NEO212 Orphan Drug Designation (ODD) for three different indications: (i) glioma, (ii) brain metastases from breast cancer, and (iii) nasopharyngeal carcinoma.

Figure 3: Chemical structure of NEO212: NEO100 conjugated to temozolomide.



NEO212 was initially designed as a therapeutic molecule with potential enhanced capability of crossing the blood-brain barrier to address the urgent clinical need for better treatments of intracranial malignancies, such as glioblastoma and brain-metastatic lesions from peripheral cancers. In mouse models data indicated that orally-administered[1] NEO212 enters the brain in higher quantities than oral TMZ alone. While NEO212 has been investigated in multiple preclinical studies, it has so far not been studied in humans. Based on preclinical studies, the following potential beneficial features of this compound can be summarized as follows:

- NEO212 might exert greater activity than the sum of its parts; i.e., a mere combination of the individual components, TMZ plus POH at equimolar ratios, does not appear to mimic the activity of the conjugated compound, both *in vitro* and in mouse tumor models *in vivo* (Chen TC et al., *Molecular Cancer Therapeutics* 13:1181, 2014; Chen TC et al., *Cancer Letters* 358:144, 2015; Chen TC et al., *Journal of Biomedical Sciences* 22:71, 2015; Cho HY et al., *Molecular Cancer Therapeutics* 13:2004, 2014; Jhaveri N et al., *Cancer Letters* 371:240, 2016; Marin-Ramos NI et al., *Oncoscience* 5:148, 2018; Marin-Ramos NI et al., *Molecular Cancer Therapeutics* 17:625, 2018).

- In mouse tumor models, NEO212 displayed intracranial therapeutic activity not only against glioblastoma (Cho HY et al., *Molecular Cancer Therapeutics* 13:2004, 2014; Jhaveri N et al., *Cancer Letters* 371:240, 2016; Marin-Ramos NI et al., *Oncoscience* 5:148, 2018; Marin-Ramos NI et al., *Molecular Cancer Therapeutics* 17:625, 2018; Minea RO et al., *PLoS One* 15(9):e0238238, 2020) but also against brain-metastatic breast cancer xenografts (Chen TC et al., *Molecular Cancer Therapeutics* 13:1181, 2014) (**Figure 4**).

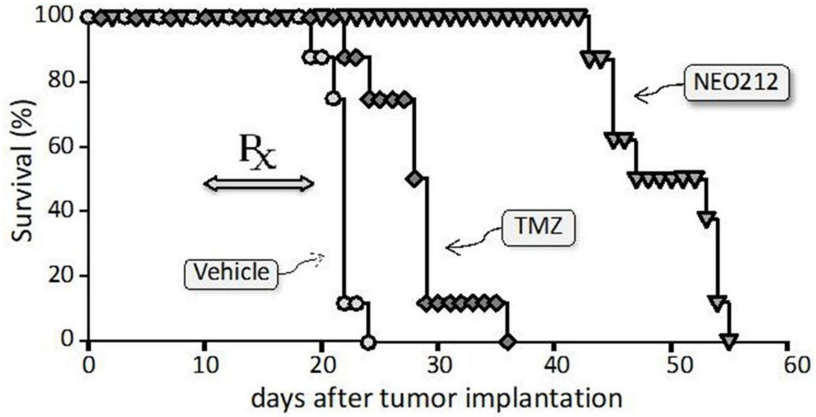
- Besides intracranial tumors in mouse tumor models, NEO212 showed activity against peripheral cancers in mouse tumor models, including subcutaneous melanoma (Chen TC et al., *Cancer Letters* 358:144, 2015), nasopharyngeal carcinoma (Chen TC et al., *Journal of Biomedical Sciences* 22:71, 2015; Xie L et al., *Oncotarget* 7:1651, 2016) ovarian carcinoma (Song X et al., *Journal of Experimental and Clinical Cancer Research* 38:239, 2019), lung cancer (Song X et al., *Cell Death & Disease* 9:202, 2018; Song X et al., *Scientific Reports* 6:22762, 2016; Chang M et al., *Journal of Experimental and Clinical Cancer Research* 37:250, 2018), cutaneous T-cell lymphoma (Silva-Hirschberg C et al., *Therapeutic Advances in Medical Oncology* 11:1758835919891567, 2019), and cytosine arabinoside-resistant leukemia (Schönthal AH et al., *Cancers* 13(14):3385, 2021).

- The activity of NEO212 was also documented with the use of primary patient samples implanted into mice, including glioblastoma stem cells (Jhaveri N et al., *Cancer Letters* 371:240, 2016; Marin-Ramos NI et al., *Oncoscience* 5:148, 2018) as well as xenografts of a variety of TMZ-resistant glioma and melanoma lines, where drug resistance was based on different molecular mechanisms (Chen TC et al., *Cancer Letters* 358:144, 2015; Cho HY et al., *Molecular Cancer Therapeutics* 13:2004, 2014).

- In all tested in *vivo* models, NEO212 was administered orally in the range of 5-50 mg/kg (once per day, repeat dosing). This dose range seemed well tolerated by mice, rats, and dogs and did not result in detectable signs of toxicity.

1 Confirm oral route.

Figure 4: Representative result showing survival of mice with brain-metastatic breast cancer.



source: Chen TC et al., *Molecular Cancer Therapeutics* 13:1181, 2014

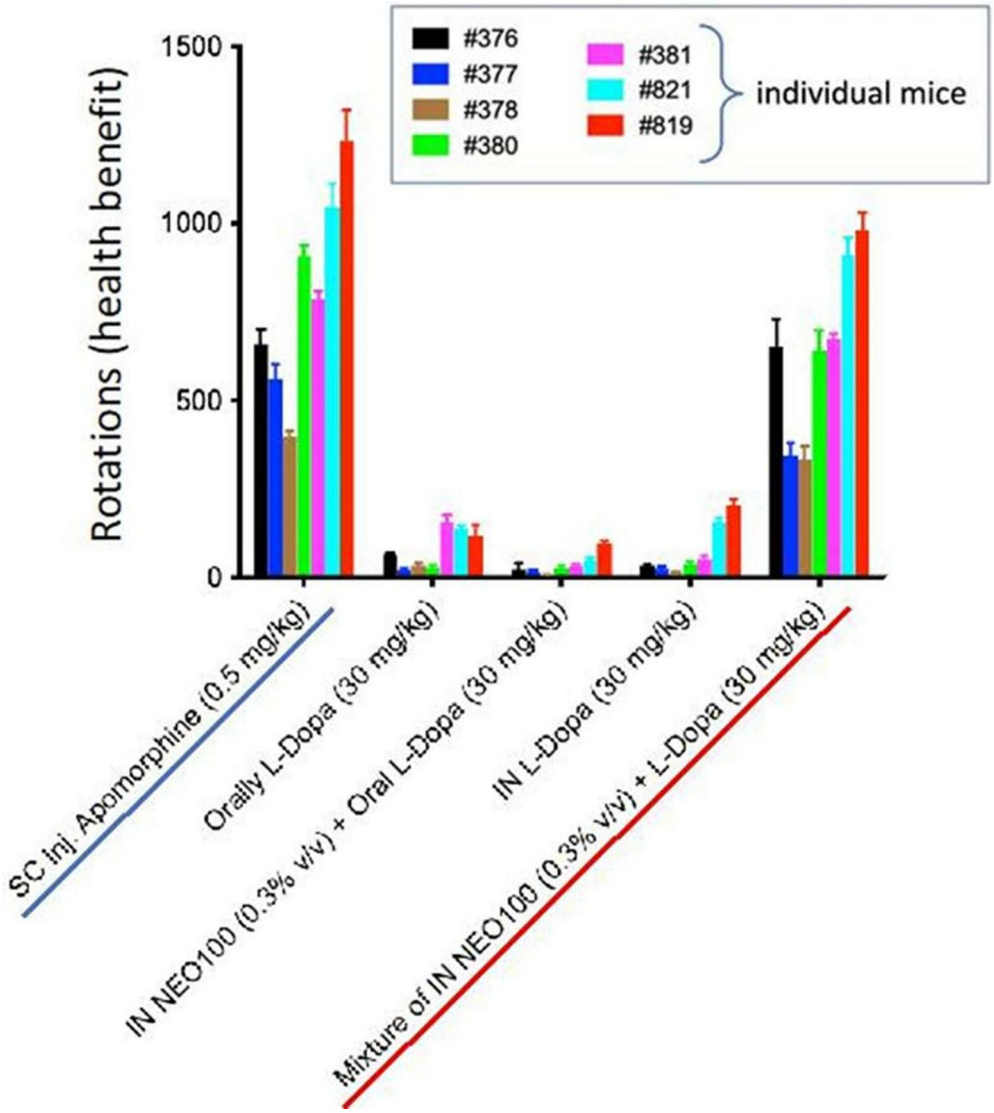
The observed activity of NEO212, which was recapitulated in a variety of preclinical tumor models, along with its low observed toxicity profile, led to our IND application to the FDA which was approved in May 2023. FDA approval allowed us to proceed for Phase I/IIa clinical trials, primarily focusing on patients with intracranial malignancies (metastatic and malignant primary brain cancer types). Although NEO212 also showed activity against peripheral cancer types (melanoma, lung cancer, breast cancer, and others) in pre-clinical studies, our first clinical trial will focus on patients with aggressive brain cancer types because the clinical need is the greatest here; due to the significant clinical need because no therapies exist. Because NEO212 was designed for blood-brain barrier penetration, we would expect that it might reveal its most valuable impact in patients with brain malignancies. However, studies with NEO212 in humans have not yet started.

Details: **3.** Intranasal co-delivery of NEO100 with levodopa for Parkinson's disease (preclinical stage).

Our preclinical research in mouse brain tumor models indicated that intranasal delivery of NEO100 may facilitate nose-to-brain transport of NEO100 itself and potentially enabled co-delivered pharmaceutics to be carried along this axis and enter the brain as well. For example, intranasal co-delivery of NEO100 with bortezomib (a drug marketed under the trade name Velcade®) seemed to allow bortezomib to enter the mouse's brain resulting in activity against brain cancer. Without NEO100, bortezomib could not enter the brain (Wang W et al., *Journal of Neurosurgery* 132(3):959, 2019).

Given preclinical results of NEO100's ability to act as a vehicle to carry other pharmaceutics into the brain, we considered its application to neurological diseases, such as Parkinson's disease (PD) or Alzheimer's disease (AD), which are increasing in numbers as the U.S. population is aging. PD Patients are treated with levodopa (L-Dopa) pills, which must be dosed precisely. These pills have common side effects, such as hypotension, nausea, confusion, and dyskinesia. Therefore, intranasal delivery with direct nose-to-brain transport would be highly desirable because it is could potentially offer better brain-directed delivery without exposing the entire body to the drug, minimizing the undesirable side effects. As well, smaller doses can be given. In our work, we used mice with PD-type lesions in their brains and co-administered NEO100 together with L-Dopa by intranasal delivery. Our results suggest that intranasal co-delivery of NEO100 and L-Dopa suppresses PD symptoms in these mice. Intranasal delivery of L-Dopa without the added NEO100 did not achieve this beneficial effect (**Figure 5**).

Figure 5: Mixture of NEO100 with L-Dopa (red underline), when given intranasally, could potentially restore healthy brain function of PD in mice as does a subcutaneous injection of apomorphine (blue underline).



From: Wang W et al., manuscript in preparation.

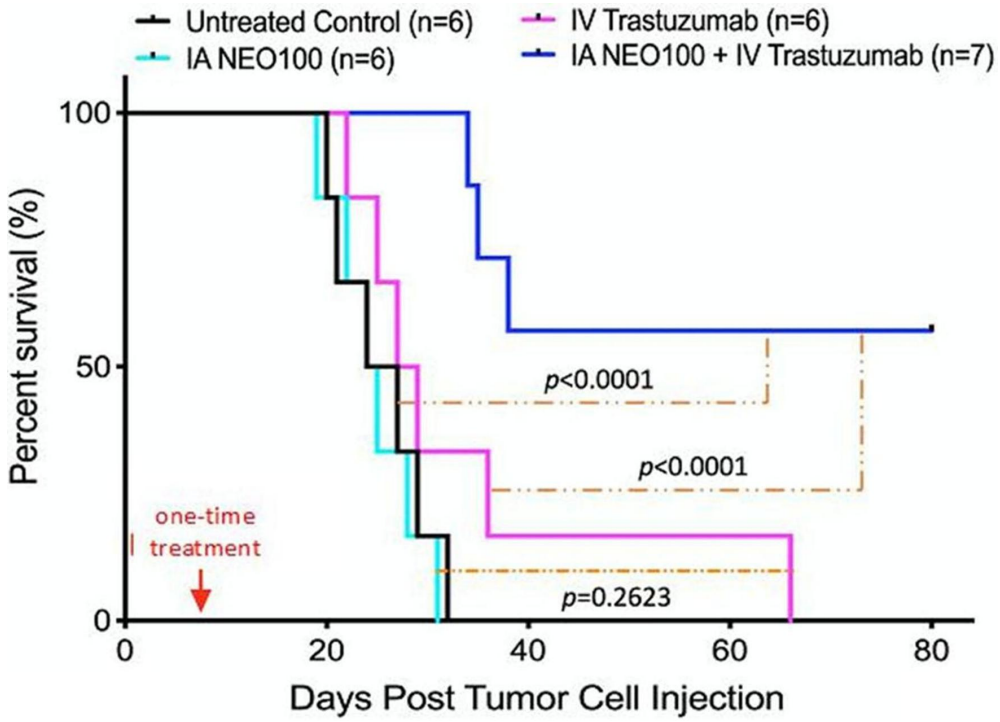
The health benefits of this approach in the mice were analyzed by determining the physical activity of the mice, in particular their ability to rotate to one side. Untreated PD mice are sick and unable to perform rotations, which is a symptom of the disease. But mice receiving intranasal NEO100 combined with L-Dopa appear to be physically active and perform rotations (bar graphs of mice in **Figure 5** with the label underlined in red). The figure also shows that mice injected with apomorphine recover from PD (label underlined in blue). However, compared to the ease of intranasal delivery, injections are invasive and do not support brain-targeted delivery due to the resulting systemic distribution of the injectate.

Details to **4.** Intra-arterial delivery of NEO100 to open the patient's blood-brain barrier will allow brain entry of BBB-impermeable pharmaceuticals or biologics (preclinical stage).

While intranasal applications of NEO100 may exploit direct nose-to-brain access routes and thereby circumvent the obstacle placed by the blood-brain barrier (BBB), an intra-arterial path of administering NEO100 has suggested that it also might directly confront the BBB and "open" it, diminishing its barrier function to potentially enable mostly unrestricted permeation of otherwise BBB-impermeable compounds. We established this procedure, characterized it in preclinical mouse tumor models, and shown that it may have advantages over the currently established clinical method of opening the BBB with mannitol (Wang W et al., *Neuro-Oncology* 23(1):63, 2021).

We used mouse models of brain-metastatic breast cancer positive for human epidermal growth factor receptor 2 (HER2). In humans, HER2+ breast cancer is usually treated with trastuzumab (Herceptin), a humanized monoclonal antibody, and this treatment often shows success. However, HER2+ breast cancer has a propensity to metastasize to the brain, and trastuzumab may not work as effectively because it cannot effectively penetrate the BBB. Our work has established that intra-arterial NEO100 might open the BBB of mice for a few hours, potentially allowing a brain influx of therapeutic agents that are circulating in the bloodstream. In the case of mice with HER2+ metastases in their brains, a single application of BBB opening with NEO100 seems to enable brain influx of trastuzumab that had been given by intravenous injection, and this approach resulted in the recovery of several of the animals (**Figure 6**).

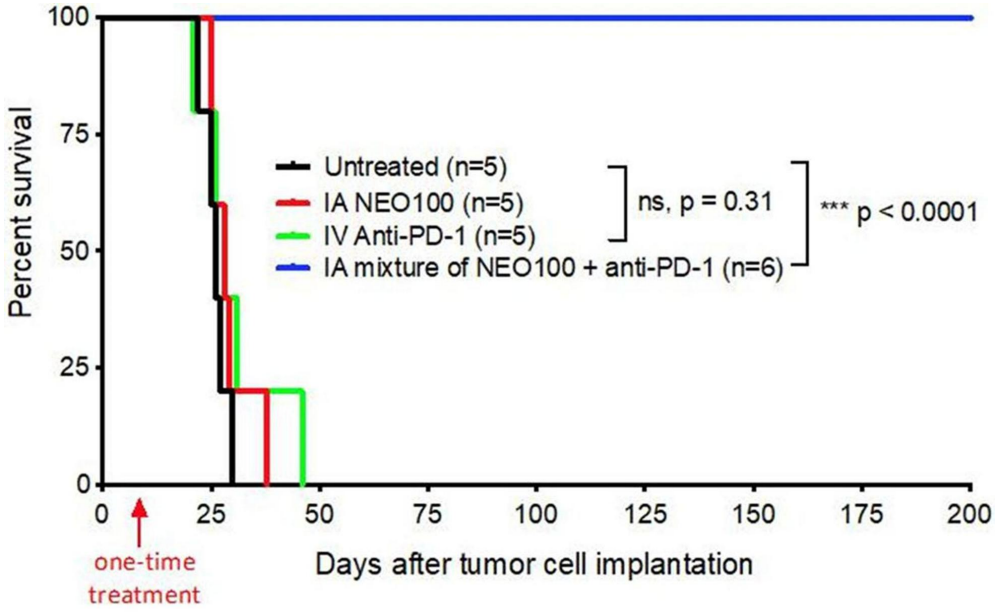
Figure 6: BBB opening by intra-arterial (IA) NEO100 achieves the absence of brain cancer of several brain-metastatic mice treated with intravenous (IV) trastuzumab.



from: Wang W et al., *Neuro-Oncology* 23(10):1656, 2021

Recent cancer therapy breakthroughs have introduced immune checkpoint-inhibitory antibodies as novel tools to treat cancer. However, as with other antibody-based therapies, these biologics' applications may be limited due to the BBB, which prevents their brain entry, i.e., brain metastases and primary malignant brain tumors such as glioblastoma. Therefore, we utilized our BBB opening method with intra-arterial NEO100 to a glioblastoma mouse model, where mice received a one-time dose of a checkpoint-inhibitory antibody within the mixture of intra-arterially applied NEO100. The outcome showed that all six mice treated in this fashion showed absence of brain cancer (blue line in **Figure 7**). In contrast, all other mice died within 4-7 weeks, including those treated with checkpoint-inhibitory antibodies in the absence of NEO100.

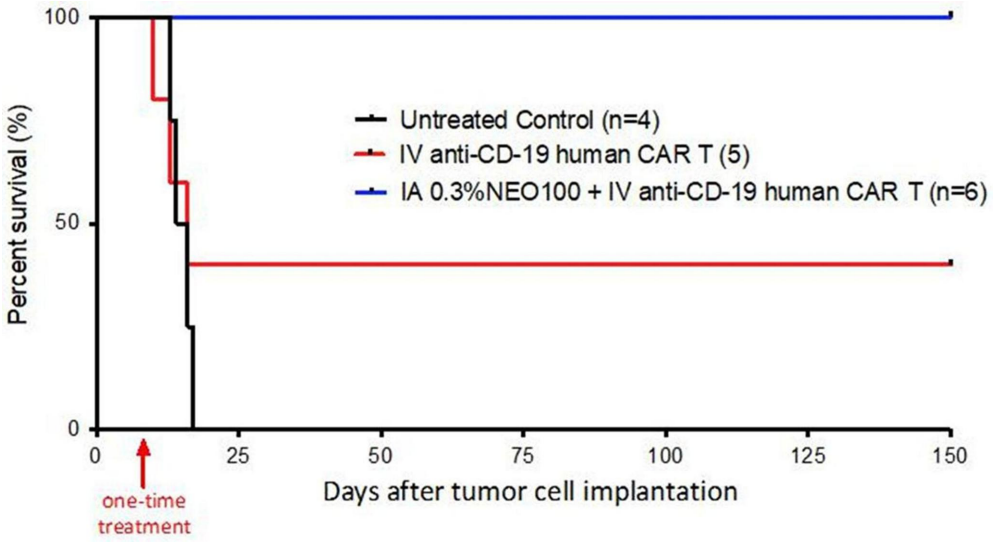
Figure 7: BBB opening by intra-arterial (IA) NEO100 achieves the absence of brain cancer for all glioblastoma mice treated with checkpoint-inhibitory antibodies.



From: Wang W et al., *Journal of Neurosurgery*, Feb 3:1-9, 2023 [online ahead of print].

Other recent breakthroughs in cancer therapy include the production of CAR T cells, where T lymphocytes are being modified to harbor a chimeric antigen receptor (CAR). While such cells have yielded impressive therapeutic advances, their activity—similar to the case of therapeutic antibodies—may be limited by their poor entry into the brain. Therefore, we applied our BBB opening method with intra-arterial NEO100 to a mouse model with intracranial lymphoma (lymphoma in the brain), where mice received a one-time dose of intravenous lymphoma-targeted CAR T cells, along with BBB opening by intra-arterial NEO100. The outcome showed that all six mice treated in this fashion showed absence of brain lymphoma (blue line in **Figure 8**). In comparison, most mice that received CAR T cells without BBB opening with intra-arterial NEO100 died within the first three weeks.

Figure 8: BBB opening by intra-arterial (IA) NEO100 shows the absence of brain cancer in all brain-lymphoma mice treated with lymphoma-directed CAR T cells.



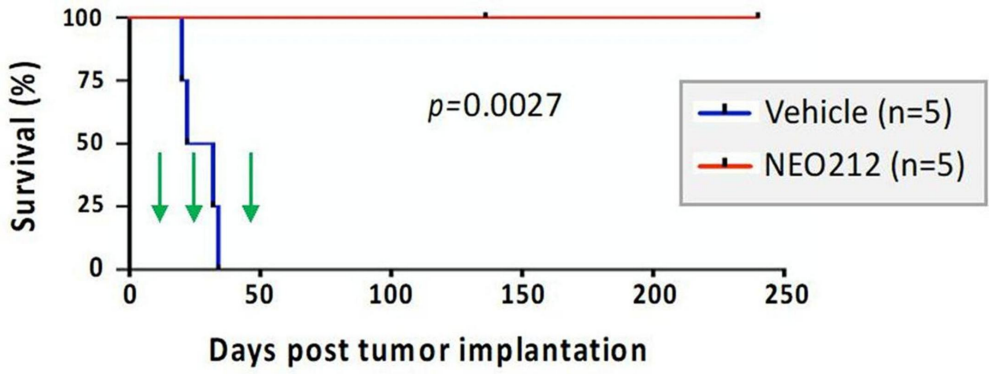
From: Wang W et al., *manuscript submitted.*

Details to **5.** Oral NEO212 for advanced cancer types, including leukemia (preclinical stage).

NEO212 was initially designed as a therapeutic molecule with enhanced capability of crossing the blood-brain barrier to address the urgent clinical need for better treatments of intracranial malignancies, such as glioblastoma and brain-metastatic lesions from peripheral cancers. At the same time, however, NEO212 has demonstrated potential potency, along with low toxicity, against cancer types outside the brain, such as lung cancer, melanoma, ovarian cancer, leukemia, and others (Chen TC et al., *Cancer Letters* 358:144, 2015; Chen TC et al., *Journal of Biomedical Sciences* 22:71, 2015; Xie L et al., *Oncotarget* 7:1651, 2016; Song X et al., *Journal of Experimental and Clinical Cancer Research* 38:239, 2019; Song X et al., *Cell Death & Disease* 9:202, 2018; Song X et al., *Scientific Reports* 6:22762, 2016; Chang M et al., *Journal of Experimental and Clinical Cancer Research* 37:250, 2018; Silva-Hirschberg C et al., *Therapeutic Advances in Medical Oncology* 11:1758835919891567, 2019; Schönthal AH et al., *Cancers* 13(14):3385, 2021).

Among the most striking examples of NEO212's potential therapeutic impact on peripheral cancer types, as established in mouse tumor models, is its effect on leukemia, particularly drug-resistant acute myeloid leukemia (AML), which in daily clinical practice remains very difficult to treat and often is fatal. First-line treatment of AML usually includes intravenous cytarabine. Still, often the tumor becomes resistant to this drug, which precludes further cytarabine treatment and generally requires subsequent hematopoietic stem cell transplantation. In our experiments, treatment of mice harboring cytarabine-resistant AML with NEO212 suggested a positive result and tolerability. Oral NEO212 was administered once daily for five days, followed by 7-14 days of a treatment holiday; this cycle was repeated twice more for three cycles in total (green arrows in **Figure 9**); there were no further treatments after week 8. All mice in this treatment group survived beyond 200 days, which might be interpreted as a positive outcome (**Figure 9**).

Figure 9: Treatment of mice harboring cytarabine-resistant AML with NEO212 results in the absence of brain cancer in all treated animals.



from: Schönthal AH et al., *Cancers* 13(14):3385, 2021.

In light of the activity of NEO212 against a variety of tumor types studied in mouse tumor models, the initial Phase I clinical trial will be conducted with patients harboring brain cancers, including primary brain cancers (such as recurrent glioblastoma) and secondary brain cancers (metastases derived from lung, breast, and melanoma). NeOnc has received the IND approval for this Phase I trial. Phase I is expected to last up to one year, followed by Phase II, which is expected to last about two years.

Extending the above, we are also designing a Phase I/IIa trial of oral NEO212 that will specifically focus on patients with newly-diagnosed glioblastoma. With current standard of care, these patients have an average life expectancy of only 15 months after initial diagnosis. Based on the encouraging results from our extensive preclinical studies, our extensive preclinical studies suggest that NEO212 may provide some benefit.

Competition and Competitive Factors

NEO100 and NEO212 address different aspects of the global central nervous system (CNS) treatment market and the brain tumor drug markets which are highly competitive, dynamic, and rapidly evolving areas of the pharmaceutical and healthcare industries. In both markets, success often hinges on a combination of clinical effectiveness, regulatory approvals, market access, pricing strategies, and effective marketing. The competition is further intensified by ongoing advances in medical science and technology, making it essential for companies to stay at the forefront of innovation and research.

Our NEO100 and NEO212 candidates will need to differentiate themselves based on efficacy, safety, cost, ease of administration, and other therapeutic benefits. As we continue our research and development, we are cognizant of these competitive dynamics and are strategizing accordingly to ensure our products bring unique and tangible benefits to patients. As a clinical company, we face many of the challenges outlined below.

Global Central Nervous System Treatment Market:

The competitive conditions in this market are:

- Wide Range of Indications: The CNS treatment market encompasses a broad range of neurological and psychiatric disorders, including epilepsy, Alzheimer's disease, Parkinson's disease, multiple sclerosis, schizophrenia, and more. Each indication has its own set of competing treatments.

- Established Players: Large pharmaceutical companies, such as Pfizer, Roche, and Novartis, have a strong presence in the CNS market, with well-established drugs and therapies for various conditions.

- Generics and Biosimilars: Many older CNS drugs have lost patent protection, leading to the availability of generic and biosimilar versions. This has intensified competition, particularly in the treatment of common conditions like depression and anxiety.

- R&D Investment: Companies invest heavily in research and development to discover and develop new CNS drugs. Advancements in neuroscience are driving innovative therapies, including novel mechanisms of action and targeted treatments.

- Regulatory Challenges: Developing CNS drugs can be challenging due to the complexity of the brain and the potential for side effects. Companies must navigate stringent regulatory processes to gain approvals from agencies like the FDA and EMA.

- Biologics and Gene Therapies: Emerging treatments, such as gene therapies and biologics, are becoming more prevalent in the CNS market. These advanced therapies often come with high costs and complex manufacturing processes.

- Market Access and Pricing: Reimbursement and pricing challenges exist, and companies must demonstrate cost-effectiveness to secure market access, especially for novel, high-cost treatments.

Global Brain Tumor Drug Market:

The competitive conditions in this market are:

- Tumor Type Variability: The market for brain tumor drugs is highly diverse due to the various types of brain tumors, including glioblastoma multiforme (GBM), meningioma, and astrocytoma, each requiring different treatment approaches.

- Surgery and Radiation Therapy: Brain tumors often require a combination of surgery and radiation therapy. Competition can be intense among medical device manufacturers and radiation therapy providers, as well as pharmaceutical companies offering adjuvant therapies.

- Targeted Therapies: Developing targeted therapies that focus on specific genetic mutations or signaling pathways associated with brain tumors is an active area of competition. Personalized medicine approaches are increasingly relevant.

- Immunotherapy: Immunotherapies are being explored for brain tumors, and competition revolves around developing effective immunotherapeutic strategies to harness the body's immune system against the tumor.

- Clinical Trials: Companies often compete based on the strength of their clinical trial results and their ability to bring new drugs to market. The effectiveness and safety of brain tumor drugs are critical factors.

- Orphan Drug Designations: Some brain tumor treatments may qualify for orphan drug designations, which can provide certain advantages, including extended exclusivity and incentives for development.

- Patient Advocacy: Patient advocacy organizations play a significant role in raising awareness and influencing drug development. Collaboration with these groups can enhance a company's competitive position.

- Research and Innovation: Continuous research and innovation in areas such as drug delivery, biomarker discovery, and imaging technologies contribute to the competitive landscape.

- Combination Therapies: Companies explore combination therapies that can enhance treatment effectiveness. Combining surgery, radiation, and chemotherapy, for example, is a common approach in brain tumor treatment.

- Global Expansion: Companies that can navigate international regulatory frameworks and secure approvals in various markets have a competitive edge.

There are numerous other pharmaceutical and biotech companies, as well as academic institutions, involved in brain tumor research and drug development, including:

- Bristol Myers Squibb (BMS): Makers of Opdivo® (nivolumab) which has been explored for glioblastoma.

- Merck & Co., Inc.: Their drug, Temozolomide (Temodar® in the US, Temodal® in Europe), is a primary treatment for glioblastoma and anaplastic astrocytoma.

- Roche: They have received accelerated US approval for Avastin® (bevacizumab) for recurrent glioblastoma.

- Novocure: Developers of the Optune® device, a non-invasive treatment for glioblastoma.

- AstraZeneca are engaged in various stages of research, development, and commercialization of treatments for brain tumors.

- Eli Lilly and Company: Conducting research in targeting brain tumors.

- Pfizer: Involvement in the development of treatments for various types of cancers, including brain tumors.

- Celldex Therapeutics: Working on drug candidates for glioblastoma.

The competition in this sector extends beyond just drug therapies. Various modalities, including radiation, surgery, and newer non-drug technologies, also vie for market share in the brain tumor treatment domains.

NEO212

NEO212 is a temozolomide conjugate that is given orally. Its main competitive landscape will be standard of care alkylating agents such as temozolomide and lomustine. It is intended that NEO212 will have an oral formulation for primary brain cancers and may also be used for metastatic brain cancers. These cancers are treated currently by surgery or radiosurgery only.

Future Growth Drivers

We anticipate several goals and plans that may potentially support our long-term growth, with some supported by additional high-growth global markets:

- Potential commercial launch of NEO100 following FDA market approval.
- Possible clinical trials & FDA approval of other POH compounds in our product pipeline.
- Exploration of NEO100 pediatric indication.
- We are currently investigating several additional proprietary chemotherapy agents that have shown preliminary positive effects in laboratory tests on various types of cancers, i.e., NEO212 oral and intranasal delivery for primary and metastatic brain cancer.
- Treatments for other CNS diseases and disorders based on our POH technology, such as Alzheimer's, Parkinson's and Epilepsy.

Manufacturing

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.

Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's current good manufacturing practice standards ("cGMP") regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA/NDA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Intellectual Property

We have exclusively licensed a large worldwide patent portfolio from USC consisting of both issued patents and pending patent applications related to NEO100, NEO212 and other products from the NeOnc patent family for multiple uses, including oncological and neurological conditions. In the United States, the Company has exclusive rights to 28 issued patents and 14 pending patent applications. Internationally, we have 65 patents issued and 28 patents applications pending.

The patent families of our product candidates are briefly described in the table below. All patents are owned by USC and exclusively licensed to us from USC. Patent Term Extension (PTE) may be available on certain patents after product approval.

Product Candidate	Title [description]	US Application #	US Patent	Expiration Date	Foreign Counterparts
NEO100	Pharmaceutical Compositions Comprising Monoterpenes [Ultra Pure]	13/040,059 13/939,834 14/817,286 14/843,097 15/040,002 15/220,135 16/575,587 17/749,293	8,507,734[1,2] 9,133,085[1] 9,480,659[1] 9,498,448[1] 9,700,524[3] 10,457,618[1] 10,899,691[1] Pending[3]	8/29/2031 6/5/2031 3/3/2031 3/3/2031 3/3/2031 3/3/2031 3/3/2031 3/3/2031*	Canada, China, China, EU (France, Germany, United Kingdom, Ireland, and Italy)
NEO212	Pharmaceutical Compositions Comprising POH Derivatives [POH conjugated to temozolomide (TMZ)]	13/566,731 14/455,371 13/818,972 15/408,866	8,916,545[2] 9,580,372[3] 9,499,461[1,2,3] 10,092,562[3]	8/26/2031 8/26/2031 8/26/2031 8/26/2031	Brazil, China, EU (Germany, Spain, France, United Kingdom Switzerland, Ireland, Italy, Netherlands, Sweden), Japan, Hong Kong
NEO 214	Pharmaceutical Compositions Comprising POH Derivatives [POH conjugated to rolipram]	16/123,729 16/388,535 17/306,167	11,077,104[3] 11,013,804[2] pending[2,3]	8/26/2031 8/26/2031 8/26/2031*	Japan, EU (Spain, France, United Kingdom, Ireland, Italy, Netherlands, Sweden)
NEO 216	Pharmaceutical Compositions Comprising POH Derivatives and Methods of Use [POH conjugated to valproic acid]	16/606,520 18/150,933	11,559,508[2] pending[3]	11/24/2038 4/18/2038*	China, EU (pending in both)
NEO 218	A Perillyl Alcohol-3-Bromopyruvate Conjugate and Methods of Treating Cancer [POH conjugated to 3- Bromopyruvate]	16/465,081	10,858,305[1,2,3]	11/29/2037	China, EU, Japan (pending in all)
NEO 400	Pharmaceutical Compositions Comprising POH Derivatives [POH conjugated with linoleic acid (LA)]	17/251,452 17/313,258 17/573,693	pending[3] pending[3] pending[2]	8/26/2031* 8/26/2031* 8/26/2031*	China, EU (pending in both)
NEO 412	Pharmaceutical Compositions Comprising Perillyl Alcohol Derivatives [Triple conjugation of perillyl alcohol, linoleic acid, and temozolomide]	15/041,743 16/126,586	9,522,918[1,2] 10,696,680[3]	2/11/2036 2/11/2036	Australia, China, EU (Germany, France, United Kingdom, Ireland), Japan

1 Method of making pharmaceutical composition
2 Pharmaceutical composition
3 Method of using pharmaceutical composition
* 20 years from the earliest filing date, subject to patent term adjustment

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 highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own are highly uncertain. The steps we and our licensor 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 licensed pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. Our pending licensed and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which prevent others from commercializing competitive product candidates. 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 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 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 or our other product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

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 patent protection.

Our licensed 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, 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.

Exclusive Patent License Agreement between USC and our Company

On March 9, 2009, Nas-Onc, Inc. (k/n/a NeOnc Technologies, Inc). entered into an exclusive, worldwide license agreement with USC, pursuant to which USC granted us a license to use certain patents and patent applications for the treatment and therapies of disease symptoms in mammals (the "USC Agreement"). The license is exclusive except for the rights granted to the US government pursuant to the Bayh-Dole Act and the right of USC and other non-profit academic research institutions to practice and improve the licensed patents for educational and research purposes. Pursuant to the USC Agreement, we (1) paid USC an upfront royalty payment of $20,000, (2) granted USC 117,236 shares of common stock, (3) will pay USC an earned royalty of 2% of Net Sales (as that term is defined in the USC Agreement), and (4) has paid and will continue to pay annual maintenance royalties of: $5,000 due January 1, 2011, $5,000 due January 1, 2012, $10,000 due January 1, 2013, and $20,000 due January 1 yearly thereafter. Annual maintenance royalties paid to USC are creditable toward earned royalties. We are also responsible for paying all reasonable patent expenses incurred by USC for filing prosecution and maintaining the licensed patents.

Under the USC Agreement, payments will not be due to USC upon reaching certain development milestones. As of December 31, 2023, we have paid USC $479,621. Of the $479,621 paid to USC, $240,000 was a maintenance royalty payment. In the event of suspected patent infringement, the parties may agree to jointly institute suit, wherein the parties will share equally all costs and any recovery, with control of such lawsuit being by agreement between us and USC. Absent an agreement to jointly institute a suit, USC has the sole right to institute suit, at its option, where USC will bear the cost of such litigation and retain all recovery. In the event that USC does not institute the lawsuit, we may bring suit, at its option, and bear all such costs. Any recovery obtain by us must be shared with USC, after litigation costs reimbursement, as royalties on Net Sales for the remaining recovery. These rights and obligations were changed pursuant to the Amended License Agreement discussed below.

The USC Agreement is sublicensable subject to the same terms, except that (1) sublicensees may not grant sublicenses, (2) the earned royalty may be increased as to sublicensees, (3) the sublicense reverts to USC in the event the USC Agreement is terminated as to us and, (4) additional issue and maintenance fees are owed to USC for each sublicense. These rights and obligations were changed pursuant to the Second Amendment and Restated Agreement discussed below.

We may challenge the licensed patents upon 90 days' notice and payment of all royalties due. If we are unsuccessful in its challenge, the earned royalty will thereafter be increased by a factor of three. These rights and obligations were changed pursuant to the Restated Agreement discussed below.

The term of the USC Agreement extends until the last to expire of the licensed patents. The Term of the Agreement was changed pursuant to the Restated Agreement discussed below.

The USC Agreement may be terminated by either party upon 30 days' notice or upon material breach, wherein the breaching party is permitted 30 days to remedy such breach. USC may terminate immediately if (1) we attempt to sublicense, transfer or assign its rights contrary to the terms of the agreement, (2) we do not maintain the required insurance coverage, or (3) we are determined to be insolvent. These rights and obligations were changed pursuant to the Restated Agreement discussed below.

The parties amended the USC Agreement on April 5, 2023 ("Amended License Agreement"). The Amended License Agreement added NeOnc Technologies Holdings, Inc. as a licensee. The Amended License Agreement also added additional patents and patent applications to the prior license grant and requires us to obtain and record fully executed assignments of the added patents/applications demonstrating USC's ownership in all relevant jurisdictions. Pursuant to the Amended License Agreement, we agreed to issue USC 560,000 additional shares of our common stock. The 560,000 shares were issued to USC on October 11, 2023.

In addition, the Amended License Agreement provides for an 4% earned royalty on Net Sales on licensed products protected by the newly added patents on a country by-country basis. In the event that a licensed product is protected by patents from both the USC Agreement and the Amended License Agreement, the higher royalty will apply. The Amended License Agreement also recognizes a Royalty Credit, in the event that we must obtain additional licenses from third parties in order to sell the licensed products. The Amended License Agreement also grants us control the prosecution of any patent application and maintenance of any patent included within Licensed Patents. We continue to be responsible for all costs associated with the prosecution and maintenance of the licensed patents. The Amendment also changed the parties enforcement obligations. Specifically, we shall have the first right, following consultation with USC, at our sole expense, to file suit against any alleged infringer or in defense of any Third Party claim. Any recovery or settlement in excess of litigation costs paid to us will be shared with USC as if it were Sublicense Revenue as defined in the USC Agreement. USC must consent to any settlement that is detrimental to USC or USC's intellectual property rights. If we elect not to file suit against an alleged infringer, then upon such election, we will be deemed to have assigned to USC all rights, causes of action, and damages resulting from the alleged infringement. USC then has the sole right to institute suit, at its option.

The parties further amended the USC Agreement on May 30, 2023 ("Second Amendment"). The Second Amendment revised the license agreement to permit sublicensees to sublicense the patents pursuant to specific terms.

On November 19, 2023, the Company and USC entered into an Amended and Restated Exclusive License Agreement (the "Restated Agreement"). The Restated Agreement addressed and clarified certain reporting obligations of the Company under the USC Agreement and addressed certain financial and other obligations, defaults, and deficiencies in connection with the Company's performance under the USC Agreement. In satisfaction prior unpaid sublicense issue royalties and annual maintenance royalties due for sublicensees, the Company must pay USC $230,000 by March 31, 2024. On July 17, 2024, the restated agreement was amended to extend the payment date of the $230,000 to the earlier of September 1, 2025 or withing five days of a public offering. In connection with the Restated Agreement, the Company recorded the settlement amount of $230,000 in the accompanying consolidated statement of operations for the year ended December 31, 2023, and accounts payable to USC in the accompanying consolidated balance sheet as of December 31, 2024 and 2023.

The Restated Agreement provides for the same annual maintenance royalties of $20,000 per year above as well as the earned royalty of 2% or 4% on Net Sales on Licensed Products based on patent coverage (with the higher royalty applied when the Licensed Product is protected by patents from both the USC Agreement and the Amended License Agreement) and on a country-by-country basis. As above, the Restated Agreement recognizes the Royalty Credit.

In the event that we, or our sublicensee (other than OEP (discussed below)), challenges a Licensed Patent the annual maintenance royalty, milestone payments and the earned royalty percentage rated will be doubled during the pendency of such challenge. At the conclusion of such challenge, if a Valid Claim that covers the Licensed Product, Licensed Service or Licensed Process is held valid and enforceable then such ongoing royalty payments will be tripled. We must also reimburse USC for all costs incurred in connection with such challenge. Further, we must provide USC at least 180 day's written notice prior to our, or our sublicensee (excluding OEP) challenging a Licensed Patent. The notice is required to contain the prior art and a description of the facts and arguments that support the invalidity or unenforceability contention. We are required to discuss same with USC in an attempt to resolve the issues.

As above, we may grant sublicenses and our sublicensees may further grant licenses through one tier. By way of reference, on November 8, 2013, we entered into a collaboration agreement ("OEP Agreement") with OEP, pursuant to which NeOnc licensed to OEP the right to commercialize NEO100 in those territories specified in the OEP Agreement. As to the OEP Agreement, the Restated Agreement waives any prior breach by us of the USC Agreement and permits the OEP sublicense despite inconsistencies with certain terms of the Restated Agreement. On February 20, 2024, OEP and the Company entered into a settlement agreement whereby the Company and OEP terminated the OEP Agreement in exchange for a payment in the amount of $4,000,000 payable by the Company to OEP within ten days of the close of the Company's initial public offering.

As above, pursuant to the Restated Agreement we maintain us sole control the prosecution of any patent application and maintenance of any patent included within licensed patents. We continue to be responsible for all costs associated with the prosecution and maintenance of the licensed patents. In addition, the parties enforcement obligations as described in the Amended License Agreement remain unchanged. Specifically, we have the first right, following consultation with USC, at our sole expense, to file suit against any alleged infringer or in defense of any Third Party claim. Any recovery or settlement in excess of litigation costs paid to us will be shared with USC as if it were sublicense revenue. USC must consent to any settlement that is detrimental to USC or USC's intellectual property rights. If we elect not to file suit against an alleged infringer, then upon such election, we will be deemed to have assigned to USC all rights, causes of action, and damages resulting from the alleged infringement. USC then has the sole right to institute suit, at its option.

The Restated Agreement changes the Term of the license. Specifically, the term is now tied to our royalty obligations under the Restated Agreement. We are obligated to pay royalties as to each Licensed Product, Licensed Service or Licensed Process on a country-by-country basis until (a) the last to expire Licensed Patent covering such product/service/process or (b) for 15 years after the date of first commercial sale of such product/service/process where such product/service/process is not covered by a Valid Claim of a Licensed Patent but such product/service/process was developed or made using any Licensed Process. The Term of the license ends when no further royalty obligations are due.

Last, as to termination, the Restated Agreement provides that the parties may mutually agree to terminate. Further, USC may immediately terminate if (a) we do not make payments when due and fail to cure, (b) we default on our indemnification or insurance obligations, (c) we are determined to be insolvent, (d) if any of our officers, directors or employees are convicted of a felony related to the development, manufacture use, marketing, distribution or sale of the Licensed Product, (e) if an audit shows an underpayment by us or a sublicensee of 15% or more for any 12 month period, or (f) we default in the performance of our other obligations in the agreement, and in each case fail to cure. We may terminate the license by giving 180 days advance written notice.

Upon any termination of the license (other than expiration of the Term), then the Restated Agreement grants to USC a non-exclusive worldwide fully paid license, with the right to sublicense to the Licensed Product Data, which includes all pre-clinical, clinical and other regulatory data generated by or on behalf of the Company relating to the Licensed Product and generated after the effective date of the USC Agreement.

Settlement Agreements with Licensees

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 will pay OEP $4.0 million within ten days of the closing date of the Company's initial public offering. As the Company believes this offering is not the Company's initial public offering but rather only a Direct Listing of its common stock, the Company does not intend to make payment to OEP as a result of this offering. OEP recently informed the Company that it believes the Company is currently obligated to pay such amount; while the Company does 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 the Company's ability to raise additional proceeds from the sale of its securities.

Government Regulation and Product Approval

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the PHSA, and regulations and guidance documents implementing these laws. The FDCA, PHSA and their corresponding regulations govern, among other things, the testing, manufacturing, safety, purity, potency, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving pharmaceutical products. Consent from the FDA is required before conducting human clinical testing of drug products. FDA approval of a new drug application (NDA) or a biologics license application (BLA) also must be obtained before marketing a new drug or biological product. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the continued expenditure of substantial time and financial resources.

U.S. Small Molecule New Drug Product Development Process

Any new drug product must be approved by the FDA before it may be legally marketed in the United States. FDA approval is also required before marketing an approved drug product for a new indication or condition of use. The process required by the FDA before a new drug product candidate may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests and in vivo studies in accordance with the FDA's Good Laboratory Practice (GLP) regulations and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- Submission to the FDA of an investigational new drug (IND) application, which allows human clinical trials to begin unless FDA objects (issues a "clinical hold") within 30 calendar days;

- Approval by an independent institutional review board (IRB), reviewing each proposed clinical trial and clinical site before each clinical trial may be initiated;

- Performance of adequate and well-controlled human clinical trials in accordance with the protocol contained in the approved IND and in accordance with the FDA's Good Clinical Practice (GCP) regulations, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product candidate for its intended use;

- Preparation and submission to the FDA of a new drug application (NDA) for marketing approval that includes substantial evidence of safety and efficacy from results of nonclinical testing and clinical trials;

- Review of the product by an FDA advisory committee, if applicable;

- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product candidate is produced to assess compliance with current Good Manufacturing Practice (cGMP) requirements and to assure that the facilities, methods and controls are adequate to preserve the product candidate's identity, safety, strength, quality, potency and purity;

- Potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and

- Payment of user fees and FDA review and approval of the NDA.

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of the FDA's pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Before testing any product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as in vivo animal studies to assess the potential safety and activity of the product candidate and to establish a rationale for therapeutic use. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

Concurrent with clinical trials, companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

A clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes active 30 calendar days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA also may impose partial or full clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not begin, or recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, that issues arise that partially or fully suspend or terminate such studies.

Human Clinical Trials Under an IND

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators which generally are physicians not employed by, or under, the control of the trial sponsor. Clinical trials must be conducted under written study protocols detailing, among other things, the objectives of the trial, subject selection and exclusion, the trial procedures, the parameters to be used in monitoring safety, the criteria to be evaluated, and a statistical analysis plan. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND.

Further, clinical trials must be conducted in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval by an IRB at each study site participating in the clinical trial or a central IRB. An IRB is charged with protecting the welfare and rights of trial participants and considers items such as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject, or their legal representative, reviews and approves the study protocol, and must monitor the clinical trial until completed.

Human clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- *Phase I.* The product candidate initially is introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early understanding of its value in treating patients. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- *Phase II*. The product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase III*. Phase III clinical trials are commonly referred to as “pivotal” or “registrational” studies, which typically denotes a study which presents the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a product. In Phase III studies, the product candidate is administered to an expanded patient population, generally at multiple geographically dispersed clinical trial sites in adequate and well-controlled clinical trials to generate sufficient data to statistically demonstrate the efficacy and safety of the product for approval. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase IV clinical trials, may be required by FDA, or may be voluntarily conducted after initial approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA.

Written IND safety reports must be promptly submitted to the FDA and the investigators for: serious and unexpected adverse events; any findings from other studies, in vivo laboratory tests or in vitro testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information. Relevant additional information obtained by the sponsor that pertains to a previously submitted IND safety report must be submitted as a follow-up IND safety report. Such report should be submitted within 15 calendar days after the sponsor receives the information.

Information about certain clinical trials, including a description of the study and, in some cases, study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website. Manufacturers or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious or life-threatening diseases or conditions where no other comparable or satisfactory therapeutic options exist must also have a publicly available policy on evaluating and responding to requests for expanded access, sometimes called “compassionate use,” requests.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor that regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of the trial. This group, known as a Data and Safety Monitoring Board (DSMB) or Data and Safety Monitoring Committee (DSMC), may also review interim data to assess the continuing validity and scientific merit of the clinical trial. This group receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determined there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

Compliance with Current Good Manufacturing Practices (cGMP) Requirements

Manufacturers of pharmaceutical products must comply with applicable cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Establishments may be subject to periodic, unannounced inspections by government authorities to ensure compliance with cGMP requirements and other laws. Discovery of problems may result in a government entity placing restrictions on a product, manufacturer or holder of an approved NDA, and may extend to requiring withdrawal of the product from the market. The FDA will not approve a NDA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specification.

Concurrent with clinical trials, companies usually complete additional preclinical studies and must also develop additional information about the physical characteristics of the product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents or of causing other adverse events with the use of small molecule products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In relation to the clinical trials that may be conducted in other countries with a view to obtaining a marketing authorization, there are comparable cGMP requirements and other regulatory rules that are implemented nationally.

U.S. FDA Review and Approval Process

Assuming successful completion of the required clinical and preclinical testing, the results of the preclinical tests and clinical trials together with detailed information relating to the product's CMC, including negative or ambiguous results as well as positive findings, and proposed labeling, among other things, are submitted to the FDA for NDA (new drug application) approval to market the product for one or more indications.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each NDA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. The PDUFA also imposes an annual program fee for approved therapeutic products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

In addition, under the Pediatric Research Equity Act (PREA), an NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and potential of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe. Also, applications for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, in place of the PREA investigations, sponsors must submit, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Orphan products are also exempt from the PREA requirements.

The FDA reviews a NDA within 60 days of submission to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In that event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth, substantive review of the NDA.

The FDA reviews the NDA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, has an acceptable purity profile and whether the product candidate is being manufactured in accordance with cGMP to assure and preserve the product candidate's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel therapeutic products or therapeutic products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, (REMS) is necessary to assure the safe use of the product candidate. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. A REMS could include medication guides, physician communication plans and elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving a NDA, the FDA will inspect the facilities at which the product candidate is manufactured. The FDA will not approve the product candidate if it determines that the manufacturing processes and facilities are not in compliance with cGMP requirements or otherwise are not adequate to assure consistent production of the product candidate within required specifications. Additionally, before approving a NDA, the FDA typically will inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements.

On the basis of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

If a product candidate receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA may also require post-marketing clinical trials, sometimes referred to as Phase IV clinical trials, designed to further assess a product's safety, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Every five years, the FDA agrees to specified performance goals in the review of NDAs under the PDUFA. One such current goal is to review standard NDAs in ten months after the FDA accepts the NDA for filing, and priority NDAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for Fast Track status any time before receiving NDA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product may be eligible for priority review if it is intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product may also be eligible for accelerated approval if it is intended to treat a serious or life-threatening condition and generally provide a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug may be eligible for designation as a Breakthrough Therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy designation include the same benefits as Fast Track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast Track designation, priority review, accelerated approval and Breakthrough Therapy designation do not change the standards for approval, but may expedite the development or approval process.

Post-Approval Requirements

After approval, there also are continuing annual program user fee requirements for approved products, excluding, under certain circumstances, orphan products.

Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to cGMP requirements. Manufacturers are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

Other post-approval requirements applicable to pharmaceutical products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information and complying with electronic record and signature requirements. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency of pharmacological products.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with current cGMP and other requirements, which impose certain procedural and documentation requirements upon us and third-party manufacturers. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with current cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. In addition, changes to the manufacturing process or facility generally require prior FDA approval or notification before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing.

Adverse event reporting and submission of periodic reports, including annual reports and deviation reports, are required following FDA approval of a NDA. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, license suspension or revocation, imposition of a partial or full clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and result in adverse publicity, among other adverse consequences.

A sponsor also must comply with the FDA's advertising and promotion requirements, such as the prohibition on promoting products for uses or in patient populations that are inconsistent with the product's approved labeling (known as "off-label use"). The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations relating to the promotion of off-label uses may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Companies, however, may generally share truthful and non-misleading information that is otherwise consistent with a product's FDA approved labeling. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal actions and adverse publicity. These actions could include refusal to approve pending applications or supplemental applications, withdrawal of an approval, clinical hold, suspension or termination of a clinical trial by an IRB, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or other monetary penalties, refusals of government contracts, mandated corrective advertising or communications with healthcare providers, debarment, restitution, disgorgement of profits or other civil or criminal penalties.

Broadly equivalent requirements and controls typically apply in other countries to the submission of marketing authorization applications and, post-approval, to the holding of such marketing authorizations.

The Hatch-Waxman Amendments and Generic Competition

Orange Book Listing

Once a drug product is approved under an NDA, the product is listed in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. An NDA-approved drug product will be designated in the Orange Book as a Reference Listed Drug (RLD). Sponsors of approved NDAs are required to list with the FDA patents whose claims cover the product's active ingredient, formulation, or an approved method of using the drug.

Patent Term Extensions

Depending upon the timing, duration and specifics of FDA approval of the use of our therapeutic candidates, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments to the FDCA (Hatch-Waxman"). Hatch-Waxman permits a patent restoration term of up to five years as compensation for patent term lost during drug product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product or therapeutic candidate's approval date. The patent term restoration period is generally one half of the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product or therapeutic candidate is eligible for the extension and the application for extension must be made prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA(s).

ANDA Approval Process for Generic Drugs

Hatch-Waxman also established an abbreviated FDA approval process for generic drugs that are shown to be pharmaceutically equivalent and bioequivalent to drugs previously approved by the FDA through the NDA process. Approval to market and distribute these drugs is obtained by filing an abbreviated new drug application, or ANDA, with the FDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In some cases involving drugs with no or limited systemic absorption, an ANDA must include clinical endpoint (efficacy) studies in order to demonstrate bioequivalence. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

Section 505(b)(2) NDA Approval Process

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA under a "full" NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and enables the applicant to rely, in part, on the FDA's previous approval of a similar product, and/or published literature, in support of the safety and/or efficacy of its drug product. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved or for any new indication sought by the Section 505(b)(2) applicant.

ANDA and 505(b)(2) products may be significantly less costly to bring to market than the reference listed drug, and companies that produce generic products are generally able to offer them at lower prices. Moreover, generic versions of RLDs are often automatically substituted for the RLD by pharmacies when dispensing a prescription written for the RLD. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

ANDA and 505(b)(2) NDA Patent Certification Requirements

Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a Section 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA, as applicable, that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is, in the applicant's opinion, invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. If an ANDA or 505(b)(2) NDA is submitted to FDA with a Paragraph IV Certification, the applicant must also provide a "Paragraph IV Notification" to the holder of the NDA for the RLD and to the owner of the listed patent(s) being challenged by the applicant, providing a detailed written statement of the bases for the applicant's position that the relevant patent(s) is invalid or would not be infringed. If the patent owner brings a patent infringement lawsuit against the applicant within 45 days of the Paragraph IV Notification, FDA approval of the ANDA or 505(b)(2) NDA will be automatically stayed for 30 months, or until 7-1/2 years after the RLD's NDA approval date if the ANDA or 505(b)(2) NDA was filed between 4 years and 5 years after the NDA approval. Any such stay will be terminated earlier if the court rules that the patent is invalid or would not be infringed. The applicant may, in certain circumstances, elect to submit a "section viii" statement with respect to a listed method of use patent, certifying that the proposed ANDA or 505(b)(2) product's labeling does not contain (or carves out) any language that would infringe a method of use patented listed in the Orange Book for the RLD.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the reference drug has expired as described in further detail below.

Regulatory Exclusivities

New Chemical Entity Exclusivity

The Hatch-Waxman Amendments provide a period of five years of non-patent marketing exclusivity for the first approved drug containing a new chemical entity ("NCE") as an active ingredient. An NCE is an active moiety that has not been approved by the FDA in any other NDA. A fixed combination drug product may receive NCE exclusivity if one of its active ingredients is an NCE, but not if all of its active ingredients have previously been approved. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA or 505(b)(2) NDA seeking approval of a product that contains the same active moiety, except that the FDA may accept such an application for filing after four years if the application includes a paragraph IV certification to a listed patent. In the case of such applications accepted for filing between four and five years after approval of the reference drug, the 30-Month Stay of approval triggered by a timely patent infringement lawsuit is extended by the amount of time necessary to extend the stay until 7-1/2 years after the approval of the reference drug NDA.

New Clinical Trial (3-Year) Exclusivity

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular indication or condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability studies) was essential to the approval of the application or supplemental application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or Section 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the 3-year exclusivity period.

Orphan Drug Designation and Orphan Exclusivity Under the Orphan Drug Act

The FDA may grant orphan designation to a drug product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products is designated as an orphan drug and receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. Under the Best Pharmaceuticals for Children Act, or BPCA, certain therapeutic candidates may obtain an additional six months of exclusivity if the sponsor conducts pediatric research and submits new clinical information requested in writing by the FDA, referred to as a Written Request, relating to the use of the active moiety of the product or therapeutic candidate in children. The data do not need to support a label change for pediatric use; rather, the additional protection is granted if the pediatric clinical trial is deemed to have fairly responded to the FDA's Written Request. Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product or therapeutic candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population. The issuance of a Written Request does not require the sponsor to undertake the described trials. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Other Healthcare Laws and Regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services (HHS) and its various divisions, including the Office of Inspector General, the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Healthcare providers and third-party payors play a primary role in the recommendation and use of pharmaceutical products that are granted marketing approval. Arrangements with third-party payors, existing or potential customers and referral sources, including healthcare providers, are subject to broadly applicable fraud and abuse laws and regulations, and these laws and regulations may constrain the business or financial arrangements and relationships through which manufacturers conduct clinical research, market, sell and distribute the products for which they obtain marketing approval. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or kind, in exchange for, or to induce, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, formulary managers and other individuals and entities on the other. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to commit a violation;

- The federal civil and criminal false claims, including the civil FCA, and Civil Monetary Penalties Laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Certain marketing practices, including off-label promotion, also may implicate the FCA. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, therapeutic products and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or the CMS, information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation; and

- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; 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 or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and drug pricing and/or marketing expenditures; and state and local laws requiring the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Further, we may be subject to data privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 (HITECH), and its respective implementing regulations imposes certain requirements, including mandatory contractual terms, on covered entities, business associates and their covered subcontractors relating to the privacy, security, and transmission of certain individually identifiable health information known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, subcontractors, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be pre-empted by HIPAA, thus complicating compliance efforts.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

In the EU, the data privacy laws are generally perceived to be stricter than those which apply in the United States and include specific requirements for the transfer of personal data outside the EU to the United States to ensure that EU standards of data privacy will be applied to such data.

Violation of the laws described above or any other governmental laws and regulations may result in significant penalties, including administrative, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, and additional reporting requirements and oversight if a person becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of FDA-approved drugs for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost of medical products and services, in addition to their safety and efficacy. New metrics frequently are used as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. In order to obtain coverage and reimbursement for any product that might be approved for sale, it may be necessary to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and rational of the cost of the products, in addition to the costs required to obtain regulatory approvals. If third-party payors do not consider a product to be cost saving when compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost of a particular product candidate to currently available therapies. EU member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations may not allow favorable reimbursement and pricing arrangements.

Health Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

By way of example, in March 2010, the ACA was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our business are:

- An annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- A methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- Extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- A Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;

- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and

- A Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical research, along with funding for such research.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, 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, in August 2022, President Biden signed the Inflation Reduction Act of 2022 (the IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing 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.

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 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.

The heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics, also has resulted in 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, President Trump 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 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. Additionally, 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. 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, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and therapeutic 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. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies.

We expect that these initiatives, as well as other healthcare reform measures that may be adopted in the future, as well as the trend toward managed healthcare and increasing influence of managed care organizations, may result in more rigorous coverage criteria and lower reimbursement, and in 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-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Data Privacy and Security

In the ordinary course of our business, we collect, process and store confidential and sensitive information, including personal information, intellectual property, trade secrets, and proprietary information owned or controlled by ourselves or other third parties. We, and third parties upon whom we rely, use sophisticated information technology, software and services to process, store, use, generate, transfer and disclose information, as well as other sensitive information controlled by ourselves or other third parties.

We may also be subject to federal, state, and foreign data privacy and security laws and regulations. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners, vendors, or other third parties on whom we rely. The legislative and regulatory framework related to the collection, use, retention, safeguarding, disclosure, sharing, transfer, security and other processing of personal data worldwide is rapidly evolving. The number and scope of data protection laws and regulations is changing, subject to differing applications and interpretations, and may be inconsistent among jurisdictions, or in conflict with other rules, laws or other data processing obligations. Efforts to ensure that our current and future business arrangements, including our relationship with our CROs or other vendors who process data on our behalf, comply with applicable data privacy and data security laws and regulations will involve substantial costs.

For example, HIPAA, as amended by HITECH, and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health plans and health care clearinghouses, known as covered entities, as well as their business associates and covered subcontractors that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to civil and criminal penalties. Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Likewise, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, such as the California Consumer Privacy Act of 2018 (CCPA), which has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States. Although the CCPA exempts certain data processed in the context of clinical trials, the CCPA, to the extent applicable to our business and operations, may increase our compliance costs and potential liability with respect to the personal information we maintain about California residents. The CCPA among other effects, creates individual privacy rights for California consumers (as defined in the law), places increased privacy and security obligations on entities handling certain personal data of consumers or households, requires covered companies to provide disclosures to consumers regarding data collection, use and sharing practices, requires covered companies to allow users to opt-out of certain sales or transfers of personal information, and provides consumers with a private right of action for certain data breaches. The CCPA became effective on January 1, 2020, and the California Attorney General's authority to begin bringing enforcement actions began July 1, 2020. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Further, the California Privacy Rights Act (CPRA) was recently voted into law by California residents. The CPRA significantly amends the CCPA, and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA went into effect on January 1, 2023, and become enforceable on July 1, 2023. A similar law, the Consumer Data Protection Act (CDPA), was recently passed in Virginia and went into effect on January 1, 2023.

We also are or will become subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in the EU, we are subject to Regulation (EU) 2016/679, the GDPR, in relation to our collection, control, processing, and other use of personal data (i.e. data relating to an identified or identifiable living individual). We process personal data in relation to participants in our clinical trials in the European Economic Area (EEA), including the health and medical information of these participants. The GDPR is directly applicable in each EU and EEA Member State, however, it provides that EU and EEA Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. As noted above, the GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to EEA rules with respect to cross-border transfers of personal data out of the EEA. As noted above, recent legal developments in the EU have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States, e.g. on July 16, 2020, the Court of Justice of the European Union (CJEU), invalidated the EU-U.S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. On June 4, 2021, the European Commission adopted new standard contractual clauses under the GDPR for data transfers from entities that are subject to the GDPR to transfer personal data outside of the EEA. The new standard contractual clauses impose additional obligations, including the obligation to conduct a transfer impact assessment and, depending on a party's role in the transfer, to implement additional security measures and to update internal privacy practices. If we elect to rely on the standard contractual clauses for data transfers, we may be required to incur significant time and resources to update our contractual arrangements and to comply with new obligations. Additionally, on September 8, 2020, the Swiss Data Protection Authority (the Federal Data Protection and Information Commissioner) concluded that the Swiss-U.S. Privacy Shield does not provide an adequate level of protection for personal data transfer from Switzerland to the U.S. pursuant to the Swiss Federal Act on Data Protection. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of €20.0 million or 4% of total global annual turnover. Further, following the withdrawal of the United Kingdom from the EU on January 31, 2020, pursuant to the transitional arrangements agreed between the United Kingdom and the EU, we will have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million / £17 million or 4% of global turnover. Following December 31, 2020, and the expiry of the post-Brexit transitional arrangements between the United Kingdom and EU, although it is likely that the data protection obligations of the GDPR will continue to apply to UK-related processing of personal data in substantially unvaried form and fashion, for at least the short term thereafter, the relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear. For example, it is not yet clear whether the United Kingdom will be the subject of a so-called adequacy decision of the European Commission, and it is therefore unclear how data transfers between EU/EEA Member States and the United Kingdom will be treated. Any changes relating to the UK and EU position regarding aspects of data protection law may lead to additional compliance costs and could increase our overall risk. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, an inability to process personal data or to operate in certain jurisdictions, or potential civil claims including class action type litigation.

Moreover, we use third-party service providers and subprocessors to help us operate our business and engage in processing on our behalf. If we, our service providers, partners, or other relevant third-parties have experienced, or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure or disclosure of sensitive information, or compromise related to the security, confidentiality, integrity of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation, or an inability to process data in some jurisdictions. Furthermore, applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security breaches, including affected individuals, customers, and regulators. Such disclosures are costly, and the disclosure or the failure to comply with such requirements, could result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions.

For more information on the potential impact of the GDPR, and associated EEA data protection laws, on our business, see the section titled "*Risk Factors—Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business*."

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in other countries that impose similar obligations.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and individuals from engaging in certain activities to obtain or retain business abroad or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value, directly or indirectly, to any foreign government official, government staff member, official or employee of a public international organization, or a political party or political candidate for the purpose of influencing any act or decision of the foreign entity in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA includes interactions with healthcare professionals of foreign state-owned or affiliated hospitals, universities, or research institutions. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

Equivalent laws have been adopted in other foreign countries that impose similar or arguably broader obligations.

Employees

As of December 31, 2023, we had three full-time employees. There are also four PhD professionals and one lab technician who are paid by USC which is then reimbursed by us. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Properties

We do not currently own or lease any properties.

Legal Proceedings

We may in the future be involved in actual and/or threatened legal proceedings, claims, investigations and government inquiries arising in the ordinary course of our business, including legal proceedings, claims, investigations and government inquiries involving intellectual property, data privacy and data protection, privacy and other torts, illegal or objectionable content, consumer protection, securities, employment, contractual rights, civil rights infringement, false or misleading advertising, or other legal claims relating to our business.

MANAGEMENT

Directors, Executive Officers and Director Nominees

Our directors, executive officers and director nominees are listed below as of the date of this prospectus. The executive officers are full-time employees.

Name	Position	Age
Directors and Executive Officers:		
Dr. Thomas C. Chen, M.D., Ph.D.	Chief Executive Officer and Chairman	59
Patrick Walters	Chief Operating Officer	69
Keithly Garnett	Chief Financial Officer	49
Amir Heshmatpour	Executive Chairman and Secretary	56
Dr. Victoria Medvec, Ph.D.	Director	58
Bader Almonawer	Director	32
Dr. Steven L. Giannotta	Director	77
Jim Delshad	Director	84
Dr. Ming-Fu Chiang	Director	70

Each of our directors holds office until the next annual meeting of our shareholders or until his/her successor has been elected and qualified, or until his/her death, resignation, or removal. Our executive officers are appointed by our board of directors and hold office until their death, resignation, or removal from office.

Business Experience

The following is a brief overview of the education and business experience of each of our directors, executive officers and director nominees during at least the past five years, including their principal occupations or employment during the period, the name and principal business of the organization by which they were employed.

Directors and Executive Officers:

Dr. Thomas C. Chen, M.D., Ph.D., has served as NeOnc Technologies Holdings, Inc.'s Chief Executive Officer since April 2023 and Chairman since May 2023. Dr. Chen has served as NeOnc Technologies, Inc.'s Chief Executive Officer, Chairman and Chief Medical Officer of the Board since its inception. Since July 1997, Dr. Chen has worked as a Neurosurgeon at Keck Medicine of USC and a Professor Neurological Surgery at the University of Southern California Keck School of Medicine ("USC"). He has been the Director of Surgical Neuro-Oncology and Professor of Neurosurgery & Pathology. Dr. Chen's work is widely published, including 148+ peer-reviewed clinical studies. He maintains a clinical practice in both surgical neuro-oncology and spine surgery, as well as heads a research laboratory focused on glioma biology. He graduated summa cum laude from the University of Illinois at Urbana-Champaign with Bronze Tablet honors and Phi Beta Kappa. He graduated from University of California San Francisco with M.D. degree, and was in the top 10% of his class, awarded Alpha Omega Alpha. He earned his Ph.D. in pathobiology from University of Southern California where he wrote his thesis on the role of immunotherapy in malignant brain tumors. We believe that Dr. Chen's extensive knowledge of NeOnc's business and his extensive corporate and leadership experience as the founder of NeOnc and its Chief Executive Officer qualifies him to serve on our Board of Directors.

Patrick Walters has served as NeOnc Technologies Holdings, Inc.'s Chief Operating Officer since April 2023. Mr. Walters has served as NeOnc Technologies, Inc.'s Chief Financial Officer from 2009 to January 2023. Mr. Walters has served as NeOnc Technologies, Inc.'s Chief Operating Officer and Director from January 2023 to April 2023. For over 30 years, Mr. Walters has held senior management positions in corporate finance, financial reporting, planning analysis, operations, business development, and strategic planning. He started his career at Deloitte & Co., earning his CPA license. He has spent 16 years as a senior financial executive at Sony Pictures as the SVP of Worldwide Finance for Theatrical Films. He also spent five years managing a Forbes 400 family office as the managing director. His vast industry experience includes Biotech, Retail, Service, Entertainment, Publishing, Start-up, Banking, Venture Capital, and a Family Office. Mr. Walters is in the process of reactivating his CPA license. Mr. Walters holds a Bachelor of Arts degree in Economics Accounting from California State University, Northridge.

Keithly Garnett has served as NeOnc Technologies Holdings, Inc.'s Chief Financial Officer since April 2023 and director since January 2023. Mr. Garnett spent over 17 years with Ernst & Young LLP in their Transaction Advisory Services practice. During that time, he specialized in business valuation modelling and strategy. His services were provided in support of audit related work for financial reporting, tax planning and management planning. His client list included companies such as Amgen, Edwards Life Sciences, Medtronic, etc. In any given year, he led over 50 transaction analyses and/or review for publicly traded companies, in connection with their SEC financial reporting requirements. From March 2017 to January 2023, Mr. Garnett was a Director at Sycamore Valuation. Since January 2021, Mr. Garnett has worked as the Chief Financial Officer of AFH Holding & Advisory, a single member family office based in Malibu. From 2018 to 2022, he was involved with the Shuttle Pharmaceutical Holdings public offering, which was successfully listed on the Nasdaq in 2022. Mr. Garnett holds a Master's in Business Administration with a concentration in Corporate Financial Management, and a Bachelor of Science degree in Business Management. He also completed the Columbia University Executive Education program with a certificate from the Chief Financial Officer program.

Amir Heshmatpour has served on NeOnc Technologies Holdings, Inc.'s board of directors since January 2023. Mr. Heshmatpour founded AFH Holding and Advisory LLC ("AFH") in July 2005. Since July 2005, Mr. Heshmatpour has been the Managing Director of AFH. Mr. Heshmatpour, through AFH, his family office, has been involved in multiple biotech transactions from private to public. From 2018 to 2022, through a special purpose vehicle, Shuttle Pharmaceuticals Holdings Inc. ("SPH"), Mr. Heshmatpour restructured the board of directors, management, and recapitalized an IPO of a Georgetown phase II oncology asset. The SPV was created in 2018 and eventually was successfully listed on NASDAQ in 2022. Since then, he has been involved in NeOnc Technologies Inc., where he has provided strategic advisory services. Mr. Heshmatpour has a certification from the UCLA Anderson School of Business in corporate governance. He is also involved in the UCLA Anderson School of Business Management, Price Center, as a member of the Board of Advisors. In February 2024, Mr. Heshmatpour joined the Board of Directors of Make-A-Wish CVS in Los Angeles. We believe that Mr. Heshmatpour's extensive corporate and leadership experience qualifies him to serve on our Board of Directors.

Dr. Victoria Medvec, Ph.D. Since 1995, Dr. Victoria Medvec has been the Adeline Barry Davee Professor of Management and Organizations at the Kellogg School of Management at Northwestern University. In addition, Dr. Medvec is a co-founder and the Executive Director of the Center for Executive Women at the Kellogg School. Since 2002 Dr. Medvec has served as the CEO of Medvec and Associates, a consulting firm focused on high stakes negotiations and strategic decisions. Dr. Medvec received her Ph. D in psychology from Cornell University and Bachelor of Arts degree in Economics, Management, and Psychology from Bucknell University. Dr Medvec is a renowned expert in the areas of negotiations, executive decision making, influence, and corporate governance. Dr. Medvec's research is published in top academic journals and she is the author of the best-selling book, Negotiate Without Fear. Dr. Medvec has served on both public and private company Boards across many industries, including banking, human resources and benefits administration. She also is a Ringleader in Ringleader Ventures, a unique venture fund matching start up technologies with corporate needs. We believe that Dr. Victoria Medvec's extensive corporate and leadership experience qualifies her to serve on our Board of Directors.

Bader Almonawer. Mr. Almonawer is an experienced professional with more than a decade of experience in venture capital, investment banking, and business consulting and development. Since 2013, Mr. Almonawer has served as Managing Partner for Arabian Group, overseeing its venture capital investments. In 2017, he founded Oasis Capital, a VC fund, and invested in numerous startups at their early stages, many of which have since grown into multibillion-dollar corporations. Mr. Almonawer has a background in investment banking and consulting; he has amassed valuable experience at McKinsey & Company from 2016 to 2016, Citigroup's M&A advisory from 2021 to 2023, Wafra Inc.'s Alternative Investments Division from 2021 to 2021, and the World Bank from 2016 to 2017. After receiving his Bachelor in Science in Industrial Engineering and Operations Research from Penn State University, Mr. Almonawer earned a Master of Arts in Economics and Financial Policy at Cornell University earning Pi Alpha Alpha honors. Mr. Almonawer received his Master of Business Administration from Massachusetts Institute of Technology where he received the Halaby Fellowship, a Merit-based Fellowship recognizing his outstanding academic excellence and professional achievements. We believe that Mr. Bader Almonawer's experience qualifies him to serve on our Board of Directors.

Dr. Steven L. Giannotta. Dr Giannotta joined the USC Department of Neurosurgery in 1980 and has since become internationally recognized for his groundbreaking work in cerebrovascular disease, including pioneering "hyperdynamic therapy"; as a clinical approach to combat cerebral vasospasm. His research interests encompass cerebral blood flow, ischemia, and the impact of ethnic differences on cerebrovascular disorders. Dr. Giannotta's clinical achievements include performing over 1,000 intracranial aneurysm surgeries and developing a comprehensive, multidisciplinary approach to complex cerebrovascular conditions. Dr. Giannotta earned his degree and completed his residency at the University of Michigan. He continues to serve as the Chair of Neurological Surgery at USC Keck, and as a Professor of Neurosurgery and a practicing neurosurgeon. We believe that Dr. Giannotta's experience qualifies him to serve on our Board of Directors.

Jim Delshad. Honorable Jimmy Delshad, served two terms as Mayor of Beverly Hills, starting in 2007, pioneering "Smart City" initiatives that transformed the city into a model of technological advancement and security. He holds the honorary title of "Goodwill Ambassador of Beverly Hills" in recognition of his contributions to the city. Mr. Delshad served as President of Magbit Foundation 2002 to 2006 and Chairman from 2006 to 2010. Over the past two decades he has provided management consulting services, which includes strategic advisory services across private, public, and non-profit sectors. His expertise spans government affairs, real estate, and healthcare, with a strong emphasis on non-profit development and donor engagement. We believe that Mr. Delshad's experience qualifies him to serve on our Board of Directors.

Dr. Ming-Fu Chiang. Dr. Chiang was a neurosurgeon and the former Vice-Director of the Department of Surgery and former Chairman of Neurosurgery at Mackay Memorial Hospital in Taipei, Taiwan from August 1991 to June 2020. Since July 2020, he is a practicing neurosurgeon at Chung-Shan Hospital and Taiwan Adventist Hospital in Taipei, Taiwan. Dr. Chiang has a Ph.D. in neuro-oncology from Free University of Berlin, Germany, and his EMBA (Executive Management Business & Administration) from National Taiwan University. Dr. Chiang has also previously served as the CEO of NeuCen Biomedical, Inc. and Orio Biotech Inc. We believe that Dr. Chiang's experience qualifies him to serve on our Board of Directors.

Family Relationships

There are no family relationships among any of our executive officers, directors or director nominees.

Involvement in Certain Legal Proceedings

To the best of our knowledge, none of our directors or executive officers were involved in any legal proceedings described in Item 401(f) of Regulation S-K in the past ten years.

CORPORATE GOVERNANCE

Composition of our Board of Directors

Our current Board of Directors consists of Dr. Thomas C. Chen, Amir Heshmatpour and Keithly Garnett

Bader Almonawer, Dr. Victoria Medvec, Ph.D., Dr. Steven L. Giannotta, Jim Delshad and Dr. Ming-Fu Chiang will become directors on the effective date of this offering and Keithly Garnett will resign on or prior to the effective date of this offering. Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our amended and restated certificate of incorporation, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of shareholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- the Class I directors are Dr. Victoria Medvec, Ph.D and Dr. Steven L. Giannotta, and their terms will expire at the annual meeting of shareholders to be held in 2025;
- the Class II directors are Bader Almonawer, Jim Delshad and Dr. Ming-Fu Chiang, and their terms will expire at the annual meeting of shareholders to be held in 2026; and
- the Class III directors are Amir Heshmatpour and Dr. Thomas C. Chen, M.D., Ph.D., and their terms will expire at the annual meeting of shareholders to be held in 2027.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Under the listing requirements and rules of the Nasdaq Stock Market LLC (Nasdaq Listing Rules), a majority of our directors must be independent directors Bader Almonawer, Dr. Victoria Medvec, Ph.D., Dr. Steven L. Giannotta and Jim Delshad are considered independent based on the listing standards of Nasdaq. In order to promote open discussion among independent directors, our Board intends to adopt a policy of regularly conducting executive sessions of independent directors at scheduled meetings led by the lead independent director and at such other times requested by other independent directors. Executive sessions shall not include Dr. Thomas Chen, M.D., Ph.D., Mr. Amir Heshmatpour or Dr. Ming-Fu Chiang.

Committees of our Board of Directors

Our Board of Directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our Board of Directors and will be effective upon the effectiveness of the registration statement of which this prospectus is a part. The Board of Directors may also establish other committees from time to time to assist our company and the board of directors. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq Global Market and SEC rules and regulations, if applicable. Upon our listing on the Nasdaq Global Market, our committees' charters will be available on our website at www.NeOnctech.com. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be part of this prospectus.

Audit Committee

Our audit committee will consist of Bader Almonawer, Dr. Victoria Medvec, Ph.D and Jim Delshad. Our Board of Directors has determined that each of Bader Almonawer, Dr. Victoria Medvec, Ph.D. and Jim Delshad satisfies the independence requirements under Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee will be Bader Almonawer, who our Board of Directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our Board of Directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The principal duties and responsibilities of our audit committee will include, among other things:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the audit committee's review and discussions with management and our independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

Compensation Committee

Our compensation committee will consist of Bader Almonawer, Dr. Victoria Medvec, Ph.D and Jim Delshad. The chair of our compensation committee will be Dr. Victoria Medvec, Ph.D.. Our Board of Directors has determined that each of Richard Bader Almonawer, Dr. Victoria Medvec, Ph.D. and Jim Delshad is independent under Nasdaq listing standards, a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The principal duties and responsibilities of our compensation committee will include, among other things:

- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation: (i) recommending to the board of directors the cash compensation of our Chief Executive Officer, and (ii) reviewing and approving grants and awards to our Chief Executive Officer under equity-based plans;

- reviewing and recommending to the board of directors the cash compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy, and policy;
- overseeing and administering our compensation and similar plans;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters and evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors; and
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee will consist of Dr. Victoria Medvec, Jim Delshad and Dr. Steven L. Giannotta, Ph.D. The chair of our nominating and corporate governance committee will be Jim Delshad. Our Board of Directors has determined that each of Bader Almonawer, Jim Delshad and Dr. Steven L. Giannotta is independent under Nasdaq listing standards.

The nominating and corporate governance committee's responsibilities include, among other things:

- developing and recommending to the board of directors' criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by shareholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- reviewing and recommending to the board of directors' appropriate corporate governance guidelines; and
- overseeing the evaluation of our board of directors.

Corporate Governance

Prior to the effectiveness of the registration statement of which this prospectus is a part, we will adopt a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions. Following the effectiveness of the registration statement of which this prospectus is a part, a current copy of this code will be posted on the Corporate Governance section of our website, which is located at www.NeOncco.com. The information on our website is deemed not to be incorporated in this prospectus or to be a part of this prospectus. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Scientific Advisory Board

We have assembled a scientific advisory board with expertise in oncology and clinical trials. The members of our scientific advisory board have made significant scientific contributions in their individual fields. Members of our scientific advisory board provide strategic advice to us in fields pertinent to gynecologic oncology and perform other such services as may be mutually determined by us and the scientific advisory board member. Our scientific advisory board meets on an as-needed basis, based on our need for advice in their fields of expertise from time to time.

We provide compensation for their time and on a per meeting basis to members of our scientific advisory board. We also reimburse each member of our scientific advisory board for all reasonable and necessary travel expenses in connection with the performance of his services. Our scientific advisory board includes: Axel H. Schönthal, Ph.D. and Dr. David M. Peereboom,.

Board Leadership Structure

Our Board of Directors and management believe that the choice of whether the Chair of our Board of Directors should be an executive of our company, or a non-executive or independent director, depends upon a number of factors, taking into account the candidates for the position and the best interests of our company and our shareholders. Dr. Chen serves as the Board Chair. Dr. Chen's operating and leadership experience as an officer and director of our company since its inception made him a compelling choice for Board Chair. Mr. Bader Almonawer will serve as lead independent director of our Board of Directors. As lead independent director, Mr. Bader Almonawer will preside over executive sessions of the independent directors and serves as a liaison between the independent directors and our management team.

Risk Oversight

Our Board oversees a company-wide approach to risk management. Our Board will determine the appropriate risk level for us generally, assess the specific risks faced by us and review the steps taken by management to manage those risks. While our Board has ultimate oversight responsibility for the risk management process, its committees will oversee risk in certain specified areas.

Specifically, our compensation committee will be responsible for overseeing the management of risks relating to our executive compensation plans and arrangements, and the incentives created by the compensation awards it administers. Our audit committee will oversee management of enterprise risks and financial risks, as well as potential conflicts of interest. Our Board is responsible for overseeing the management of risks associated with the independence of our board of directors.

Compensation Committee Interlocks and Insider Participation

None of our officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more officers serving as a member of our board of directors.

Director and Officer Indemnification Agreements

We intend to enter into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request. The indemnification agreements and our amended and restated certificate of incorporation and amended and restated bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

EXECUTIVE COMPENSATION

The following table provides certain information regarding compensation awarded to, earned by or paid to persons serving as our principal executive officer and our principal financial officer during the year ended December 31, 2024 and 2023.

Summary Compensation Table

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	Other Compensation ($)	Total ($)
Dr. Thomas C. Chen –	2024	$ 212,000	$ 0	$ 0	$ 0	$ 0	$ 0	$ 0	$ 212,000
Chief Executive Officer	2023	$ 194,333	$ 0	$ 0	$ 0	$ 0	$ 0	$ 0	$ 194,333
Patrick Walters –	2024	$ 195,000	$ 0	$ 0	$ 0	$ 0	$ 0	$ 0	$ 195,000
Chief Operating Officer[(1)]	2023	$ 178,750	$ 0	$ 0	$ 0	$ 0	$ 0	$ 0	$ 178,750
Keithly Garnett –	2024	$ 179,000	$ 0	$ 0	$ 0	$ 0	$ 0	$ 0	$ 179,000
Chief Financial Officer	2023	$ 164,083	$ 0	$ 0	$ 0	$ 0	$ 0	$ 0	$ 164,083

(1) Mr. Walters served as our Chief Financial Officer until April 7, 2023.

In January 2024, 800,000 restricted stock units were granted to Dr. Thomas C. Chen, M.D., Ph.D. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Dr. Chen's individual grant agreement.

In January 2024, 300,000 restricted stock units were granted to Patrick Walters. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Mr. Walter's individual grant agreement.

In January 2024, 360,000 restricted stock units were granted to Keithly Garnett. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Mr. Garnett's individual grant agreement.

In October 2024, 200,000 restricted stock units were granted to Dr. Thomas C. Chen, M.D., Ph.D, all of which will vest seven months after the effective date of this offering.

Employment Agreements

On January 4, 2024, the Company entered into an employment agreement ("Employment Agreement") with Dr. Thomas C. Chen to serve as Chief Executive Officer and Chief Scientific Officer of the Company. The term of the Employment Agreement will commence upon the effective date of the initial public offering and continue for a period of seven months. The term will automatically renew for successive one-year periods until either party delivers written notice of their intent not to renew at least fifteen days prior to the expiration of the then effective term. The Employment Agreement provided for a base salary of $212,000. In addition, Dr. Chen shall be eligible to participate in any bonus or incentive programs established by the Company. The Employment Agreement may be terminated by either the Company or Dr. Chen at any time and for any reason or for no reason at all, subject to the terms of the Employment Agreement. Upon termination with good cause of the Employment Agreement by Dr. Chen, Dr. Chen shall be entitled to receive (i) his base salary until the end of the three month severance period reduced by any cash remuneration paid to Dr. Chen during the severance period, and (ii) benefits. Dr. Chen's employment may also be terminated by the Company at any time, with cause, death or disability (as defined in the Employment Agreement). Upon termination without cause of the Employment Agreement by the Company, Dr. Chen shall be entitled to receive (i) his base salary until the end of the severance period, and (ii) accrued compensation and benefits. Upon the termination of the Employment Agreement due to a permanent disability, Dr. Chen shall be entitled to receive payments equal to the base salary for the severance period.

On January 4, 2024, the Company entered into an employment agreement ("Employment Agreement") with Patrick Walters to serve as Chief Operating Officer of the Company. The term of the Employment Agreement will commence upon the effective date of the initial public offering and continue for a period of seven months. The term will automatically renew for successive one-year periods until either party delivers written notice of their intent not to renew at least fifteen days prior to the expiration of the then effective term. The Employment Agreement provided for a base salary of $195,000. In addition, Mr. Walters shall be eligible to participate in any bonus or incentive programs established by the Company. The Employment Agreement may be terminated by either the Company or Mr. Walters at any time and for any reason or for no reason at all, subject to the terms of the Employment Agreement. Upon termination with good cause of the Employment Agreement by Mr. Walters, Mr. Walters shall be entitled to receive (i) his base salary until the end of the three month severance period reduced by any cash remuneration paid to Mr. Walters during the severance period, and (ii) benefits. Mr. Walters's employment may also be terminated by the Company at any time, with cause, death or disability (as defined in the Employment Agreement). Upon termination without cause of the Employment Agreement by the Company, Mr. Walters shall be entitled to receive (i) his base salary until the end of the severance period, and (ii) accrued compensation and benefits. Upon the termination of the Employment Agreement due to a permanent disability, Mr. Walters shall be entitled to receive payments equal to the base salary for the severance period.

On January 4, 2024, the Company entered into an employment agreement ("Employment Agreement") with Keithly Garnett to serve as Chief Financial Officer of the Company. The term of the Employment Agreement will commence upon the effective date of the initial public offering and continue for a period of seven months. The term will automatically renew for successive one-year periods until either party delivers written notice of their intent not to renew at least fifteen days prior to the expiration of the then effective term. The Employment Agreement provided for a base salary of $179,000. In addition, Mr. Garnett shall be eligible to participate in any bonus or incentive programs established by the Company. The Employment Agreement may be terminated by either the Company or Mr. Garnett at any time and for any reason or for no reason at all, subject to the terms of the Employment Agreement. Upon termination with good cause of the Employment Agreement by Mr. Garnett, Mr. Garnett shall be entitled to receive (i) his base salary until the end of the three month severance period reduced by any cash remuneration paid to Mr. Garnett during the severance period, and (ii) benefits. Mr. Garnett's employment may also be terminated by the Company at any time, with cause, death or disability (as defined in the Employment Agreement). Upon termination without cause of the Employment Agreement by the Company, Mr. Garnett shall be entitled to receive (i) his base salary until the end of the severance period, and (ii) accrued compensation and benefits. Upon the termination of the Employment Agreement due to a permanent disability, Mr. Garnett shall be entitled to receive payments equal to the base salary for the severance period.

Non-Employee Director Compensation

We did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2022.

In January 2024, 1,000,000 restricted stock units were granted to Amir Heshmatpour. In October 2024, 200,000 restricted stock units were granted to Amir Heshmatpour. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

In February 2024, 50,000 restricted stock units were granted to Dr. Victoria Medvec, Ph.D. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

In February 2024, 50,000 restricted stock units were granted to Bader Almonawer. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

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 will vest one hundred percent (100%) seven months following the effective date of this offering.

2023 Incentive Stock Plan

We have adopted a 2023 Incentive Stock Plan (the "2023 Plan"). An aggregate of 3,440,000 shares of our common stock is currently reserved for issuance and available for awards under the 2023 Plan, including incentive stock options granted under the 2023 Plan, which amount will increase, if necessary, to twenty percent (20%) of the fully diluted capitalization of the Company on the closing of this offering. The 2023 Plan administrator may grant awards to any employee, director, consultant, or other person providing services to us or our affiliates. In January and February 2024, a total of 2,660,000 restricted stock units were granted to our executive officers and directors further to the 2023 Plan as described below. The 2023 Plan is currently administered by the Board. The 2023 Plan administrator has the authority to determine, within the limits of the express provisions of the 2023 Plan, the individuals to whom awards will be granted, the nature, amount and terms of such awards and the objectives and conditions for earning such awards. The Board may at any time amend or terminate the 2023 Plan, provided that no such action may be taken that adversely affects any rights or obligations with respect to any awards previously made under the 2023 Plan without the consent of the recipient. No awards may be made under the 2023 Plan after the tenth anniversary of its effective date.

Awards under the 2023 Plan may include incentive stock options, nonqualified stock options, restricted shares of common stock and restricted stock units.

Stock Options. The 2023 Plan administrator may grant to a participant options to purchase our common stock that qualify as incentive stock options for purposes of Section 422 of the Internal Revenue Code ("incentive stock options"), options that do not qualify as incentive stock options ("non-qualified stock options") or a combination thereof. The terms and conditions of stock option grants, including the quantity, price, vesting periods, and other conditions on exercise will be determined by the 2023 Plan administrator. The exercise price for stock options will be determined by the 2023 Plan administrator in its discretion, but non-qualified stock options and incentive stock options may not be less than 100% of the fair market value of one share of our company's common stock on the date when the stock option is granted. Additionally, in the case of incentive stock Options granted to a holder of more than 10% of the total combined voting power of all classes of our stock on the date of grant, the exercise price may not be less than 110% of the fair market value of one share of common stock on the date the stock option is granted. Stock options must be exercised within a period fixed by the 2023 Plan administrator that may not exceed ten years from the date of grant, except that in the case of incentive stock options granted to a holder of more than 10% of the total combined voting power of all classes of our stock on the date of grant, the exercise period may not exceed five years. At the 2023 Plan administrator's discretion, payment for shares of common stock on the exercise of stock options may be made in cash, shares of our common stock held by the participant or in any other form of consideration acceptable to the 2023 Plan administrator (including one or more forms of "cashless" or "net" exercise).

Restricted Shares and Restricted Units. The 2023 Plan administrator may award to a participant shares of common stock subject to specified restrictions. Restricted shares, or restricted stock units, are subject to forfeiture if the participant does not meet certain conditions such as continued employment over a specified forfeiture period and/or the attainment of specified performance targets over the forfeiture period.

In January 2024, 800,000 restricted stock units were granted to Dr. Thomas C. Chen, M.D., Ph.D. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Dr. Chen's individual grant agreement.

In January 2024, 300,000 restricted stock units were granted to Patrick Walters. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Mr. Walter's individual grant agreement.

In January 2024, 360,000 restricted stock units were granted to Keithly Garnett. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Mr. Garnett's individual grant agreement.

In January 2024, 1,000,000 restricted stock units were granted to Amir Heshmatpour. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

In February 2024, 50,000 restricted stock units were granted to Dr. Victoria Medvec, Ph.D. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

In February 2024, 50,000 restricted stock units were granted to Bader Almonawer. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

In October 2024, 200,000 restricted stock units were granted to each of Dr. Thomas C. Chen, M.D., Ph.D and Amir Heshmatpour. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

With respect to that potion of the aforementioned restricted stock units that vest based upon performance criteria, the Board determined that it would be to the competitive advantage and interest of the Company and its stockholders to grant an award of restricted stock units the vesting of which will be predicate on certain performance metrics being met as a whole, as an inducement to remain in the service of our Company and as an incentive for increased efforts during such service.

The number of restricted stock units issued with performance criteria vesting metrics that are ultimately vested with respect to each grantee will depend upon the achievement of such performance metrics, taken as a whole, as set forth in each individual grant agreement. The actual number of such restricted stock units vested with respect to each grantee will be determined at meetings of the Compensation Committee of the Board (the "Committee") to be held semi-annually following the completion of the year ended December 31 at which time the Committee will certify whether it believes in its sole discretion that sufficient performance criteria have been satisfied to justify the vesting, in whole or in part, of such restricted stock units. The Committee may certify in its sole discretion that all, none or a percentage of such performance based grants should be deemed vested and the grantee will acknowledge that certification shall be binding and non-appealable and that he/she shall have no legal right to contest such certification.

The Committee is permitted to waive any vesting conditions applicable to any stock award or grant of restricted stock units.

PRINCIPAL AND REGISTERED STOCKHOLDERS

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth:

- certain information regarding the beneficial ownership of our voting securities as of the date of this prospectus by (i) each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our voting securities, (ii) each of our executive officers, (iii) each of our directors and director nominees and (iv) all of our directors, director nominees and executive officers as a group. Except as otherwise indicated, all persons listed below have (i) sole voting power and investment power with respect to their common stock, except to the extent that authority is shared by spouses under applicable law, and (ii) record and beneficial ownership with respect to their common stock; and

- the number of shares of our common stock held by and registered for resale by means of this prospectus for the Registered Stockholders.

We have agreed to issue 624,999 shares of common stock to unaffiliated third parties in a private placement at a price of $16.00 per share for gross proceeds of approximately $10,000,000 and to issue the Advisor 30,000 shares of common stock in connection with and at the time of the Direct Listing; such shares are not registered further to this prospectus and the Advisor is not a Registered Stockholder. All 624,999 shares of common stock are being registered by means of this registration statement and unless otherwise indicated, all information regarding the number of shares of our common stock outstanding as of the date of this prospectus, the Registered Holders and the number of shares of our common stock to be sold pursuant to this prospectus gives effect to such issuance.

The Registered Stockholders include an affiliate, HCWG, and certain other stockholders with "restricted securities" (as defined in Rule 144 under the Securities Act) who, because they acquired their common stock from an affiliate or us within the prior 12 months, would be unable to sell their securities pursuant to Rule 144 until we have been subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act for a period of at least 90 days. The Registered Stockholders may, or may not, elect to sell their common stock covered by this prospectus, as and to the extent they may determine. The Registered Stockholders may offer, sell or distribute all or a portion of the shares of common stock hereby registered publicly or through private transactions at prevailing market prices or at negotiated prices. The Registered Stockholders may elect to sell their shares in connection with this Direct Listing and in market transactions following this Direct Listing. As such, we will have no input if and when any Registered Stockholder may, or may not, elect to sell their common stock or the prices at which any such sales may occur. See "*Plan of Distribution*."

Information concerning the Registered Stockholders may change from time to time and any changed information will be set forth in supplements to this prospectus, if and when necessary. Because the Registered Stockholders may sell all, some, or none of the common stock covered by this prospectus, we cannot determine the number of common stock that will be sold by the Registered Stockholders, or the amount or percentage of shares of common stock that will be held by the Registered Stockholders upon consummation of any particular sale. In addition, the Registered Stockholders listed in the table below may have sold, transferred, or otherwise disposed of, or may sell, transfer, or otherwise dispose of, at any time and from time to time, our common stock in transactions exempt from the registration requirements of the Securities Act, after the date on which they provided the information set forth in the table below.

The Registered Stockholders are not entitled to any registration rights with respect to the common stock. However, we currently intend to use our reasonable efforts to keep the registration statement effective for a period of 90 days after the effectiveness of the registration statement. We are not party to any arrangement with any Registered Stockholder or any broker-dealer with respect to sales of common stock by the Registered Stockholders. However, we will engage a financial advisor with respect to certain other matters relating to our listing. See "*Plan of Distribution*."

As of the date of this prospectus, there are 18,745,685 shares of common stock and no shares of preferred stock issued and outstanding. In accordance with the rules of the SEC, beneficial ownership includes voting or investment power with respect to securities and includes the common stock issuable pursuant to options and warrants that are exercisable or settled within 60 days of the date of this prospectus. Shares of common stock issuable pursuant to options and warrants are deemed outstanding for computing the percentage of the class beneficially owned by the person holding such securities but are not deemed outstanding for computing the percentage of the class beneficially owned by any other person.

The Registered Stockholders have not, nor have they within the past three years had, any position, office, or other material relationship with us, other than as disclosed in this prospectus. See "*Management's Discussion & Analysis of Financial Results and Condition*" and "*Certain Relationships and Related Party Transactions*" for further information regarding the Registered Stockholders. Unless otherwise indicated, the business address of each of the individuals and entities named below is c/o NeOnc Technologies, Inc., c/o NeOnc Technologies Holding, Inc., 2 Dole Drive, Westlake Village, CA 91362.

Name and address of Beneficial Owner	Common Stock Shares	%	Shares of Common Stock Being Registered Pursuant to this Prospectus
5% Stockholders:			
HCWG LLC[1]	1,291,539	6.9%	979,039
Executive Officers, Directors and Director Nominees			
Dr. Thomas C. Chen, M.D., Ph.D.[2]	3,171,721	16.9%	-
Patrick Walters[3]	696,551	3.7%	-
Keithly Garnett[4]	55,105	0.3%	-
Amir Heshmatpour[5]	5,188,163	27.7%	-
Dr. Victoria Medvec, Ph.D.[6]	160	-	-
Bader Almonawer[7]	160	*	-
Dr. Steven L. Giannotta[8]	160	*	-
Jim Delshad[9]	160	*	-
Dr. Ming-Fu Chiang, M.D., Ph.D.[10]	823,133	4.4%	-
Directors, Director Nominees and Executive Officers as a Group (9 persons)	9,935,313	53.0%	-
Other Registered Stockholders:			
Non-Executive Officer Employees, Consultants and Service Providers	-	-	-
David H. Chen[11]	16,888	*	16,888
Shao-Hung Lee[12]	16,666	*	16,666
Fred Sahakian[13]	20,834	*	20,834
Lin Yu Tien[14]	326,137	*	91,666
Chiu-Yen Lee[15]	5,000	*	5,000
Ssu-Han Wu[16]	12,500	*	12,500
George Lin (Separate Property Trust)[17]	41,667	*	41,667
Oaklin Management[18]	556,717	*	83,334
Chen-Chih Chu[19]	16,000	*	16,000
Mei-Yun Wang[20]	4,167	*	4,167
Jen-Fu Shih[21]	4,166	*	4,166
Kenneth A. McPheeters & Marcia Hines-McPheeters[22]	4,500	*	4,500
Vincent F. Simmon[23]	1,500	*	1,500
Andre Blake[24]	6,750	*	6,750

Yu-Ting Hung[25]	2,500	*	2,500
Robert James Moreno[26]	4,166	*	4,166
Salonia Brown[27]	4,583	*	4,583
Keisha Zachary[28]	16,667	*	16,667
Robert Diaz[29]	834	*	834
Shaing-June Lin[30]	5,000	*	5,000
Esther Hsieh[31]	2,000	*	2,000
David I-Feng Hsu[32]	1,800	*	1,800
Errol S Phipps[33]	5,000	*	5,000
Marquosa Haley[34]	8,125	*	8,125
Edward Billig[35]	13,885	*	8,334
Robert Brownstone[36]	27,301	*	5,208
Aliakbar Heshmatpour[37]	160	*	160
Dana Silva[38]	160	*	160
Dariush Hosseini[39]	160	*	160
Navid Eghbalieh[40]	160	*	160
Said Eghbalieh[41]	160	*	160
Sammy Eghbalieh[42]	160	*	160
Effat Heshmatpour[43]	160	*	160
Farnad Ferdows[44]	160	*	160
Felicia Shakiba[45]	160	*	160
Flori Lukecart[46]	160	*	160
Gary Johnson[47]	160	*	160
Hal Weitzbuch[48]	160	*	160
Isaiah Nassab[49]	160	*	160
Jeffrey Goodfried[50]	160	*	160
Ken Lukecart[51]	160	*	160
Kevin Johnson[52]	160	*	160
Mahnaz Heshmatpour[53]	160	*	160
Michael Fisher[54]	160	*	160
Michael Hakim[55]	160	*	160
Mitra Heshmatpour[56]	160	*	160
Moghadam Family Trust (Amir Moghadam)[57]	160	*	160
Mohammad Hosseini[58]	160	*	160
Nasim Bahar Shomali[59]	160	*	160
Nicole Hosseini[60]	160	*	160
Nosratollah Vafaie[61]	160	*	160
Olimpia Garabet[62]	160	*	160
Ommid Ferdows[63]	160	*	160
Po Tauiliili[64]	160	*	160
Rachella Moghadam[65]	160	*	160
Roya Khorrami[66]	160	*	160
Sam Nassab[67]	160	*	160
Sanaz Amini[68]	160	*	160
Shery Heshmatpour[69]	160	*	160
Stewart Barrios[70]	160	*	160
Victor Alexandroff[71]	160	*	160

Ziba Nassab[72]	160	*	160
Ziv Leiderman[73]	160	*	160
Antonio Jimenez[74]	160	*	160
Maria Jimenez[75]	160	*	160
Erik Shear[76]	160	*	160
Damon Juha[77]	160	*	160
Albert Mazaheri[78]	160	*	160
Geoffrey Plank[79]	160	*	160
Usha Cervantes[80]	160	*	160
Hugo Correa[81]	160	*	160
Martin Gamez[82]	160	*	160
Irene Sharma[83]	160	*	160
Catalina Subia[84]	160	*	160
Jennifer Lizan[85]	160	*	160
Arnold Mark Abaigar[86]	160	*	160
Dr. Indraneel Banerji[87]	160	*	160
Jaimie D. Ables[88]	160	*	160
Justin Ostrus[89]	160	*	160
Jennifer C. Curlowicz[90]	160	*	160
Steve Pakravan[91]	160	*	160
Myhanh Nguyen[92]	160	*	160
Mila Dash[93]	160	*	160
Salaur Khorrami[94]	160	*	160
Leroy Pascal[95]	160	*	160
Stephanie Pascal[96]	160	*	160
Michael Dulan[97]	160	*	160
Carlton Sampson[98]	160	*	160
Kevin Calhoun[99]	160	*	160
William Kyle Vincent[100]	160	*	160
Frances P. Hodges[101]	160	*	160
Dorian Mullens[102]	160	*	160
Cleveland Garnett[103]	160	*	160
Jacque Mathieu[104]	160	*	160
Kenroy Dowers[105]	160	*	160
Lisa Carr Smith[106]	160	*	160
Lawrence Carter[107]	160	*	160
Lisa MacCarley[108]	160	*	160
Joshua Johnson[109]	160	*	160
Cameron Williams[110]	160	*	160
Rodney McKeever[111]	160	*	160
Roy Martin[112]	160	*	160
Lula Mullens[113]	160	*	160
Cazzie Williams[114]	160	*	160
Jeffery Ponders II[115]	160	*	160
Vince Toussaint[116]	160	*	160
Adrian Marsh[117]	160	*	160
Brad Townsend[118]	160	*	160

Jeremiah Brown[119]	160	*	160
Jacqueline Adams[120]	160	*	160
Kenny G. McPheeters[121]	160	*	160
Ken McPheeters[122]	160	*	160
Renee Y. Hines[123]	160	*	160
Salvador Bracamontes[124]	160	*	160
Kurt L. Brune[125]	160	*	160
Stephen Owen[126]	160	*	160
Edward L. Schilowitz[127]	160	*	160
Stephen Raynes[128]	160	*	160
Irwin Jacobson[129]	160	*	160
John Pietrolungo[130]	160	*	160
Laura Valan[131]	160	*	160
Charles A. Bruen[132]	160	*	160
Kathleen Shane[133]	160	*	160
Michael Edwards[134]	160	*	160
Louis Scuderi[135]	160	*	160
John Pennett[136]	160	*	160
Charles Marburg[137]	160	*	160
Parham Naghdechi[138]	160	*	160
Edgar H. Howells[139]	160	*	160
Jon Tenney [140]	160	*	160
Martin H Weiss[141]	160	*	160
John C. Liu[142]	160	*	160
Patrick Hsieh[143]	160	*	160
Jeff Wang[144]	160	*	160
Raymond Hah[145]	160	*	160
Ram Alluri[146]	160	*	160
Alexander Markarian[147]	160	*	160
John S. Oghalai[148]	160	*	160
Cheng Yu[149]	160	*	160
Benjamin Emanuel[150]	160	*	160
Marvin Gong[151]	160	*	160
Xenos Mason[152]	160	*	160
David Tran[153]	160	*	160
Aaron Cohen-Gadol[154]	160	*	160
Kyle Hurth[155]	160	*	160
John J Guarnaschelli[156]	160	*	160
Gregory Withers MD[157]	160	*	160
Murray A Thale[158]	160	*	160
Victoria Neave[159]	160	*	160
William Couldwell[160]	160	*	160
Jeffrey Oppenheimer[161]	160	*	160
Howard Tung[162]	160	*	160
Jeffrey E Thomas MD FACS[163]	160	*	160
Arun Paul Amar, MD[164]	160	*	160

SooHo Choi[165]	160	*	160
Joseph Chen[166]	160	*	160
Mark Liker[167]	160	*	160
Larry T. Khoo[168]	160	*	160
Indro Chakrabarti[169]	160	*	160
Christopher Aho[170]	160	*	160
Azadeh Farin[171]	160	*	160
Gabriel Zada[172]	160	*	160
Patrick Reid[173]	160	*	160
Joshua Lucas[174]	160	*	160
Vivek Mehta[175]	160	*	160
Fij Ohiorhenuan[176]	160	*	160
Daniel Donoho[177]	160	*	160
Phillip Bonney[178]	160	*	160
Justin C. Lee[179]	160	*	160
Saman Sizdahkhani[180]	160	*	160
Jacob Ruzevick[181]	160	*	160
Yousha Neman-Ebrahim[182]	160	*	160
Eric Lin Chang[183]	160	*	160
Jason C. Ye[184]	160	*	160
Babak Eghbalieh [185]	160	*	160
Masood Heshmatpour[186]	160	*	160
Chia-Chun Chiang[187]	160	*	160
Nalini Weisberger[188]	160	*	160
Donna P Ostrus-Rozumalski[189]	160	*	160
Tomas Gamez[190]	160	*	160
Luz Maria Castellaneos[191]	160	*	160
Guadalupe Barringa[192]	160	*	160
Aaron Sharma[193]	160	*	160
Sachendra Prakash[194]	160	*	160
Jonathan Ostrus[195]	160	*	160
Alix Rangel[196]	160	*	160
Kathy Gohari[197]	160	*	160
Michael A. Paige[198]	160	*	160
Henrik Henriksen[199]	160	*	160
Kimberly Lynn Fodera[200]	160	*	160
Galust Raymond Mkrtchyan[201]	160	*	160
Andrew Arizmendi[202]	160	*	160
Andrew Michael Arizmendi II[203]	160	*	160
Asquith Williams[204]	160	*	160
Philip McDonald, M.D.[205]	160	*	160
Alisha J. McPheeters[206]	160	*	160
Anthony McPheeters[207]	160	*	160
Michael Janniere[208]	160	*	160
Tanya White[209]	160	*	160

Barrington Jackson[210]	160	*	160
Branden Adams[211]	160	*	160
Helen Vernetta Johnson[212]	160	*	160
Anthony Fenison[213]	160	*	160
Bernard Pean[214]	160	*	160
David Greenwald[215]	160	*	160
Rosmarie Riedl[216]	160	*	160
Lawrence Koplin[217]	160	*	160
Kevin Pollak[218]	160	*	160
Kevin Cohen[219]	160	*	160
Robert M. Hertzberg[220]	160	*	160
Kereti Tuioti[221]	160	*	160
Elyse Margolin[222]	160	*	160
Christopher Joseph Billig[223]	160	*	160
Andrew Garroni[224]	160	*	160
Zhian Cao[225]	160	*	160
Portia Hein[226]	160	*	160
Howard Allen Edmond[227]	160	*	160
Robert Scheer[228]	160	*	160
Nick Payzant[229]	160	*	160
Christopher S. Lindholm[230]	160	*	160
Chad Hess[231]	160	*	160
Cooper Colescott[232]	160	*	160
Sana U. Khan[233]	160	*	160
Hilda Kasimian[234]	160	*	160
Yefim Sklyar[235]	160	*	160
James Negele[236]	160	*	160
Jean Thoren[237]	160	*	160
Nina Rodriguez[238]	160	*	160
Paul E. Kim[239]	160	*	160
Haig Minassian[240]	160	*	160
Michael L. Levy MD PhD[241]	160	*	160
Elliot Min[242]	160	*	160
Harvey M. Greenberg, M.D.[243]	160	*	160
Michael D. Marsh[244]	160	*	160
Make-A-Wish Foundation of Central Coast and Southern Central Valley[245]	15,625	*	15,625
Nathan Chen[246]	160	*	160
Monika Komosinski[247]	160	*	160
Ali Rezapour[248]	160	*	160
Johnson & Johnson Consulting LLC[249]	15,000	*	15,000
Edward McField[250]	160	*	160
Colin Caleb[251]	160	*	160
Earl Quijada[252]	160	*	160
Andretta Starks[253]	160	*	160

Anthony Tyler[254]	160	*	160
Cherita Odums[255]	160	*	160
Dale A Wright[256]	160	*	160
David Cherry[257]	160	*	160
Elizabeth Chum[258]	160	*	160
Esther Alwala[259]	160	*	160
Ivetty Regalado[260]	160	*	160
Jeri McBride[261]	160	*	160
Gabrielle A. Best Husband[262]	160	*	160
Geraldine Strother[263]	160	*	160
Isis J Bateman[264]	160	*	160
Jacqueline Posey[265]	160	*	160
Ky-Asia Colter[266]	160	*	160
Jennifer M. Jones[267]	160	*	160
Jimmy Tuti[268]	160	*	160
Joel Casiano[269]	160	*	160
Denise Lewis[270]	160	*	160
Melita Casiano[271]	160	*	160
Michael Carey[272]	160	*	160
Rene Hamilton[273]	160	*	160
Nichelle I. Carter[274]	160	*	160
Olivia Ffrench[275]	160	*	160
Ralph Faber[276]	160	*	160
Raymond l Hopkins Sr[277]	160	*	160
Robert Giddings[278]	160	*	160
Robert Kehaya[279]	160	*	160
Samanth Sherwood[280]	160	*	160
Theodore Bunch[281]	160	*	160
Robert A Cornaglia[282]	160	*	160
Ingrid Egocheaga[283]	160	*	160
Anneshia Miller[284]	160	*	160
Beatrice Hamza Bassey[285]	160	*	160
James Barry[286]	160	*	160
Maysha Mohamedi[287]	160	*	160
Laurence H. Mandell[288]	160	*	160
Michael Burns[289]	160	*	160
Thomas Blumenthal[290]	160	*	160
Mark Goldstein[291]	160	*	160
Miles Nathan[292]	160	*	160
Ramana V Bodepudi[293]	160	*	160
Terrance Hardy[294]	160	*	160
Mary Weatherford[295]	160	*	160
Rick Parzick[296]	160	*	160
Evan Meyer[297]	160	*	160

Brendan Ravenhil[298]	160	*	160
Christopher James[399]	160	*	160
Tyler Britt[300]	160	*	160
Geula Komras[301]	160	*	160
Eulalia Halloran[302]	160	*	160
Elizabeth Mandler[303]	160	*	160
Sherri K Saget Living Trust[304]	160	*	160
Francois Ghebaly[305]	160	*	160
Aubrey Saget[306]	160	*	160
Ijigayehu Asfaw[307]	160	*	160
David Joseph[308]	160	*	160
Eric Frimpong[309]	160	*	160
Anat Ebgi[310]	160	*	160
Josh Rosenblatt[311]	160	*	160
Jennifer Hoberman[312]	160	*	160
Bruce Meyer[313]	160	*	160
Lara Saget[314]	160	*	160
Berry Carter[315]	160	*	160
Paul Schroeder[316]	160	*	160
Charles L Dages[317]	160	*	160
Pär Larsson[318]	160	*	160
Adam Wallach[319]	160	*	160
George L. Sentena[320]	160	*	160
Alex Colescott[321]	160	*	160
John Lund[322]	160	*	160
Jared Metter[323]	160	*	160
Regina Keith[324]	160	*	160
Daniel McClean[325]	160	*	160
Gregory S Ritmire[326]	160	*	160
Sattar Mir[327]	160	*	160
Salina Walker[328]	160	*	160
Rand Marlis[329]	160	*	160
Stacy M.Ruiz[330]	160	*	160
Melinda Hughes[331]	160	*	160
Thomas DelPonti[332]	160	*	160
Miriam Lauter[333]	160	*	160
Monica Escalante[334]	160	*	160
April Stein[335]	160	*	160
Jordan Parzick[336]	160	*	160
Dominik Linsmayer[337]	160	*	160
Hart Levine[338]	160	*	160
Hubert Ludovic Nkoth[339]	160	*	160
Umar Rashid Foster[340]	160	*	160
Alexander Israel[341]	160	*	160
Henry Vizcarra[342]	160	*	160

Damien Jackson[343]	160	*	160
Philipp Kaiser[344]	160	*	160
Dana Delany[345]	160	*	160
Michelle Lee[346]	160	*	160
John Peter Gruen[347]	160	*	160
Alexander Khalessi[348]	160	*	160
Vance Lebron Fredrickson[349]	160	*	160
Benjamin Yim[350]	160	*	160
Ben Strickland[351]	160	*	160
Vincent Ngoc Duy Nguyen[352]	160	*	160
Steven Frankland[353]	160	*	160
Gordon Tang[354]	160	*	160
Richard Rupp[355]	160	*	160
Lawrence R Menendez[356]	160	*	160
Kevin Armstrong[357]	160	*	160
Arthur Ross[358]	160	*	160
Bradley Joseph Hertan[359]	160	*	160
Lin LeMay[360]	160	*	160
Yuh-Jer Shen[361]	160	*	160
Alex Shen[362]	160	*	160
Allan Musamali[363]	160	*	160
Angela Tunstall[364]	160	*	160
Anthony E. White[365]	160	*	160
Antonio Mc Cray[366]	160	*	160
Anupam Singh[367]	160	*	160
Brittany Karon Addison[368]	160	*	160
Chase Hall[369]	160	*	160
Cheryl Anderson[370]	160	*	160
Claire Oduor[371]	160	*	160
Donnell McNeal[372]	160	*	160
Enrique Rodriguez[373]	160	*	160
Freda Holmes[374]	160	*	160
James Aleck[375]	160	*	160
James Walters[376]	160	*	160
Jamie Stenning[377]	160	*	160
Janice M. Bolden[378]	160	*	160
Jason Griffiths[379]	160	*	160
Jose L. Rivera III[380]	160	*	160
Joshua Godfrey[381]	160	*	160
Kaleb Keller[382]	160	*	160
Kendra Brown[383]	160	*	160
Kenny F. Alce[384]	160	*	160
Ki-Eun Chang[385]	160	*	160
Linda Golden[386]	160	*	160
Linda Keefer[387]	160	*	160

Louis P. Smaldino[388]	160	*	160
Maria Stegner[389]	160	*	160
Mark E. Bair[390]	160	*	160
Michael Anvar[391]	160	*	160
Michael Hunter[392]	160	*	160
Michael Quinn[393]	160	*	160
Michael W Johnson[394]	160	*	160
Mitchell Wilson[395]	160	*	160
Owen Gardner[396]	160	*	160
Parsa Rezapour[397]	160	*	160
Rikell Ford[398]	160	*	160
Ronan Linton Frias[399]	160	*	160
Sandra Williams[400]	316	*	316
Santino Lannutti[401]	160	*	160
Sean Ngo[402]	160	*	160
Sharice Stewart[403]	160	*	160
Sheridan Kesselman[404]	160	*	160
Sherwin Wynter[405]	160	*	160
Sirage Yassin[406]	160	*	160
Tahnee Colson[407]	160	*	160
Thaynan Leite[408]	160	*	160
Vafa Mottahedin[409]	160	*	160
Wilbert F. Laveist[410]	160	*	160
Mary Susan Arditi[411]	1,875	*	1,875
Secure Net Capital LLC[412]	156,250	*	156,250
Roseline S. Tuti[413]	313	*	313
Anthony Fenison[414]	3,125	*	3,125
Yosmaira M. Ramos[415]	723	*	723
Reginald W. Williams[416]	198	*	198
Jason Griffiths[417]	625	*	625
Ali Rezapour[418]	1,000	*	1,000
Jin Ling Rui[419]	1,250	*	1,250
George Lu[420]	459,020	2.5%	459,020
Janine Frisco[421]	16,955	*	16,955
Will Shepphird[422]	160	*	160
Tirajeh Mazaheri[423]	312	*	312
Pamela Sahota[424]	312	*	312
Total Number of Shares Being Registered			2,101,313

* Less than 1%.

(1) HCWG LLC is owned 25.1% by Amir Heshmatpour, 25.5% by Thomas C. Chen M.D., Ph.D., 7.7% by Patrick Walters, 4.3% by The Hilkiah Group LLC, of which Keithly Garnett is the sole member and manager, and 37.5% by Alan Chiang. Includes 312,500 shares issuable upon exercise of outstanding warrants at a per share exercise price of $12.00.

(2) Represents shares of our common stock held of record by TR Chen Third Family Limited Partnership over which Dr. Chen and Dr. Chen's spouse, Rosa Chen, exercise sole voting and investment control. The address of TR Chen Third Family Limited Partnership is c/o NeOnc Technologies Holding, Inc., 2 Dole Drive, Westlake Village, CA 91362. In January 2024, 800,000 restricted stock units were granted to Dr. Thomas C. Chen, M.D., Ph.D. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Dr. Chen's individual grant agreement. In October 2024, 200,000 restricted stock units were granted to Dr. Thomas C. Chen, M.D., Ph.D., all of will vest seven months after the effective date of this offering. Includes 329,688 shares through beneficial ownership of HCWG LLC, which includes 79,688 shares issuable upon exercise of outstanding warrants held by HCWG LLC.

(3) In January 2024, 300,000 restricted stock units were granted to Patrick Walters. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Mr. Walter's individual grant agreement. Includes 99,063 shares through beneficial ownership of HCWG LLC, which includes 24,063 shares issuable upon exercise of outstanding warrants held by HCWG LLC.

(4) In January 2024, 360,000 restricted stock units were granted to Keithly Garnett. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Mr. Garnett's individual grant agreement. Includes 55,105 shares through beneficial ownership of HCWG LLC, which includes 13,438 shares issuable upon exercise of outstanding warrants held by HCWG LLC.

(5) In January 2024, 1,000,000 restricted stock units were granted to Amir Heshmatpour. In October 2024, 200,000 restricted stock units were granted to Amir Heshmatpour. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering. Includes 324,143 shares through beneficial ownership of HCWG LLC, which includes 78,438 shares issuable upon exercise of outstanding warrants held by HCWG LLC.

Includes (i) 3,714,020 shares of our common stock held of record by AFH Holding and Advisory, LLC, of which Mr. Heshmatpour is the sole member and over which he has sole voting and investment control; (ii) 550,000 shares of our common stock held of record by KIG LLC of which Mr. Heshmatpour's spouse, Kathy Heshmatpour, exercises sole voting and investment control; (iii) 275,000 shares held by Angelina Heshmatpour, the minor daughter of Mr. Heshmatpour, (iv) 275,000 shares held by Amir Heshmatpour, and (v) 50,000 shares held by Amir & Kathy Heshmatpour Family Fund. The address of AFH Holding and Advisory, LLC is c/o NeOnc Technologies Holding, Inc., 2 Dole Drive, Westlake Village, CA 91362.

(6) In February 2024, 50,000 restricted stock units were granted to Dr. Victoria Medvec, Ph.D. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

(7) In February 2024, 50,000 restricted stock units were granted to Bader Almonawer. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering. Additionally, he received 160 shares as a transfer from Dr. Chen and Amir Heshmatpour (collectively).

(8) In February 2025, 50,000 restricted stock units were granted to Dr. Steven L. Giannotta. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering. Additionally, he received 160 shares as a transfer from Dr. Chen and Amir Heshmatpour (collectively).

(9) In February 2025, 50,000 restricted stock units were granted to Jim Delshad. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering. Additionally, he received 160 shares as a transfer from Dr. Chen and Amir Heshmatpour (collectively).

(10) Includes 340,216 shares of our common stock held of record by Dr. Ming-Fu Chiang. In February 2025, 50,000 restricted stock units were granted to Dr. Ming-Fu Chiang. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering. Includes 482,917 shares through beneficial ownership of HCWG LLC, which includes 116,250 shares issuable upon exercise of outstanding warrants held by HCWG LLC.

(11) The address of David H. Chen is 31 Wagon Wheel Street, Pomona, CA 91766

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(13) The address of Fred Sahakian is 121 Aspen Drive, Boalsburg, PA 16827

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(15) The address of Chiu-Yen Lee is 117, no 209, sec 4, New Taipei Blvd, Xinzhuang Dist, New Taipei City

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(20) The address of Mei-Yun Wang is 3F.-8, No.2, Ln. 109, Sec 2 Chengde Rd New Taipei City

(21) The address of Jen-Fu Shih is 3F, no 7, Aly 4, Ln 345, Sec 4 Ren'ai Rd, Da'an Dist Taipei City

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(23) The address of Vincent F. Simmon is 99 Hanover St. Apt 204, Portsmouth, NH 03801

(24) The address of Andre Blake is 1290 Morada Place, Altadena, CA 91001

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(38) The address for Dana Silva is 8180 Manitoba St. #229, Los Angeles, CA 90293
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(41) The address for Said Eghbalieh is 458 N Laurel Ave, LA, CA 90048
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(58) The address for Mohammad Hosseini is 23052 Park Sorrento, Calabasas, CA 91302
(59) The address for Nasim Bahar Shomali is P.O. Box 123, Kirkland, Washington, 98083
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(61) The address for Nosratollah Vafaie is 410 South Barrington Ave, Apt #209, Los Angeles, CA 90049
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(75) The address for Maria Jimenez is 4380 Quigley Avenue, Lakewood CA, 90713

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(81) The address for Hugo Correa is 605 SYCAMORE DRIVE, SAN GABRIEL, CA 91775
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(103) The address for Cleveland Garnett is 5127 Butler Ridge Drive, Orlando, FL 34786
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(218) The address for Kevin Pollak is 2632 Wilshire Blvd, Santa Monica, CA 90403
(219) The address for Kevin Cohen is 32023 Pacific Coast Hwy, Malibu CA,90265
(220) The address for Robert M. Hertzberg is 605 Noble Road Simi Valley, CA 93065
(221) The address for Kereti Tuioti is 15 Yerba Buena Ct, Monterey, CA,93940
(222) The address for Elyse Margolin is 8484 Wilshire Blvd. 660 Beverly Hills California 90211
(223) The address for Christopher Joseph Billig is 4011 Cliffrose Ave, Moorpark, CA, 93021
(224) The address for Andrew Garroni is 8646 Edwin Drive, LA, CA 90046
(225) The address for Zhian Cao is 830 Admiral Ct., Oak Park, CA 91377
(226) The address for Portia Hein is 2525 Medlow Ave, Los Angeles, CA 90041

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(228) The address for Robert Scheer is 27329 Sand Canyon Rd. Santa Clarita, CA 91387
(229) The address for Nick Payzant is 22 Golden Poppy Dr Coto De Caza CA, 92679
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(236) The address for James Negele is 24943 Kit Carson Rd., Hidden Hills, CA 91302
(237) The address for Jean Thoren is 24943 Kit Carson Rd, Hidden Hills, CA 91302
(238) The address for Nina Rodriguez is 22030 Strathern St #21, Canoga Park, CA 91304
(239) The address for Paul E. Kim is 2416 Los Olivos Lane, La Crescenta, CA 91214
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(255) The address of Cherita Odums is 7104 N 19th Street, Philadelphia, PA 19126
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(257) The address of David Cherry is 70 Rockview Ave, North Plainfield NJ 07060
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(259) The address of Esther Alwala is 23545 E. Platte Dr. Unit D, Aurora, Colorado 80016
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(261) The address of Jeri McBride is 860 N Oakland Ave, Runnemede, NJ 08078
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(263) The address of Geraldine Strother is 5605 Gainor Rd, Philadelphia, PA 19131
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(268) The address of Jimmy Tuti is 17344 EAST LAKE PLACE, AURORA, CO 80016
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(270) The address of Denise Lewis is 501 Sage Dr, Canonsburg, PA 15317
(271) The address of Melita Casiano is 207 Columbus Drive, Franklin Park, NJ 8823
(272) The address of Michael Carey is 1419 N Brighton St, Burbank, CA 91506
(273) The address of Rene Hamilton is 304 Beech Spring Road, South Orange, NJ 07079
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(275) The address of Olivia Ffrench is 11532 Tuscany Dr, Laurel, MD 20708
(276) The address of Ralph Faber is 1202 Pepperwood Springsway, Bel Air, MD 21014
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(278) The address of Robert Giddings is 333 Hackberry Dr, New Castle, DE 19720
(279) The address of Robert Kehaya is 2900 NE 2nd Ave APT 171, Miami, FL 33137
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(281) The address of Theodore Bunch is 200 North Village Avenue Apt G 5, Rockville Centre, NY 11570
(282) The address of Robert A Cornaglia is 510 Mackin Drive, Cherry Hill, NJ 08002
(283) The address of Ingrid Egocheaga is 2900 NE 2nd Apt 171, Miami, FL 33137
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(285) The address of Beatrice Hamza Bassey is 181 East 90th St, apt 31B, New York, NY 10128
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(297) The address of Evan Meyer is 441 N. Beverly Drive Suite 200, Beverly Hills, CA 90210
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(299) The address of Christopher James is 4322 Sunset Drive, Los Angeles, CA 90027
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(303) The address of Elizabeth Mandler is 1285 South Orange Drive, Los Angeles, CA 90019
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(372) The address of Donnell McNeal is 12231-H Little Patuxent Parkway, Columbia, MD 21044
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(376) The address of James Walters is 4220 Jubilo Drive, Tarzana, CA 91356
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(379) The address of Jason Griffiths is 4858 Matilija Avenue, Sherman Oaks, CA 91423
(380) The address of Jose L. Rivera III is 500 New Road, Wilmington, De 19805
(381) The address of Joshua Godfrey is 2210 Consuelo Avenue, Santa Clara, CA 95050
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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than as disclosed below, and except for the compensation arrangements and regular salary and bonus payments made to our directors and officers in the ordinary course of business as described in "*Executive Compensation*," there have been no transactions since January 1, 2021, or any currently proposed transaction or series of similar transactions to which our company was or is to be a party, in which the amount involved exceeds $120,000 and in which any current or former director or officer of our company, any 5% or greater shareholder of our company or any member of the immediate family of any such persons had or will have a direct or indirect material interest.

Letter of Intent – AFH Holdings and Advisory, LLC

On December 19, 2022, NeOnc Technologies, Inc. entered into an engagement agreement with AFH Holdings and Advisory, LLC ("AFH"). Amir Heshmatpour is the sole member and managing director of AFH and a member of NeOnc's Board of Directors. AFH was engaged to assist NeOnc Technologies, Inc. in connection with its intent to effect a public listing. AFH was retained to assist NeOnc Technologies, Inc. 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, and earned $500,000 during the year ended December 31, 2023. AFH agreed to advance costs of up to $500,000 for such professionals on our behalf to be to be paid off with proceeds of the short term loan provided to us by HCWG LLC. As of December 31, 2023, no amounts were outstanding further to such agreement. NeOnc Technologies, Inc. also agreed to effect a share exchange with NeOnc Technologies Holdings, Inc., a special purpose entity substantially beneficially owned by Amir Heshmatpour and his affiliates.

On April 7, 2023, NeOnc Technologies, Inc. entered into a Share Exchange Agreement (the "Share Exchange") with NeOnc Technologies Holdings, Inc., whereby all of the shareholders of NeOnc Technologies, Inc. exchanged their stock in NeOnc Technologies, Inc. for a total of 10,500,000 shares of common stock in NeOnc Technologies Holdings, Inc. As a result, all shareholders of NeOnc Technologies, Inc. became shareholders of NeOnc Technologies Holdings, Inc. and NeOnc Technologies, Inc. became a wholly-owned subsidiary of NeOnc Technologies Holdings, Inc. At the consummation of this transaction, Amir Heshmatpour, AFH, and their affiliated entities, individuals, or assignees owned an aggregate of 34.4% of the fully diluted issued and outstanding common shares of NeOnc Technologies Holdings, Inc. For the year ended December 31, 2022, NeOnc Technologies Holdings, Inc. had no operations or assets other than cash paid by its shareholders for their shares ($450 in the aggregate) and liabilities of $50,000 pertaining to an amount owing to Mr. Heshmatpour for a professional retainer paid by him on behalf of our company.

In addition, NeOnc Technologies, Inc. agreed to retain AFH as an exclusive advisor on all financing and mergers and acquisitions for a period of two (2) years from the closing of a public offering. Further to the advisory arrangement, AFH shall be paid in cash an aggregate fee in an amount equal to 2% of the post-money valuation of NeOnc Technologies Holdings, Inc. immediately after the consummation of this 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 remining amount of the 2% fee to be paid in equal monthly installments for one year. AFH was paid a fee of $500,000 for the amendment.

Transactions with USC

On March 9, 2009, we entered into an exclusive license agreement with USC, pursuant to which USC granted a license to use certain patented technology related to the use of monoterpenes as a solvent, specifically perillyl alcohol. This technology is the basis of the current products under development by us. We agreed to issue USC 560,000 additional shares of our common stock and issued such shares in October 2023. Additionally, pursuant to the USC Agreement, we (1) paid USC an upfront royalty payment of $20,000, (2) granted USC 117,236 shares of common stock, (3) will pay USC an earned royalty of 2% of Net Sales (as that term is defined in the USC Agreement), and (4) has paid and will continue to pay annual maintenance royalties of: $5,000 due January 1, 2011, $5,000 due January 1, 2012, $10,000 due January 1, 2013, and $20,000 due January 1 thereafter. We have not paid any earned royalties date, since no products are being sold using such technology.

On November 19, 2023, the Company and USC entered into an Amended and Restated Exclusive License Agreement (the "Restated Agreement"). The Restated Agreement addressed and clarified certain reporting obligations of the Company under the license agreement with USC dated March 9, 2009, and addressed certain financial and other obligations, defaults, and deficiencies in connection with the Company's performance.

In connection with the Restated Agreement, the Company recorded additional license fees in the amount of $230,000 to cure deficiencies in the existing license agreement related to unpaid sub-license fees within license expense in the accompanying consolidated statement of operations for the year ended December 31, 2023, and accrued within accounts payable – related parties in the accompanying consolidated balance sheet as of December 31, 2023.

We also utilize laboratory services from USC. We have incurred approximately $461,000 and $326,000 of research and development-related costs from USC for the years ended December 31, 2024 and 2023, respectively. We incurred approximately $20,000 and $41,000 of patent maintenance and legal-related expenses for the years ended December 31, 2024 and 2023, respectively. At December 31, 2024 and 2023, we owed USC approximately $272,328 and $277,000, respectively. From time to time prior to January 1, 2023, the Company has been unable to reimburse USC for such costs. Therefore, USC deducted certain amounts due to the Chairman for compensation for his services as faculty at USC to satisfy the amounts due from the Company to USC. In 2024, the Company reached an agreement to convert a portion of amount owed as of such date in the amount of $1,377,096 to 114,758 common shares at $12 per share (the share price of the most recent financing round) and is recorded as a portion of the common stock issued for settlement of vendor payable in the Consolidated Statements of Changes in Shareholders' Deficit for December 31, 2024.

Accrued compensation

The Company has incurred $785,996 and $798,743 for the years ended December 31, 2024 and 2023, respectively for compensation to the management team, all of whom are shareholders. This compensation is recorded in the consolidated statement of operations as part of general and administrative expenses. The amount accrued for compensation for the management team was $693,163 and $1,091,243 as of December 31, 2024 and 2023, respectively. On June 14, 2024**,** the Company reached an agreement with the management team to convert $412,500 of the outstanding accrued compensation to 34,375 shares of common stock at $12 per share.

Short-term loans

In April 2023, we entered into a non-interest bearing, non-convertible promissory note with HCWG LLC. HCWG LLC is owned 31.25% by Amir Heshmatpour, 18.75% by Dr. Thomas Chen, 18.75% by Dr. Alan Chiang (a former director), 15.625% by Patrick Walters and 15.625% by The Hilkiah Group LLC (an entity wholly-owned by Keithly Garnett, our Chief Financial Officer). 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 at December 31, 2023. The outstanding amounts under this Bridge Loan are payable at the earlier of the IPO date or December 4, 2024, (the "Maturity Date").

Through December 31, 2024 and 2023, the Company had received under the Bridge Loan an aggregate of 7,337,408 and $5,968,987, respectively. 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 year ended December 31, 2024 and 2023, amounted to $2,557,055 and 2,721,747, respectively, and are included in interest expense in the accompanying consolidated statement of operations. Summary of the bridge loan activity for the years ended December 31, 2024 and 2023, respectively, is as follows:

	For the year ended December 31, 2024	For the year ended December 31, 2023
Bridge loan roll-forward		
Principal outstanding	$ 9,802,697	$ -
Borrowings	1,368,422	5,968,987
OID	1,368,422	5,968,987
Repayments	(791,077)	(2,135,277)
Total principal outstanding before conversion	11,748,464	9,802,697
Conversion to common stock	(11,748,464)	-
Principal; outstanding	$ -	$ 9,802,697

	For the year ended December 31, 2023
Bridge loan	
Principal Outstanding	$ 9,802,697
Less: Unrecognized OID	(3,247,240)
Total:	$ 6,555,457

On June 14, 2024, we reached an agreement with HCWG to convert the outstanding principal and interest on the Bridge Loan totaling $11,748,464 to 979,039 shares of common stock at $12 per share. The fair value of the common stock issued for the conversions was valued based upon the pricing from a recent financing round which was $12 a share. The difference between the carrying value of the debt as of the date of the extinguishment of $9,678,541 and the fair value of the shares issued to settle to the debt as of the date of the extinguishment of $11,748,464 is recorded as a loss on extinguishment of Bridge Loan in the accompanying consolidated statement of operations in the amount of $2,069,923. As a result of this conversion, the Bridge Loan was terminated and is no longer available to us for borrowing.

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. The Executive Chairman is to receive a total of $600,000 upon repayment of such advances, including OID, absent default. The Company shall pay the Executive Chairman the entire unpaid principal balance on the earlier of one year following the date of the effective date of the agreement or the date of the direct listing on the Nasdaq Global Market.

Stock-Based Compensation

As of December 31, 2022 there were 24,328 vested stock options outstanding under the 2013 Option Plan, which were cancelled in January 2023. These options had a weighted average exercise price of $0.36 per share. There were no grants during the year ended December 31, 2024 and 2023. As of December 31, 2024 and 2023, there were no stock options outstanding. There is no further activity expected under the 2013 Option Plan.

In January 2024, 800,000 restricted stock units were granted to Dr. Thomas C. Chen, M.D., Ph.D. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Dr. Chen's individual grant agreement.

In January 2024, 300,000 restricted stock units were granted to Patrick Walters. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Mr. Walter's individual grant agreement.

In January 2024, 360,000 restricted stock units were granted to Keithly Garnett. Two-thirds of such restricted stock units will be time vested; one-third (1/3) will vest seven months after the effective date of this offering and one-third will vest in equal monthly installments over a one (1) year period commencing on the eighth month from the effective date of this offering. The remaining one-third will be performance-based, the vesting of which will be predicate on certain performance metrics being met as set forth in Mr. Garnett's individual grant agreement.

In January 2024, 1,000,000 restricted stock units were granted to Amir Heshmatpour. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

In February 2024, 50,000 restricted stock units were granted to Dr. Victoria Medvec, Ph.D. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

In February 2024, 50,000 restricted stock units were granted to Bader Almonawer. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

In October 2024, 200,000 restricted stock units were granted to each of Amir Heshmatpour and Dr. Thomas C. Chen, M.D., Ph.D.. The forgoing restricted stock units will vest one hundred percent (100%) seven months following the effective date of this offering.

Vesting of the restricted stock units above are contingent on completion of a listing on NASDAQ. Due to the listing condition, which is uncertain, these restricted stock units are not considered issued for accounting purposes and no fair value charge has been recognized in our consolidated statement of operations to these restricted stock units as of December 31, 2024.

Collaboration and License Agreement between NeOnc and Orient EuroPharma Co., Ltd.

On November 8, 2013, we entered into a Collaboration and License Agreement with Orient EuroPharma Co., Ltd. ("OEP"), which is partially owned by Alan Chiang, a former director, pursuant to which NeOnc licensed OEP the right to commercialize NEO100. On February 20, 2024, OEP and the Company entered into a settlement agreement whereas the Company and OEP terminated the OEP Agreement in exchange for a payment in the amount of $4,000,000 payable by the Company to OEP within ten days of the close of our initial public offering.

License Agreement by and between NeOnc Technologies and Neucen Biomedical Co., Ltd

On December 5, 2015, we previously entered into a License Agreement with Neucen Biomedical Co. Ltd. ("Neucen"), which is owned in part by the spouse of Dr. Alan Chiang and Thomas Chen, pursuant to which NeOnc licensed to Neucen the right to commercialize NEO212. We terminated this License Agreement on May 30, 2023.

Brownstone Note

On February 17, 2022, the Company issued R & J Brownstone Trust dated September 17, 2001 ("Brownstone") a Convertible Promissory Note (the "Brownstone Note") in the amount of $50,000. On January 31, 2024, the Company assigned the Brownstone Note to HCWG LLC (a related party). On January 31, 2024, the Note was assigned to HCWG LLC (an entity owned by certain of our shareholders, directors, and officers) and the Note was amended to increase the principal balance to $62,500.

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. 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. The interest rate increases to 14% if the Line of Credit Agreement is extended.

DESCRIPTION OF SECURITIES

General

The following description summarizes the most important terms of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the completion of this offering. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which have been filed as exhibits to the Registration Statement of which this prospectus is a part, and by the applicable provisions of Delaware law.

Our authorized capital stock consists of 110,000,000 shares of capital stock, of which (i) 100,000,000 shares are common stock with a par value $0.0001 per share and (ii) 10,000,000 shares are preferred stock with a par value of $0.0001 per share. All of our authorized shares of preferred stock are undesignated. As of the date of this prospectus, there are 18,745,865 shares of common stock and no shares of preferred stock issued and outstanding.

Common Stock

Voting Rights

Holders of common stock are entitled to one vote per share on all matters to be voted upon by the shareholders, including the election of directors. Such holders are not entitled to vote cumulatively for the election of directors. Our amended and restated certificate of incorporation that will become effective immediately prior to the completion of this offering establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election by a plurality of the votes cast at each annual meeting of our shareholders, with the directors in the other classes continuing for the remainder of their respective three-year terms. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws and our amended and restated certificate of incorporation, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, shareholder notices, actions by written consent, and exclusive jurisdiction.

Dividends

Subject to preferences that may be applicable to any outstanding preferred stock, our common shareholders are entitled to receive ratably such dividends, if any, as may be declared from time to time by the board of directors out of funds legally available for that purpose. We have never declared or paid any cash dividends on our capital stock. We currently expect to retain future earnings, if any, to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future. See the section titled "*Dividend Policy*" for further information.

Liquidation Rights

In the event of our liquidation, dissolution or winding up, our common shareholders are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding.

No Preemptive or Similar Rights

Our common shareholders have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

Upon filing of our amended and restated certificate of incorporation that will become effective immediately prior to the completion of this offering, our board of directors is authorized, without action by the shareholders, to designate and issue up to 10,000,000 shares of preferred stock in one or more series and to designate the powers, preferences and rights of each series, which may be greater than the rights of the common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of the common stock until the board of directors determines the specific rights of the holders of such preferred stock. However, the effects might include, among other things:

- impairing dividend rights of the common stock;
- diluting the voting power of the common stock;
- impairing the liquidation rights of the common stock; and
- delaying or preventing a change in control of us without further action by the shareholders

Convertible Promissory Note

In 2022, NeOnc Technologies, Inc. issued a $50,000 convertible note to a shareholder due August 30, 2023 ("Note"). The Note bears interest at 2% per annum and is convertible. The Note and all accrued interest thereon is convertible, at the option of the noteholder, into the class and series of equity securities ("Conversion Stock") that is sold by us in its next issuance of equity securities in a Financing Transaction (as defined below), consummated after the issuance date of the note. A Financing Transaction is a sale, other than in an initial public offering, of equity securities by us to investors for cash. The Financing Transaction does not include the issuance of stock, options, or warrants to service providers in connection with the rendition of such services or to third parties in connection with the contribution of non-cash assets to us. The number of shares of Conversion Stock to be issued to the noteholder upon such conversion shall be equal to the quotient obtained by dividing (i) the entire principal amount of the Note plus accrued interest by (ii) the Financing Transaction conversion price, which shall be equal to 75% of the price paid for one share of Conversion Stock by the investors in the Financing Transaction. The entire principal amount of and accrued interest of the Note shall automatically be converted, without further action on the part of the noteholder or us, into the class and series of stock issued by us, at the closing of an initial public offering. The number of shares of stock to be issued to the holder upon such conversion shall be equal to the quotient obtained by dividing (i) the entire principal amount of the Note plus accrued interest by (ii) the initial public offering conversion price, which shall be equal to 75% of the price paid for one share of Conversion Stock by the investors in the initial public offering. On January 31, 2024, the Note was assigned to HCWG LLC (an entity owned by certain shareholders, directors, and officers of the Company). Additionally, as part of the assignment, the Note was amended to increase the principal balance to $62,500, amend the maturity date to the date that the Company completes its initial public offering, and the Note was subordinated to the Bridge Loan (defined herein).

Warrants

In October 2024 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.

Anti-Takeover Provisions

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Because our shareholders do not have cumulative voting rights, our shareholders holding a plurality of the outstanding shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation and our amended and restated bylaws, each to be effective immediately prior to the closing of this offering, will provide for shareholder actions at a duly called meeting of shareholders. A special meeting of shareholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer or president. Our amended and restated bylaws will establish an advance notice procedure for shareholder proposals to be brought before an annual meeting of our shareholders, including proposed nominations of persons for election to our board of directors.

As described above in "*Management—Corporate Governance,"* in accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, our board of directors will be divided into three classes with staggered three-year terms.

The foregoing provisions will make it more difficult for our existing shareholders to replace our Board of Directors as well as for another party to obtain control of us by replacing our Board of Directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing shareholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our Board of Directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested shareholder for a period of three years after the date that such shareholder became an interested shareholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the shareholder becoming an interested shareholder;

- upon closing of the transaction that resulted in the shareholder becoming an interested shareholder, the interested shareholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested shareholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the shareholders, and not by written consent, by the affirmative vote of at least 66 2⁄3% of the outstanding voting stock that is not owned by the interested shareholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested shareholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested shareholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested shareholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested shareholder; or

- the receipt by the interested shareholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested shareholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested shareholder status did own, 15% or more of the outstanding voting stock of the corporation.

Exclusive forum for adjudication of disputes provision which limits the forum to the Delaware Court of Chancery for certain shareholder litigation matters actions against us, which may limit an investor's ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or shareholders.

Our amended and restated bylaws, that will become effective immediately prior to the completion of this offering, dictate that, unless we consent in writing to the selection of an alternative forum, the Delaware Court of Chancery (or, if the Delaware Court of Chancery does not have jurisdiction, the federal district court for the State of Delaware) is, to the fullest extent permitted by law, the sole and exclusive forum for certain actions including derivative action or proceeding brought on our behalf; an action asserting a breach of fiduciary duty owed by any current or former officer, director, employee or to the shareholders of our company; any claim arising under Delaware corporate law, our certificate of incorporation or our bylaws, as amended from time to time; and any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of our company shall be deemed to have notice of and consented to the provisions of our amended and restated bylaws.

However, this provision of our amended and restated bylaws will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Furthermore, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, or the rules and regulations promulgated thereunder. We note, however, that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. There is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

A Delaware corporation is allowed to mandate in its corporate governance documents a chosen forum for the resolution of state law-based shareholder actions, derivative suits and other intra-corporate disputes. With respect to such state law claims, our management believes limiting state law based claims to Delaware will provide the most appropriate outcomes as the risk of another forum misapplying Delaware law is avoided, Delaware courts have a well-developed body of case law and limiting the forum will preclude costly and duplicative litigation and avoids the risk of inconsistent outcomes. Additionally, Delaware Chancery Courts can typically resolve disputes on an accelerated schedule when compared to other forums.

The choice of forum provisions contained in our amended and restated bylaws may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with our company or any of our directors, officers, other employees or shareholders, which may discourage lawsuits with respect to such claims. Alternatively, the enforceability of similar choice of forum provisions in other issuers' bylaws and certificates of incorporation has been challenged in legal proceedings, and it is possible that in connection with any applicable action brought against our company, a court could find the choice of forum provisions contained in our bylaws, as amended. to be inapplicable or unenforceable in such action. As a result, we could incur additional costs associated with resolving such actions in other jurisdictions, which could harm our business, operating results and financial condition.

Transfer Agent and Registrar

We have appointed VStock Transfer LLC, 18 Lafayette Pl Woodmere, NY 11598, telephone: (212) 828-8436, as the transfer agent for our common stock

Trading Symbol and Market

We have been approved to list our shares of common stock listed on the Nasdaq Global Market under the symbol "NTHI".

SHARES ELIGIBLE FOR FUTURE SALE

Before the closing of this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

As of the date of this prospectus, a total of shares of our common stock are outstanding. Of these shares, all of the common stock sold in this offering by us will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act.

The remaining shares of common stock are "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. Restricted securities may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Regulation S under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible shareholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible shareholder under Rule 144, such shareholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such shareholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately 187,446 shares immediately after this offering; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a shareholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

Form S-8 Registration Statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable under our 2023 Plan. This registration statement will become effective immediately on filing. Shares covered by this registration statement will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

Lock-up Arrangement

Pursuant to that certain Share Exchange Agreement, dated April 7, 2023 (the "Share Exchange"), for a period of six (6) months from the effective date of this prospectus, all shareholders who were issued shares further to the Share Exchange have agreed with the Company not to lend; offer; pledge; sell or otherwise transfer or dispose of, directly or indirectly, 80% of such shares; the Company has subsequently allowed such stockholders to make private transfers of such shares.

SALE PRICE HISTORY OF OUR CAPITAL STOCK

We have been approved to list our common stock on Nasdaq. There has been no prior public market for our common stock. Our common stock has a limited history of trading in private transactions. From inception through December 31, 2023, we raised an aggregate of approximately $13,117,000 in gross proceeds from the sales of our stock at an average price of $1.25 per share. In June 2024, we issued an aggregate of 1,140,672 shares of common stock in private placements upon the conversion of an aggregate of approximately $13,688,000 of indebtedness at a price of $12.00 per share. Between June and December 31, 2024, we issued an aggregate of 384,646 shares of common stock in private placements at a price of $12.00 per share for gross proceeds of approximately $4,615,751. We have also engaged RBW Capital Partners LLC as a placement agent, all securities offered through Dawson James Securities, Inc., for the sale of shares of our common stock to unaffiliated third parties in a private placement at a price of $16.00 per share, such issuance to occur prior to the date of this Prospectus. To date, we have agreements with investors to sell 624,999 shares of common stock at the private placement price of $16.00 per share for gross proceeds of approximately $10,000,000. All 624,999 shares of common stock are being registered by means of this registration statement. While the Advisor is expected to consider this information in connection with setting the opening public price of our common stock, this information may have little or no relation to broader market demand for our common stock and thus the opening public price and subsequent public price of our common stock on Nasdaq. As a result, you should not place undue reliance on these historical private sale prices as it may differ materially from the opening public price and subsequent public price of our common stock on Nasdaq.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a general discussion of material U.S. federal income tax considerations and certain U.S. federal estate tax considerations relating to the acquisition, ownership, and disposition of our common stock applicable to non-U.S. holders that purchase our common stock in this offering and hold it as a "capital asset" within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended, or the Code (generally, property held for investment). For purposes of this discussion, a "non-U.S. holder" means a beneficial owner of our common stock (other than an entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes, any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or entity treated as a corporation for United States federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more "United States persons," as defined under the Code, or U.S. persons, have the authority to control all substantial decisions of the trust or (ii) such trust has made a valid election to be treated as a U.S. person for U.S. federal income tax purposes.

If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner therein will generally depend on the status of the partner and the activities of the partnership. Partners of a partnership holding our common stock should consult their tax advisors as to the particular U.S. federal income tax consequences applicable to them.

This discussion is based on current provisions of the Code, final, temporary and proposed Treasury regulations promulgated thereunder, or the Treasury Regulations, judicial decisions, published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or IRS, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described herein. There can be no assurance that the IRS will not challenge one or more of the tax consequences described herein.

This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes, other U.S. federal tax, the alternative minimum tax, or the unearned income Medicare contribution tax on net investment income. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- banks, insurance companies and other financial institutions;
- brokers or dealers or traders in securities;
- tax-exempt organizations;
- pension plans;
- persons who hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment or who have elected to mark securities to market;
- controlled foreign corporations, passive foreign investment companies, and corporations that accumulate earnings to avoid U.S. federal income tax;

- non-U.S. governments; and
- U.S. expatriates and former citizens or long-term residents of the United States.

THIS SUMMARY IS NOT INTENDED TO CONSTITUTE A COMPLETE DESCRIPTION OF ALL TAX CONSEQUENCES FOR NON-U.S. HOLDERS RELATING TO THE OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK. PROSPECTIVE HOLDERS OF OUR COMMON STOCK SHOULD CONSULT WITH THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES TO THEM (INCLUDING THE APPLICATION AND EFFECT OF ANY STATE, LOCAL, NON-U.S. INCOME AND OTHER TAX LAWS) OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK.

Distributions

As discussed under "*Dividend Policy*" above, we do not expect to make distributions on our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts of distributions not treated as dividends for U.S. federal income tax purposes will first constitute a tax-free return of capital of the non-U.S. holder's investment and be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock, but not below zero. Any remaining excess will be treated as capital gain and will be treated as described below under "*Gain on Sale or Other Disposition of Common Stock*." Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of the withholding rules discussed below we or the applicable withholding agent may treat the entire distribution as a dividend. Any such distributions will also be subject to the discussions below under the headings "*FATCA*" and "*Backup Withholding, Information Reporting and Other Reporting Requirements*."

Subject to the discussion in the next two paragraphs, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends we pay to a non-U.S. holder that are effectively connected with such non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable tax treaty, are attributable to a U.S. permanent establishment or a fixed base maintained by such non-U.S. holder) will generally be exempt from the U.S. federal withholding tax described above, if the non-U.S. holder complies with applicable certification and disclosure requirements (generally including provision of a valid IRS Form W-8ECI (or applicable successor form) certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States). Instead, such dividends generally will be subject to U.S. federal income tax on a net income basis, at regular U.S. federal income tax rates as would apply if such holder were a U.S. person (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is classified as a corporation for U.S. federal income tax purposes may also be subject to an additional "branch profits tax" at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty and the specific methods available to them to satisfy these requirements.

Gain on Sale or Other Disposition of Common Stock

Subject to the discussion below under the headings "*FATCA*" and "*Backup Withholding, Information Reporting and Other Reporting Requirements,*" a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of the non-U.S. holder's shares of our common stock unless:

- the gain is effectively connected with a trade or business carried on by the non-U.S. holder within the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment or fixed base maintained by such non-U.S. holder);

- the non-U.S. holder is an individual and is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are met; or

- we are or have been a "U.S. real property holding corporation" for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding such disposition or such non-U.S. holder's holding period of our common stock, and, provided that our common stock is regularly traded in an established securities market within the meaning of applicable Treasury Regulations, the non-U.S. holder has held, directly, indirectly, or constructively, at any time during said period, more than 5% of our common stock.

Gain that is effectively connected with the conduct of a trade or business in the United States generally will be subject to U.S. federal income tax on a net income tax basis, at regular U.S. federal income tax rates that apply to U.S. persons. If the non-U.S. holder is a non-U.S. corporation, the branch profits tax described above also may apply to such effectively connected gain. An individual non-U.S. holder who is subject to U.S. federal income tax because the non-U.S. holder was present in the United States for 183 days or more during the year of sale or other disposition of our common stock will be subject to a flat 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the gain derived from such sale or other disposition, which may be offset by certain U.S. source capital losses, if any. We believe that we are not and we do not anticipate becoming a U.S. real property holding corporation for U.S. federal income tax purposes. Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

FATCA

Withholding taxes may be imposed under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including deemed dividends) paid on our common stock, to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial U.S. owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the U.S. governing FATCA may be subject to the reporting rules of that intergovernmental agreement. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we or the applicable withholding agent may treat the entire distribution as a dividend. Although withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations would eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Under certain circumstances, a non-U.S. holder will be eligible for refunds or credits of withholding taxes imposed under FATCA by timely filing a U.S. federal income tax return. Prospective investors should consult their tax advisors regarding the potential application of these withholding provisions.

Backup Withholding, Information Reporting and Other Reporting Requirements

We must report annually to the IRS and to each non-U.S. holder the amount of any distributions paid to, and the tax withheld with respect to, each non-U.S. holder. These reporting requirements apply regardless of whether withholding was reduced or eliminated by an applicable income tax treaty. Copies of this information reporting may also be made available under the provisions of a specific income tax treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

A non-U.S. holder will generally be subject to backup withholding for dividends on our common stock paid to such holder unless such holder certifies under penalties of perjury that, among other things, it is a non-U.S. holder (provided that the payor does not have actual knowledge or reason to know that such holder is a U.S. person) or otherwise establishes an exemption.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or non-U.S., unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Backup withholding is not an additional income tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder generally can be credited against the non-U.S. holder's U.S. federal income tax liability, if any, or refunded, provided that the required information is furnished to the IRS in a timely manner. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

U.S. Federal Estate Tax

Shares of our common stock that are owned or treated as owned by an individual who is not a citizen or resident of the United States (as specially defined for U.S. federal estate tax purposes) at the time of death are considered U.S. situs assets and will be included in the individual's gross estate for U.S. federal estate tax purposes. Such shares, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

The preceding discussion of material U.S. federal income tax considerations and certain U.S. federal estate tax considerations is for information only. It is not legal or tax advice. Prospective investors should consult their tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of our common stock, including the consequences of any proposed changes in applicable laws.

PLAN OF DISTRIBUTION

The Registered Stockholders, and their pledgees, donees, transferees, assignees, or other successors in interest may sell their shares of common stock covered hereby pursuant to brokerage transactions on Nasdaq, or other public exchanges or registered alternative trading venues, at prevailing market prices at any time after the common stock are listed for trading. We are not party to any arrangement with any Registered Stockholder or any broker-dealer with respect to sales of shares of common stock by the Registered Stockholders, except we have engaged the Advisor with respect to certain other matters relating to the registration of our common stock and listing of our common stock, as further described below. As such, we do not anticipate receiving notice as to if and when any Registered Stockholder may, or may not, elect to sell their shares of common stock or the prices at which any such sales may occur, and there can be no assurance that any Registered Stockholders will sell any or all of their shares of common stock covered by this prospectus.

We will not receive any proceeds from the sale of shares of common stock by the Registered Stockholders. We will recognize costs related to this direct listing and our transition to a publicly-traded company consisting of professional fees and other expenses. We will expense these amounts in the period incurred and not deduct these costs from net proceeds to the issuer as they would be in an initial public offering.

On the day that our shares of common stock are initially listed on Nasdaq, Nasdaq will begin accepting, but not executing, pre-opening buy and sell orders and will begin to continuously generate the indicative Current Reference Price on the basis of such accepted orders. The Current Reference Price is calculated each second and, during a 10-minute "Display Only" period, is disseminated, along with other indicative imbalance information, to market participants by Nasdaq on its NOII and BookViewer tools. Following the "Display Only" period, a "Pre-Launch" period begins, during which the Advisor, in its capacity as our financial advisor, must notify Nasdaq that our shares are "ready to trade." Once the Advisor has notified Nasdaq that our shares of common stock are ready to trade, Nasdaq will confirm the Current Reference Price for our shares of common stock, in accordance with Nasdaq rules. If the Advisor then approves proceeding at the Current Reference Price, the applicable orders that have been entered will then be executed at such price and regular trading of our shares of common stock on Nasdaq will commence, subject to Nasdaq conducting validation checks in accordance with Nasdaq rules.

Under Nasdaq rules, the Current Reference Price means: (i) the single price at which the maximum number of orders to buy or sell can be matched; (ii) if there is more than one price at which the maximum number of orders to buy or sell can be matched, then it is the price that minimizes the imbalance between orders to buy or sell (i.e. minimizes the number of shares that would remain unmatched at such price); (iii) if more than one price exists under (ii), then it is the entered price (i.e. the specified price entered in an order by a customer to buy or sell) at which our shares of common stock will remain unmatched (i.e. will not be bought or sold); and (iv) if more than one price exists under (iii), a price determined by Nasdaq in consultation with the Advisor in its capacity as our financial advisor. In the event that more than one price exists under (iii), the Advisor will exercise any consultation rights only to the extent that it can do so consistent with the anti-manipulation provisions of the federal securities laws, including Regulation M, or applicable relief granted thereunder.

In determining the Current Reference Price, Nasdaq's cross algorithms will match orders that have been entered into and accepted by Nasdaq's system. This occurs with respect to a potential Current Reference Price when orders to buy shares of common stock at an entered bid price that is greater than or equal to such potential Current Reference Price are matched with orders to sell a like number of shares of common stock at an entered asking price that is less than or equal to such potential Current Reference Price. To illustrate, as a hypothetical example of the calculation of the Current Reference Price, if Nasdaq's cross algorithms matched all accepted orders as described above, and two limit orders remained — a limit order to buy 500 shares of common stock at an entered bid price of $10.01 per share and a limit order to sell 200 shares of common stock at an entered asking price of $10.00 per share — the Current Reference Price would be selected as follows:

- Under clause (i), if the Current Reference Price is $10.00, then the maximum number of additional shares that can be matched is 200. If the Current Reference Price is $10.01, then the Maximum number of additional shares that can be matched is also 200, which means that the same maximum number of additional shares would be matched at the price of either $10.00 or $10.01.

- Because more than one price under clause (i) exists, under clause (ii), the Current Reference Price would be the price that minimizes the imbalance between orders to buy or sell (i.e., minimizes the number of shares that would remain unmatched at such price). Selecting either $10.00 or $10.01 as the Current Reference Price would create the same imbalance in the limit orders that cannot be matched, because at either price 300 shares would not be matched.

- Because more than one price under clause (ii) exists, under clause (iii), the Current Reference Price would be the entered price at which orders for shares of common stock at such entered price will remain unmatched. In such case, choosing $10.01 would cause 300 shares of the 500-share limit order with the entered price of $10.01 to remain unmatched, compared to choosing $10.00, where all 200 shares of the limit order with the entered price of $10.00 would be matched, and no shares at such entered price remain unmatched. Thus, Nasdaq would select $10.01 as the Current Reference Price, because orders for shares at such entered price will remain unmatched. The above example (including the prices) is provided solely by way of illustration.

The Advisor will determine when our shares of common stock are ready to trade and approve proceeding at the Current Reference Price primarily based on considerations of volume, timing and price. In particular, the Advisor will determine, based primarily on pre-opening buy and sell orders, when a reasonable amount of volume will cross on the opening trade such that sufficient price discovery has been made to open trading at the Current Reference Price. If the Advisor does not approve proceeding at the Current Reference Price (for example, due to the absence of adequate pre-opening buy and sell interest), the Advisor will request that Nasdaq delay the opening until such a time that sufficient price discovery has been made to ensure that a reasonable amount of volume crosses on the opening trade. Further, in the highly unlikely event that Nasdaq consults with the Advisor as described in clause (iv) of the definition of Current Reference Price, the Advisor would request that Nasdaq delay the opening to ensure a single opening price within clauses (i), (ii) or (iii) of the definition of the Current Reference Price. Under Nasdaq rules, in the event of such delay, prior to terminating such delay, there will be a 10-minute "Display Only" period during which market participants may enter quotes and orders in shares of our common stock in Nasdaq systems. In addition, beginning at 4:00 a.m., market participants may enter orders in shares of our common stock on Nasdaq. Such orders will be accepted and entered into the system. After the conclusion of the 10-minute "Display Only" period, our common stock will enter a "Pre-Launch" period of indeterminate duration. The "Pre-Launch" period will end and shares of our common stock will be released for trading by Nasdaq when certain conditions are met, including Nasdaq's receipt of notice from the Advisor that our shares of common stock are ready to trade, after which the Nasdaq system will calculate the Current Reference Price at that time and display it to the Advisor. If the Advisor then approves proceeding, the Nasdaq system will conduct certain validation checks. The Advisor, with concurrence of Nasdaq, may determine at any point during the delay process up through the conclusion of the "Pre-Launch" period to postpone and reschedule the Direct Listing. The Registered Stockholders will not be involved in Nasdaq's price-setting mechanism and will not coordinate or be in communication with the Advisor including with respect to any decision by the Advisor to delay or proceed with trading; the Advisor will be issued of our common stock in connection with and at the time of the Direct Listing; such shares are not registered further to this prospectus and the Advisor is not a Registered Stockholder. While we will not be involved in Nasdaq's price-setting mechanism, it is expected that we may coordinate or communicate with the Advisor with respect to any decision to delay or proceed with trading.

Similar to a Nasdaq-listed firm-commitment underwritten initial public offering, in connection with the listing of our shares of common stock, buyers and sellers who have subscribed will have access to Nasdaq's Order Imbalance Indicator, or the Net Order Imbalance Indicator, a widely available, subscription-based data feed, prior to submitting buy or sell orders. Nasdaq's electronic trading platform simulates auctions every second to calculate a Current Reference Price, the number of shares of common stock that can be paired off the Current Reference Price, the number of shares of common stock that would remain unexecuted at the Current Reference Price and whether a buy-side or sell-side imbalance exists, or whether there is no imbalance, to disseminate that information continuously to buyers and sellers via the Net Order Imbalance Indicator data feed.

However, because this is not an initial public offering being conducted on a firm-commitment underwritten basis, there will be no traditional book building process (that is, an organized process pursuant to which buy and sell interest is coordinated in advance to some prescribed level – the "book"). Moreover, prior to the opening trade, there will not be a price at which underwriters initially sold shares of common stock to the public, as there would be in a firm-commitment underwritten initial public offering. The lack of an initial public offering price could impact the range of buy and sell orders collected by Nasdaq from various broker-dealers. Consequently, the public price of our shares of common stock may be more volatile than in an initial public offering underwritten on a firm-commitment basis and could, upon being listed on Nasdaq, decline significantly and rapidly.

In addition, to list on Nasdaq, we are also required to have at least four registered and active market makers. We expect that the Advisor will act as a registered and active market maker and will engage other market makers.

In addition to sales made pursuant to this prospectus, the shares of common stock covered by this prospectus may be sold by the Registered Stockholders in private transactions exempt from the registration requirements of the Securities Act. Under the securities laws of some states, shares of common stock may be sold in such states only through registered or licensed brokers or dealers.

A Registered Stockholder may from time to time transfer, distribute (including distributions in kind by Registered Stockholders that are investment funds), pledge, assign, or grant a security interest in some or all the shares of common stock owned by it and, if it defaults in the performance of its secured obligations, the transferees, distributees, pledgees, assignees, or secured parties may offer and sell the shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under applicable provisions of the Securities Act amending the list of the Registered Stockholders to include the transferee, distributee, pledgee, assignee, or other successors in interest as Registered Stockholders under this prospectus. The Registered Stockholders also may transfer the shares in other circumstances, in which case the transferees, distributes, pledgees, or other successors in interest will be the registered beneficial owners for purposes of this prospectus.

A Registered Stockholder that is an entity may elect to make an in-kind distribution of common stock to its members, partners, or stockholders pursuant to the registration statement of which this prospectus forms a part by delivering a prospectus.

If any of the Registered Stockholders utilize a broker-dealer in the sale of the shares of common stock being offered by this prospectus, such broker-dealer may receive commissions in the form of discounts, concessions or commissions from such Registered Stockholder or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal.

We have engaged the Advisor, RBW Capital Partners LLC, as our financial advisor to advise and assist us with respect to certain matters relating to the Direct Listing. The services expected to be performed by the Advisor will include providing advice and assistance with respect to defining objectives, analyzing, structuring and planning the Direct Listing and developing and assisting with our investor communication strategy in relation to the Direct Listing. In connection with its engagement as our financial advisor, the Advisor will be entitled to a fee of $250,000 upon the successful consummation of the Direct Listing. The Advisor will also be paid up to $100,000 for fees and expenses of legal counsel and other out-of-pocket expenses. All fees to be paid to the Advisor are entirely contingent on the successful completion of the Direct Listing. We have also agreed to issue the Advisor 30,000 shares of common stock in connection with and at the time of the Direct Listing; such shares are not registered further to this prospectus and the Advisor is not a Registered Stockholder.

We have also engaged RBW Capital Partners LLC as a placement agent, all securities offered through Dawson James Securities, Inc., for the sale of shares of our common stock to unaffiliated third parties in a private placement at a price of $16.00 per share, such issuance to occur prior to the date of this Prospectus. We will pay RBW Capital Partners LLC a placement fee equal to 12% of the total gross dollar amount of the capital that is raised in the private placement by RBW Capital Partners LLC. To date, we have agreements with investors to sell 624,999 shares of common stock at the private placement price of $16.00 per share for gross proceeds of approximately $10,000,000. All 624,999 shares of common stock are being registered by means of this registration statement.

The Advisor will not be engaged to otherwise facilitate or coordinate price discovery activities or the solicitation and/or sales of shares of our common stock in consultation with us, and will not be permitted to, and will not be instructed by us to, plan or actively participate in any investor education activities, except as described herein.

Prior to the financial advisory services provided by the Advisor to us in connection with the listing of our securities, neither the Advisor nor any affiliates of the Advisor have provided services of any kind to us.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Manatt, Phelps & Phillips LLP, Costa Mesa, California

EXPERTS

The consolidated financial statements of NeOnc Technologies Holdings, Inc as of December 31, 2024 and 2023 and for the years then ended, appearing in this prospectus have been audited by Marcum LLP, independent registered public accounting firm, as set forth in their report thereon, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, appearing elsewhere in this prospectus, and are included in reliance on the report of such firm given upon their authority as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is http://www.sec.gov.

On the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available at http://www.sec.gov.

We also maintain a website at www.NeOncco.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

NEONC TECHNOLOGIES HOLDINGS, INC.
CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

NEONC TECHNOLOGIES HOLDINGS, INC.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
NeOnc Technologies Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of NeOnc Technologies Holdings, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, changes in shareholders' deficit, and cash flows for each of the two years in the period ended December 31 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit**s** to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit**s** we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2022.

Philadelphia, PA
February 26, 2025

NEONC TECHNOLOGIES HOLDINGS, INC.
Consolidated Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current Assets		
Cash	$ 64,893	$ 31,862
Deferred offering costs	1,071,947	970,582
Debt issuance costs - current	671,804	-
Prepaid expenses and other	386,559	262,932
Total Current Assets	2,195,203	1,265,376
Non-Current Assets		
Debt issuance costs – net of current portion	1,198,512	
Right of use asset - operating lease	23,526	-
Total Assets	**$ 3,417,241**	**$ 1,265,376**
Liabilities and Shareholders' Deficit		
Current Liabilities		
Accounts payable	$ 2,893,079	$ 1,565,968
Accounts payable - related parties	628,277	1,390,961
Litigation settlement payable	4,641,250	4,600,000
Accrued compensation	734,874	1,091,243
Bridge loan - related party	-	6,555,457
Lease liability, current	24,722	-
Note payable - related party, at fair value	-	50,000
Total Current Liabilities	8,927,202	15,253,629
Commitments and contingencies		
Shareholders' Deficit:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; no shares were issued and outstanding as of December 31, 2024 and 2023, respectively	-	-
Common stock, $0.0001 par value, 100,000,000 shares authorized; 18,090,526 and 16,560,000 shares issued and outstanding as of December 31, 2024 and 2023, respectively	1,809	1,656
Additional paid in capital	45,101,675	24,720,072
Accumulated deficit	(50,608,445)	(38,709,981)
Total Shareholders' Deficit	(5,504,961)	(13,988,253)
Total Liabilities and Shareholders' Deficit	**$ 3,417,241**	**$ 1,265,376**

See accompanying notes to the consolidated financial statements.

NEONC TECHNOLOGIES HOLDINGS, INC.
Consolidated Statements of Operations

	For the For the Year Ended December 31,	
	2024	**2023**
Revenues:		
Revenue	$ 83,000	$ 70,462
Operating Expenses:		
Research and development	3,045,239	1,534,114
Legal and professional	2,000,623	1,907,687
General and administrative	1,638,410	1,488,557
Advisory fee	500,000	500,000
Litigation settlement expense, net	41,250	4,100,000
License expense	-	2,737,773
Total Operating Expenses	7,225,522	12,268,132
Loss From Operations	(7,142,522)	(12,197,669)
Other Income and Expense:		
Interest income	16,133	-
Amortization of debt issuance costs	(145,097)	-
Interest expense - related parties	(2,557,055)	(2,723,396)
Loss on extinguishment of Bridge loan – related party	(2,069,923)	-
Net Loss	$ (11,898,464)	$ (14,921,065)
Loss per share:		
Net loss per share - basic and diluted	$ (0.69)	$ (1.02)
Weighted average number of common shares outstanding during the period - basic and diluted	17,342,755	14,681,111

See accompanying notes to the consolidated financial statements.

NEONC TECHNOLOGIES HOLDINGS, INC.
Consolidated Statements of Changes in Shareholders' Deficit

	Common Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance - January 1, 2023	10,500,000	$ 1,050	$ 22,212,455	$ (23,788,916)	$ (1,575,411)
Common stock issued for share exchange	5,500,000	550	(100)	-	450
Common stock issued for license fee	560,000	56	2,507,717	-	2,507,773
Net loss	-	-	-	(14,921,065)	(14,921,065)
Balance - December 31, 2023	16,560,000	$ 1,656	$ 24,720,072	$ (38,709,981)	$ (13,988,253)
Balance - January 1, 2024	16,560,000	$ 1,656	$ 24,720,072	$ (38,709,981)	$ (13,988,253)
Sale of common stock, net of costs	384,646	38	4,615,751	-	4,615,789
Common stock issued for bridge loan conversion	979,039	98	11,748,366	-	11,748,464
Common stock issued for settlement of vendor payable	127,258	13	1,527,077	-	1,527,090
Common stock issued for settlement of accrued compensation	34,375	3	412,497	-	412,500
Common stock issued for note payable conversion	5,208	1	62,499	-	62,500
Warrants issued for line of credit	-	-	2,015,413	-	2,015,413
Net loss	-	-	-	(11,898,464)	(11,898,464)
Balance - December 31, 2024	18,090,526	$ 1,809	$ 45,101,675	$ (50,608,445)	$ (5,504,961)

See accompanying notes to the consolidated financial statements.

NEONC TECHNOLOGIES HOLDINGS, INC.
Consolidated Statements of Cash Flows

	For the For the Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (11,898,464)	$ (14,921,065)
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	1,997,775
Accretion of original issue discount on bridge loan - related party	2,557,055	2,721,747
Amortization of right to use asset	245,945	-
Amortization of debt issuance costs	145,097	-
Common stock issued for license fee, at fair value	-	2,507,773
Litigation settlement expense, net	-	4,100,000
Write off of deferred offering costs	703,796	-
Loss on extinguishment of bridge loan	2,069,923	-
Changes in operating assets and liabilities:		
Prepaid expenses	(123,627)	(24,774)
Accrued compensation	56,131	678,743
Lease liability	(244,748)	-
Accounts payable and accounts payable - related parties	1,798,583	1,059,789
Net cash used in operating activities	(4,213,916)	(1,880,012)
Cash flows from financing activities:		
Proceeds from related party loans	892,028	3,507,972
Repayment of related party loans	(791,077)	(2,135,277)
Deferred offering costs	(469,793)	(94,569)
Proceeds from sale of common stock, net	4,615,789	450
Net cash provided by financing activities	4,246,947	1,278,576
Net increase (decrease) in cash	33,031	(601,436)
Cash - beginning of period	31,862	633,298
Cash - end of period	$ 64,893	$ 31,862
Supplemental disclosure of non-cash financing activities:		
Original issue discount on bridge loan - related party	$ 1,368,421	$ 5,968,987
Increase in bridge loan payable - prepaid and deferred offering costs paid directly by bridge loan provider on behalf of the Company	$ 31,346	$ 463,241
Conversion of bridge loan to common stock	$ 11,748,464	$ -
Conversion of accrued compensation to common stock	$ 412,500	$ -
Conversion of accounts payable to common stock	$ 1,527,090	$ -
Warrants issued for line of credit commitment	$ 2,015,413	$ -
Right of use asset at lease commencement	$ 536,605	$ -
Decrease in right of use asset and liability from lease amendment	$ 267,134	$ -
Deferred offering costs within accounts payable	$ 325,000	$ 475,000

See accompanying notes to the 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").

In December 2022, the Company signed a Letter of Intent ("LOI") with an investment advisory firm AFH Holdings and Advisory, LLC ("AFH") to create a newly formed corporation called NeOnc Technologies Holding Company, Inc. ("NTHI") to facilitate future fundraising transactions (see Note 3). On April 7, 2023, the Company entered into share exchange agreements whereby all of the common shareholders of NTI exchanged all of their stock in NTI for a total of 10,500,000 shares of NTHI common stock in the share exchange ("Share Exchange"). At the consummation of the Share Exchange transaction, AFH and its affiliated entities, individuals, or assignees owned an aggregate of 34.4% (5,500,000 shares) of the fully diluted issued and outstanding common shares of the Company. For a period of two years after an IPO or direct listing, AFH will also act as an investment advisor in future financing transactions. Except for the completed exchange transaction described above, there is no assurance of consummation of any of the transactions contemplated by the LOI. There can be no assurance that a fundraising transaction can be completed.

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 December 31, 2024, the Company had cash totaling $64,893. For the year ended December 31, 2024, the Company incurred a net loss of $11,898,464 and has an accumulated deficit of $50,608,445 at December 31, 2024. The Company has financed its working capital requirements to date primarily through the issuance of common stock, preferred stock, shareholder loans and a short-term bridge loan.

As of December 31, 2024, the Company is preparing for a direct listing on a national exchange ("DL") of its common stock, however, there is no certainty that the DL can be completed. 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 will need to raise additional funding to complete the development of its products and commence the market launch, assuming regulatory approval is obtained. 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.

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. As of December 31, 2024, the broker dealer has closed on commitments from investors of $10,000,000 to purchase common stock at $16 per share which as of December 31, 2024 are being held in escrow until the Company has an effective registration statement on file with the SEC. The Company is in the process of filing with the SEC for a registration statement, however no assurance can be given that the Company will complete the process.

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

These accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), including all pronouncements of the U.S. Securities and Exchange Commission applicable to annual financial statements.

Principles of consolidation

The accompanying consolidated financial statements and related notes to the 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

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 December 31, 2024 and 2023, the Company did not have any cash equivalents.

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 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 are expected to be recognized in equity upon the completion of the securities offering. 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.

Notes payable

The Company has elected to account for notes payable to a shareholder using the fair value option in accordance with the guidance contained in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 825-10-25. The fair value option provides an option to elect fair value as an alternative measurement for selected financial assets, financial liabilities, unrecognized firm commitments, and written loan commitments. See Note 4 for additional information.

The Original Issue Discount ("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.

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 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.

Licenses of intellectual property ("IP")

The Company evaluates intellectual property licensing agreements in accordance with ASC 808, *Collaborative Arrangements*. If the license to the Company's IP is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from consideration allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the licenses. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measurement of performance and related revenue recognition. Determining the revenue recognition of IP licenses requires significant judgment and is discussed in further detail for each of the Company's license and collaboration agreements in Note 5.

At the inception of each arrangement that includes development or regulatory milestone payments, the Company evaluates the probability of reaching the milestones. The Company estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur in the future, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's, such as regulatory approvals, are not considered probable of being achieved until those approvals are received.

Therefore, revenue recognized is constrained as management cannot assert that a revenue reversal would not be possible. The transaction price is then allocated to each performance obligation on a residual basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achieving such development milestones and any related constraints. The Company adjusts its estimate of the overall transaction price if necessary. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the adjustment period. To date, the Company has not recognized any milestone revenue resulting from any of its agreements.

When performance obligations are not required of the Company or following the completion of the performance obligation period, such amounts are recognized as revenue upon transfer of control of the goods or services to the customer. Generally, all amounts received or due other than sales-based milestones and royalties are classified as license and collaboration revenue.

Sales-based milestones and royalties will be recognized as royalty revenue at the later of when the related sales occur or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Revenue

The Company recognized point-in-time revenue of $83,000 and $70,462 for the years ended December 31, 2024 and 2023, 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.

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 year ended December 31, 2024, there are potentially dilutive securities outstanding of 312,500 warrants and 3,060,000 restricted stock units, which are not included in the diluted net loss per share calculation since their effect is anti-dilutive.

For the year ended December 31, 2023, there are no potentially dilutive securities outstanding.

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. 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 carryforwards. 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 December 31, 2024 and 2023 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 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 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.

NTI agreed to affect a share exchange with a special purpose entity (NTHI) substantially owned by AFH, whereby AFH retained approximately 34.4% of the shares of the combined entity after the Share Exchange. The Share Exchange occurred on April 7, 2024 (see Note 1). The Company has accounted for the Share Exchange transaction as a reverse recapitalization with NTI as the accounting acquirer. At the time of the Share Exchange, NTHI had no operations and did not meet the definition of a "business" as defined under U.S. GAAP. Since NTI is the accounting acquirer, its historical financial statements became the Company's historical financial statements, and such assets and liabilities continued to be recorded at their historical carrying values. The historical common and preferred stock of NTI have been retroactively adjusted for all periods presented to reflect the conversion of preferred stock of NTI to common stock of NTI prior to the Share Exchange and the exchange ratio from the Share Exchange (0.1465 shares of common stock of NTHI for 1 share of common stock of NTI).

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 2% fee to be paid in equal monthly installments for one year. AFH was paid a fee of $500,000 for the amendment and the fee is included in advisory fee expense in the December 31, 2024 consolidated statement of operations. For the year ended December 31, 2023, AFH earned a fee of $500,000 for its advisory work, which is included in advisory fee expense in the consolidated statement of operations.

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. Further to the advisory arrangement, AFH shall be paid an aggregate fee in an amount equal to 2% of the post-money valuation of the Company immediately after the effective time of the public offering.

Further, AFH agreed to advance costs of up to $500,000 to the Company for fees paid to service providers related to a financing transaction and were repaid out of proceeds from the short-term loan provided to the company by HCWG LLC. As of December 31, 2024 and 2023, no amounts were outstanding further to the agreement.

Transactions with USC

On March 9, 2009, the Company entered into an exclusive license agreement with USC, pursuant to which USC granted a license to use certain patented technology related to the use of monoterpenes as a solvent, specifically *perillyl alcohol*. This technology is the basis of the current products under development by the Company. The Company granted USC 117,236 shares of common stock in exchange for the license. Additionally, the Company is required to pay an annual patent maintenance cost of $20,000 and a 2% royalty on all net sales, as defined. The Company has not incurred any royalties through December 31, 2024, since no products are being sold using such technology.

On April 5, 2023, NeOnc amended the license agreement with USC dated March 9, 2009 (“Amended Agreement”) to include all of the worldwide patents developed by the Company related to the biotechnology under development by the Company. The Amended Agreement also had added the Company as an additional licensee. In addition, the Amended Agreement contained the following provisions:

- The Company issued 560,000 shares of common stock of NTHI on October 11, 2023 to USC. The Company had not issued such shares within 15 days of the effective date of the Amended Agreement, as required by the Amended Agreement, and received a waiver from USC to forgo any material breach of the Amended Agreement for such failures. The fair value of the common stock was issued for the license was valued based upon the pricing from a recent financing round adjusted for the dilution from the Share Exchange. The Company recorded license expense in the amount of $2,507,773 in the accompanying consolidated statement of operations equal to the estimated fair value of the shares to be issued to USC.

- The Company will pay USC 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.

- The Company will assume responsibility for patent-related costs.

On November 19, 2023, the Company and USC entered into an Amended and Restated Exclusive License Agreement (the “Restated Agreement”). The Restated Agreement addressed and clarified certain reporting obligations of the Company under the license agreement with USC dated March 9, 2009 (“Amended Agreement”), and addressed certain financial and other obligations, defaults, and deficiencies in connection with the Company’s performance under the Amended Agreement. In connection with the Restated Agreement, the Company recorded additional license fees in the amount of $230,000 to cure deficiencies in the March 9, 2009 agreement related to unpaid sub-license fees which is recorded as license fees in the accompanying consolidated statement of operations during the year ended December 31, 2023. On July 17, 2024 the restated agreement was amended to extend the payment date of the $230,000 to the earlier of September 1, 2025 or within five days of a public offering. Such payable is included in accounts payable - related parties in the accompanying consolidated balance sheets as of December 31, 2023 and as of December 31, 2024.

The Company also utilizes laboratory services from USC. The Company has incurred approximately $461,000 and $326,000 of research and development-related costs from USC for the years ended December 31, 2024 and 2023, respectively. The Company incurred approximately $20,000 and $41,000 of patent maintenance and legal-related expenses for the years ended December 31, 2024 and 2023, respectively. At December 31, 2024 and 2024, the Company owes USC $272,328 and $277,344 respectively, which is included in accounts payable - related parties in the accompanying consolidated balance sheets.

From time to time prior to January 1, 2023, the Company has been unable to reimburse USC for such costs. Therefore, USC deducted certain amounts due to the Chairman for compensation for his services as faculty at USC to satisfy the amounts due from the Company to USC. In 2024, the Company reached an agreement to convert a portion of amount owed as of such date in the amount of $1,377,096 to 114,758 common shares at $12 per share (the share price of the most recent financing round) and is recorded as a portion of the common stock issued for settlement of vendor payable in the Consolidated Statements of Changes in Shareholders' Deficit for December 31, 2024.

Accrued compensation

The Company has incurred $785,996 and $798,743 for the years ended December 31, 2024 and 2023, respectively for compensation to the management team, Chairman, COO and CFO, all of whom are shareholders (the "Employees"). This compensation is recorded in the consolidated statement of operations as part of general and administrative expenses. On June 30, 2024, the Employees converted $412,500 of their accrued compensation into 34,375 shares of common stock at $12.00 per share (the share price of the most recent financing round). On June 30, 2024 and in light of the current macro-economic funding environment, the Board of Directors of the Company resolved to reverse their 2023 decision to provide bonuses to certain members of management, and accordingly $251,576 was recorded as a reduction of compensation expense in the year ended December 31, 2024. The amount accrued for the management team, including related payroll taxes, was $734,874 and $1,091,243 as of December 31, 2024 and 2023, respectively.

NOTE 4 – RELATED PARTY LOANS PAYABLE

Note Payable

In 2023, the Company issued $50,000 of convertible notes to a shareholder due August 30, 2024 ("Note"). The Note bears interest at 2% per annum. This Note and all accrued interest thereon is convertible, at the option of the noteholder, into the class and series of equity securities ("Conversion Stock") that is sold by the Company in its next issuance of equity securities in a Financing Transaction (as defined below), consummated after the issuance date of the note. A Financing Transaction is a sale, other than an initial public offering ("IPO"), of equity securities by the Company to investors for cash. The Financing Transaction does not include the issuance of stock, options, or warrants to service providers in connection with the rendition of such services or to third parties in connection with the contribution of non-cash assets to the Company. The number of shares of Conversion Stock to be issued to the noteholder upon such conversion shall be equal to the quotient obtained by dividing (i) the entire principal amount of this Note plus accrued interest by (ii) the Financing Transaction Conversion Price (as defined below). The Financing Transaction Conversion Price shall be equal to seventy-five percent (75%) of the price paid for one share of Conversion Stock by the investors in the Financing Transaction. The entire principal amount of and accrued interest on this Note shall automatically be converted, without further action on the part of the noteholder or the Company, into the class and series of stock issued by the Company, at the closing of an IPO. The number of shares of stock to be issued to the holder upon such conversion shall be equal to the quotient obtained by dividing (i) the entire principal amount of this Note plus accrued interest by (ii) the IPO Conversion Price (as defined in the Note). On January 31, 2024, the Note was assigned to HCWG LLC (an entity owned by certain shareholders, directors, and officers of the Company). Additionally, as part of the assignment, the Note was amended to increase the principal balance to $62,500, amend the maturity date to the date that the Company completes its initial public offering, and the Note was subordinated to the Bridge Loan (defined below).

The Company has elected to account for the Note under the fair value option (See Note 2). The fair value of the Note (classified within Level 3 of the fair value hierarchy) approximated the face amount of $50,000 at both December 31, 2024 and 2023. As such, no adjustment was made to the carrying value of the Note.

On June 30, 2024, the Company and noteholder entered an agreement with HCWG LLC to assume the Note. As part of the agreement, an outstanding interest of $2,250 at the time of the assignment, plus an additional interest charge of $10,250 upon assignment of the loan, was converted to principal, for a total principal balance of $62,500. The additional interest of $10,250 is recorded as an interest expense in the accompanying consolidated statement of operations. On July 23, 2024, the note was converted into 5,208 shares of common stock.

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 at December 4, 2023. 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 December 31, 2024 and 2023, the Company had received under the Bridge Loan an aggregate of $7,337,408 and $5,968,987, respectively. 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 year ended December 31, 2024 and 2023, amounted to $2,557,055 and 2,721,747, respectively, and are included in interest expense in the accompanying consolidated statement of operations. Summary of the bridge loan activity for the years ended December 31, 2024 and 2023, respectively, is as follows:

	For the year ended December 31, 2024	For the year ended December 31, 2023
Bridge loan - rollforward		
Principal outstanding	$ 9,802,697	$ -
Borrowings	1,368,422	5,968,987
OID	1,368,422	5,968,987
Repayments	(791,077)	(2,135,277)
Total principal outstanding before conversion	11,748,464	9,802,697
Conversion to common stock	(11,748,464)	-
Principal; outstanding	$ -	$ 9,802,697

	For the year ended December 31, 2023
Bridge loan	
Principal Outstanding	$ 9,802,697
Less: Unrecognized OID	(3,247,240)
Total:	$ 6,555,457

On June 14, 2024, the Company reached an agreement with HCWG LLC to convert the outstanding principal and interest on the Bridge Loan totaling $11,748,464 to 979,039 shares of common stock at $12 per share. The fair value of the common stock issued for the conversions was valued based upon the pricing from a recent financing round which was $12 a share. The difference between the carrying value of the debt as of the date of the extinguishment of $9,678,541 and the fair value of the shares issued to settle to the debt as of the date of the extinguishment of $11,748,464 is recorded as a loss on extinguishment. 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 consolidated balance sheet at December 31, 2024.

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. The Company recorded lease expense of $245,944 and $0 during the year ended December 31, 2024, and 2023, respectively, within general and administrative expenses on the consolidated statements of operations. Cash paid for amounts included in the measurement of lease liability was $275,000 and $0, respectively, during the year ended December 31, 2024, and 2023, 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. Future lease payments under non-cancellable operating leases are detailed as follows:

	December 31, 2024
Future Operating Lease Payments	
2025	$ 25,000
Total lease payments	25,000
Less imputed interest	(278)
Present value of lease payments	24,722
Less: current portion	(24,722)
Lease liability, net of current portion	$ -

Note 6 – Common and preferred Stock

NeOnc Technologies Holdings, Inc.

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. See Note 1 for discussion of the issuance of common shares pursuant to the Share Exchange. As of December 31, 2024, no preferred shares have been issued. During the year ended December 31, 2024, the Company sold 384,646 shares of common stock at a price of $12 per share for gross proceeds of $4,615,789.

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.

NOTE 7 – COLLABORATION AND LICENSE AGREEMENTS

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").

Pursuant to the terms of the Agreement, OEP will bear the cost of, and be responsible for, among other things, developing pre-clinical materials, conducting the clinical studies and other developmental activities for the Licensed Products, and bear the cost of and be responsible for, among other things, preparing and filing applications for regulatory approval in the Territory and for commercializing Licensed Products in the Territory, and will use commercially reasonable efforts to commercialize Licensed Products and obtain pricing approval for Licensed Products in the Territory.

As part of the Agreement, OEP agreed to compensate the Company as follows:

- Reimbursement of the costs related to an Investigational New Drug Application filing with the FDA, which was received in 2014 and 2016.
- $200,000 paid upon signing the agreement in 2013, and
- Specified clinical milestone payments of up to $1,900,000. The Company received a milestone payment of $300,000 during the year ended December 31, 2020 upon completion of the first phase of clinical trials. The Company has received no other clinical milestone payments through December 31, 2024.

The Company has determined that the arrangement is within the scope of ASC 808, *Collaborative Arrangements,* as both NeOnc and OEP are active participants in the activity, and they are both exposed to significant risks and rewards dependent on the commercial success of the activity. The Company has determined two performance obligations under the arrangement – the scientific development phase and the clinical trial evaluation phase. The Company had deferred recognition of revenue on the $200,000 paid upon signing the agreement and the $300,000 milestone payment received in 2020 as the clinical trial evaluation phase had not yet been completed at that time.

If, after completion of Phase II clinical trials, the Company enters into one or more agreements to license any of the patent rights or Licensed Products to a party other than OEP, then the Company will reimburse specified amounts based upon amounts paid by OEP to the Company, not to exceed $3,000,000 to be paid as various milestones are met.

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. As part of the settlement, the license was terminated and all rights in the underlying licensed territories have been returned to the Company. The Company recognized $4,000,000 as a litigation settlement expense in the accompanying consolidated statement of operations during the year ended December 31, 2023, and had recorded an associated litigation settlement payable in the accompanying consolidated balance sheets as of December 31, 2024 and 2023.

License Agreement – Neucen Biomedical Co., Ltd.

On December 5, 2015, the Company entered into a license agreement with Neucen Biomedical Co., Ltd. ("NB"), a shareholder of the Company, in which NeOnc will license to NB the right to commercialize the Company's drug NEO212, a conjugate of perillyl alcohol and temozolomide ("NB Licensed Product") in the territories specified in the license agreement ("NB Territory").

Pursuant to the terms of the Agreement, NB will bear the cost of, and be responsible for, among other things, developing pre-clinical materials, conducting the clinical studies and other developmental activities for the NB Licensed Products, and bear the cost of, and be responsible for, among other things, preparing and filing applications for regulatory approval in the NB Territory and for commercializing NB Licensed Products in the NB Territory, and obtain pricing approval for NB Licensed Products in the NB Territory.

NB must pay the Company tiered royalties of 1-5% on net sales of NB Licensed Products in the NB Territory. The Company received no sales milestones or royalties through December 31, 2024, as no commercialized products are using such technology.

In June 2023, NB and NTHI mutually agreed to terminate this license agreement, and no consideration was paid or received related to such termination.

Note 8 – 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 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 years ended December 31, 2024 and 2023, respectively.

	For the Year Ended December 31,	
	2024	**2023**
Revenues	$ 83,000	$ 70,462
Less: Significant and other segment expenses:		
NEO100	1,200,624	702,226
NEO100-02	320,987	-
NEO212	870,634	279,859
Pediatric	191,593	169,777
Laboratory	460,559	326,272
Other	841	55,980
Total clinical trial expense	3,045,238	1,534,114
Legal and accounting	1,178,812	1,907,687
Offering costs	821,812	-
Employee expenses	686,131	798,743
Advisory services	500,000	500,000
Lease amortization	245,944	-
Advertising	349,278	141,109
General and administrative expense	357,057	550,354
Litigation settlement expense, net	41,250	4,100,000
License expense	-	2,737,773
Interest expense - related parties and loss on extinguishment of bridge loan	4,626,978	2,721,747
Amortization expense	145,097	-
Interest income	(16,133)	-
Net loss	$ (11,898,464)	$ (14,921,065)

NOTE 9 – 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.

In January and February 2024, 2,460,000 and 200,000, respectively, restricted stock units ("RSUs") were granted to the executive officers and directors further to the 2023 Plan as described above. Of the total RSUs granted 1,686,667 vest 100% seven months from the date that the Company lists on a national exchange, 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 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.

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 the Board of Directors were canceled. These granted RSUs vest seven months from the effective date the Company lists on a national exchange. As of December 31, 2024, 380,000 common shares remain unissued in the 2023 Plan.

Since the terms of the grants are not fixed due to the uncertainty of the timing and completion of a listing on a national exchange as of December 31, 2024, the RSU's are not considered issued and outstanding, and no expense related to such instruments is recognized.

NOTE 10 – COMMITMENTS AND CONTINGENCIES

Contingent Fee Arrangements

Placement Agent

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 expires 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.

During the year ended December 31, 2024, we entered into agreements with investors to sell 624,999 shares of common stock at the private placement price of $16.00 per share for gross proceeds of approximately $10,000,000 (the "Private Placement") which are currently being held in escrow until the Company has an effective registration statement on file with the SEC. In connection with the Private Placement, the Company incurred placement agent fees from Broker of $235,000 of which $225,000 is payable upon the release of the Private Placement funds from escrow. Such amounts are recorded within deferred offering costs on the consolidated balance sheet at December 31, 2024.

On January 29, 2025, the Company amended the agreement with RBW Capital Partners LLC, a division of Dawson James Securities, Inc., increasing the placement fee to 12% from 8% of the gross proceeds, and eliminated the 1% non-accountable expense fee.

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 fee and expenses of legal counsel in the amount of $100,000 is included in accounts payable and deferred offering costs in the accompanying consolidated balance sheets as of December 31, 2024. The agreement expired on January 3, 2024, and was amended and restated on January 23, 2025 to extend the term for another six months through July 23, 2025.

During the year ended December 31, 2023, the Company incurred $475,000 in fees with service providers which were payable upon completion of a previous planned offering, and are included in accounts payable on the December 31, 2023 consolidated balance sheet. As a result of the termination of the previous planned offering during the year ended December 31, 2024, such amounts became immediately payable and are no longer payable contingent on completion of a planned offering.

Deferred Offering Costs

As of December 31, 2023, the Company had recorded deferred offering costs of $970,582 related to a previous planned offering. During the year ended December 31, 2024, the Company terminated the previous planned offering and determined that some of those costs no longer met the criteria for capitalization as they were specific to the previous planned offering. As a result, the Company wrote off $703,796 of such costs, which was recorded within legal and professional expense on the consolidated statement of operations for the year ended December 31, 2024. Total deferred costs relating to the Private Placement and direct listing at December 31, 2024 totaled $225,000 and are recorded as deferred offering costs on the consolidated balance sheet at December 31, 2024.

Line of Credit Commitment

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 December 31, 2024.

In connection with the agreement, the Company issued HCWG five-year warrants to purchase up to 312,500 shares of our common stock at a per-share exercise price of $12.00. These warrants expire on October 23, 2029. As of December 31, 2024, there were 312,500 warrants issued, outstanding and fully vested.

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 consolidated statement of stockholders' equity for the year ended December 31, 2024, and as debt issuance costs on the balance sheet. At December 31, 2024, unamortized debt issuance costs total $1,870,316 on the balance sheet.

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 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 Company cannot 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.

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 December 31, 2024 and 2023, the Company had no liabilities recorded for loss contingencies, except as below.

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 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 2023.

On March 31, 2024, a 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, therefore an additional $16,250 of interest expense is recognized in the accompanying consolidated statement of operations during the year ended December 31, 2024.

NOTE 11 - INCOME TAXES

The Company has no significant current income taxes due because of the losses generated each year.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and those used for income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. In accordance with ASC 740, the Company recorded a valuation allowance to fully offset the gross deferred tax asset because it is not "more likely than not" that the Company will realize future benefits associated with these deferred tax assets at December 31, 2024 and 2023. The valuation allowance increased by approximately $2,700,000 and $4,200,000 for the years ended December 31, 2024 and 2023, respectively.

Significant components of the Company's deferred tax assets at December 31, 2024 and 2023 as follows:

	For the For the Year Ended December 31,	
	2024	**2023**
Deferred tax assets:		
Net operating losses	$ 8,398,192	$ 5,452,848
Share based compensation	2,405,371	2,405,371
Interest expense	87,260	849,349
Deferred research and development costs	1,230,953	614,609
Accrued wages	205,765	305,548
Accrued litigation cots	1,299,550	1,288,000
Deferred revenue and other	37,940	37,940
Total deferred tax assets	13,665,031	10,953,665
Valuation allowance	(13,665,031)	(10,953,665)
Deferred tax asset, net of valuation allowance	$ -	$ -

The difference between income taxes at the statutory federal income tax rate and income taxes reported in the consolidated statements of operations is attributable to a full valuation allowance recorded in all periods since inception.

The provision for income taxes for the taxable years ended December 31, 2024 and 2023 differs from the statutory federal income tax rate for the years ended December 31, 2024 and 2023 as follows:

	For the For the Year Ended December 31,	
	2024	**2023**
Tax benefit at the federal statutory rate	21%	21%
State tax, net of federal benefit	$ 7%	7%
Permanent differences	0%	0%
Change in valuation allowance	-28%	-28%
Effective income tax rate	$ 0%	0%

At December 31, 2024, the Company had Federal net operating loss carryforwards of approximately $30,000,000 which will begin to expire in 2035. Of the total Federal net operating losses, the amounts incurred after 2017 of approximately $22,800,000 will carry forward indefinitely. Sections 382 and 383 of the Internal Revenue Code, and similar state regulations, contain provisions that may limit the NOL carryforwards available to be used to offset income in any given year upon the occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in ownership in excess of 50% over a three-year period, the amount of the NOL carryforwards that the Company may utilize in any year may be limited. Although the Company has not undertaken a formal analysis, it is likely that such an ownership change occurred prior to 2020. The years 2021 through 2024 are subject to examination by taxing authorities.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's financial statements as of December 31, 2024 or 2023. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date. No tax audits were commenced or were in process for the taxable years that ended December 31, 2024 and 2023. No tax related interest or penalties were incurred during the years ended December 31, 2024 and 2023.

NOTE 12 – SUBSEQUENT EVENTS

The Company has evaluated subsequent events through February 26, 2025, the date these financial statements were available to be issued and determined the following subsequent events have been identified and would require adjustment to our disclosure in the financial statement except as disclosed in Note 10:

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. The Executive Chairman is to receive a total of $600,000 upon repayment of such advances, including OID, absent default. The Company shall pay the Executive Chairman the entire unpaid principal balance on the earlier of one year following the date of the effective date of the agreement or the date of the direct listing on the Nasdaq Global Market.

2,101,313 Shares

NEONC TECHNOLOGIES HOLDINGS, INC.

Common Stock

March 25, 2025

Through and including April 19, 2025 (the 25th day after the listing date of our common stock), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus.