UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31 , 2023

OR

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

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NO. 001-14888

INOVIO
POWERING DNA MEDICINES™

INOVIO PHARMACEUTICALS, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Delaware	**33-0969592**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
660 W. Germantown Pike , Suite 110 Plymouth Meeting , Pennsylvania	**19462**
(Address of principal executive offices)	**(Zip Code)**

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (267) 440-4200

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
COMMON STOCK, $0.001 PAR VALUE	INO	Nasdaq Global Select Market

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No x

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ☐

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity (which consists solely of shares of Common Stock) held by non-affiliates of the Registrant as of June 30, 2023 was approximately $ 119.7 million based on $5.40 per share, the closing price on that date of the Registrant's Common Stock (retroactively giving effect to a 1-for-12 reverse stock split that became effective in January 2024) on the Nasdaq Global Select Market (prior to being transferred to the Nasdaq Capital Market in November 2023).

The number of shares outstanding of the Registrant's Common Stock, $0.001 par value, was 23,370,365 as of March 1, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2024 Annual Meeting of Stockholders (the "Proxy Statement') are incorporated by reference into Part III of this Report. Such Proxy Statement will be filed with the Commission not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2023.

TABLE OF CONTENTS

PART I

ITEM 1. BUSINESS

This Annual Report on Form 10-K (including the following section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations), or this Annual Report, contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this Annual Report. Additionally, statements concerning future matters, including statements regarding our business, our financial position, the research and development of our products and other statements regarding matters that are not historical are forward-looking statements.

Although forward-looking statements in this Annual Report reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include without limitation those discussed under the heading "Risk Factors" below, as well as those discussed elsewhere in this Annual Report. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report. Readers are urged to carefully review and consider the various disclosures made in this Annual Report, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

This Annual Report includes trademarks and registered trademarks of INOVIO Pharmaceuticals, Inc. Products or service names of other companies mentioned in this Annual Report may be trademarks or registered trademarks of their respective owners. References herein to "we," "our," "us," "INOVIO" or the "Company" refer to INOVIO Pharmaceuticals, Inc. and its consolidated subsidiaries. References herein to "DNA medicines" refers to our product candidates in development for diseases associated with human papillomavirus (HPV), cancer, and infectious diseases.

Summary Risk Factors

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects. These risks are discussed more fully in Part I, Item 1A., Risk Factors herein. These risk factors include, but are not limited to, the following:

- We have incurred significant losses in recent years, expect to incur significant net losses in the foreseeable future and may never become profitable.
- We have limited sources of revenue and our success is dependent on our ability to develop our DNA medicines and proprietary device technology.
- We will need substantial additional capital to develop our DNA medicines and proprietary device technology, which may prove difficult or costly to obtain.
- None of our DNA medicine candidates have been approved for sale, and we may never develop commercially successful DNA medicine products.
- DNA medicines are a novel approach to treating and preventing disease, and our CELLECTRA ® delivery devices are a novel approach to administering medicines, and negative perception of the efficacy, safety, or tolerability of any investigational medicines we develop or our devices could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals.
- If we and the contract manufacturers upon whom we rely fail to produce our proprietary devices and DNA medicine candidates in the volumes that we require on a timely basis, or at all, or if these contractors fail to comply with their obligations to us or with stringent regulations, we may face delays in the development and commercialization of our proprietary devices and DNA medicine candidates.
- If we lose or are unable to secure collaborators or partners, or if our collaborators or partners do not apply adequate resources to their relationships with us, our product development and potential for profitability will suffer.
- We have agreements with government agencies that are subject to termination and uncertain future funding. Termination or cessation of funding would have a negative impact on our ability to develop certain of our pipeline candidates and/or require us to seek alternative funding sources to advance product candidates.
- Our operating results may be harmed if our corporate restructuring plans and cost reduction efforts do not achieve the anticipated results or cause undesirable consequences.

- We are currently subject to litigation and may become subject to additional litigation, which could harm our business, financial condition and reputation.
- We face intense and increasing competition and steps taken by our competitors, such as the introduction of a new, disruptive technology may impede our ability to develop and commercialize our DNA medicines.
- We have entered into collaborations with Chinese companies and rely on clinical materials manufactured in China for our development efforts. Uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, a trade war, political unrest or unstable economic conditions in China could materially adversely affect our business, financial condition and results of operations.
- It is difficult and costly to generate and protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.
- If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.
- Failure or perceived failure to comply with laws, regulations, contracts, self-regulatory schemes, notices and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase our costs and otherwise negatively affect our operating results and business.

Company Overview

We are a clinical-stage biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from diseases associated with human papillomavirus (HPV), cancer, and infectious diseases. Our platform harnesses the power of in vivo protein production, featuring optimized design and delivery of DNA medicines that teach the body to manufacture its own disease-fighting tools.

We use proprietary technology to design DNA plasmids, which are small circular DNA molecules that work like software the body’s cells can download to produce specific proteins to target and fight disease. Our proprietary investigational CELLECTRA® delivery devices help our DNA medicines enter the body’s cells for optimal effect.

Our lead candidate is INO-3107 for the treatment of recurrent respiratory papillomatosis, or RRP, a rare and debilitating disease of the respiratory tract caused by HPV infection. In our completed Phase 1/2 clinical trial of INO-3107 for the treatment of HPV-6 and HPV-11-associated RRP, 81.3% of patients experienced a reduction in the number of surgical interventions in the year following administration of INO-3107, when compared with the year prior to treatment.

In February 2023, we announced data from the second cohort of our Phase 1/2 clinical trial, which followed the announcement of data from the first cohort in October 2022. In the second cohort of 11 patients who were administered INO-3107 via an exploratory side port needle, 10 of the 11 patients (91%) saw a reduction in surgical interventions in the year following initial treatment, with the measurement beginning on Day 0, the start of trial therapy. Of these 10 patients, four did not require surgery. There was a statistically significant median decrease of three surgical interventions when comparing the year following treatment to the year prior to treatment. INO-3107 was well tolerated and immunogenic among patients in the second cohort. The safety and efficacy results for the second cohort were consistent with results announced for the first cohort in October 2022.

In the fourth quarter of 2023, we received feedback from the U.S. Food and Drug Administration, or FDA, that the data from this completed trial could be used to support the submission of a Biologic License Application, or BLA, for review under the FDA’s accelerated approval program. As part of submitting our BLA under the accelerated program, we will need to satisfy all FDA filing requirements and initiate a confirmatory clinical trial prior to BLA submission.

In addition to our development efforts with INO-3107, we are actively developing or planning to develop DNA medicines for other indications, including HPV-related anal dysplasia and oropharyngeal squamous cell carcinoma, or OPSCC; glioblastoma multiforme, or GBM, a deadly form of brain cancer; and a potential vaccine booster to protect against the Ebola virus. We were previously conducting clinical trials of a DNA medicine candidate for the treatment of HPV-related cervical high-grade squamous intraepithelial lesions, or HSIL, but announced in August 2023 that we were ceasing development for this indication in the United States. However, our collaborator ApolloBio Corporation continues to conduct a Phase 3 clinical trial of this candidate in China and plans to seek regulatory approval for and potentially commercialize the candidate in that jurisdiction.

Characteristics of DNA Medicines

DNA medicines are optimized DNA plasmids containing a gene encoding for a protein that is expressed once these plasmids are delivered into cells. We can design our plasmids to teach the body’s cells to produce a wide range of proteins, including antigens to elicit a specific immune response and monoclonal antibodies to fight a specific pathogen. These DNA medicines can generate antigen-targeted humoral and cellular immune responses based on the indication, including antigen-specific cytotoxic, or killer, T cell responses that are important for fighting cancer and viral infections. Characteristics of our DNA medicines include:

a. **T Cell Responses:** DNA medicines have demonstrated the ability to generate high levels of T cell (CD4+, CD8+, and memory) response along with antibody response. CD8+ T cell responses are thought to play an important role in clearing tumors or virally infected cells.

b. **Tolerability:** DNA medicines have been well tolerated by clinical trial participants when evaluated against multiple disease targets. Our DNA medicines have been administered over 15,000 times across more than 5,000 participants to date.

c. **Ability to Readminister:** DNA medicines have been used in clinical trials to boost immune response via repeat administration, offering the potential for continued boosting of the immune response through repeat administration.

d. **Versatility:** Our DNA medicines technology can be utilized to produce in vivo proteins or antigens key to treating or preventing various human diseases, such as cancer, viral infections or protein deficiencies.

e. **Stability of Product:** DNA medicines do not require frozen storage or shipping.

f. **Design and Manufacture:** DNA medicines can be rapidly designed and scaled, with ease of manufacturing providing a potential cost advantage.

g. **Delivery Mechanism:** Our proprietary electroporation devices increase cellular uptake and overcome the barrier posed by cell membranes that can hinder the entry of large molecules, such as DNA plasmids.

Overview of Our DNA Medicines Platform

Our DNA medicines platform consists of DNA plasmids and our CELLECTRA devices, which are used to deliver the DNA plasmids into the cell. These two components combine to create a versatile platform that has the potential to target multiple diseases and conditions.

SynCon® - DNA Plasmid Design Technology

Our precisely designed DNA plasmids are circular double-stranded DNA that have been optimized, using our proprietary technology and algorithms, to express a protein. Our plasmids can be designed to enable the body's cells to produce a wide range of proteins, including antigens to elicit a specific immune response, monoclonal antibodies to fight a specific pathogen, or therapeutic proteins to replace defective or missing proteins in the body. In the area of HPV-related diseases, for example, the expressed proteins are antigens that elicit antigen-specific T cell responses to fight HPV. We start by identifying one or more antigens that we believe are the best targets for directing the immune system toward HPV and then apply our SynCon design process, which analyzes the genetic make-up of the selected antigens from multiple strains of the virus.

For each antigen, we create a new genetic sequence that represents a nucleotide consensus sequence of the targeted antigen. In doing so, we believe we can create a differentiated sequence to help the immune system better recognize the target antigen and potentially variations of the target antigen. We have generated immune responses, including CD4+, CD8+, and memory T cells, with SynCon-designed DNA medicines against various tumor-associated antigens, as well as against different strains of certain infectious diseases in human clinical trials. Because the engineered sequences are substantially similar to the original sequences, without matching them exactly, we believe they are patentable.

Once a SynCon sequence is designed and synthesized, it is then inserted into a circular DNA plasmid with its own promoter. Promoters serve a vital role in "promoting" the expression of the protein once the DNA medicine has entered the cell. Using our technology, our DNA plasmids have been optimized to enable high expression in human cells via our proprietary gene optimization algorithm, which we refer to as GOAL. We believe these design capabilities allow us to better target appropriate immune system mechanisms and produce a higher level of protein expression compared to traditional approaches, potentially enhancing the overall ability to induce the desired immune response.

The plasmids are then manufactured in a bacterial fermentation process using scalable manufacturing technology. We have recently developed a high-yield manufacturing process which we anticipate using to manufacture our DNA medicines. The manufactured DNA medicines do not require ultracold or frozen storage or thawing prior to injection and are refrigerator stable at 2 to 8 degrees Celsius, which are key factors for both distribution and administration.

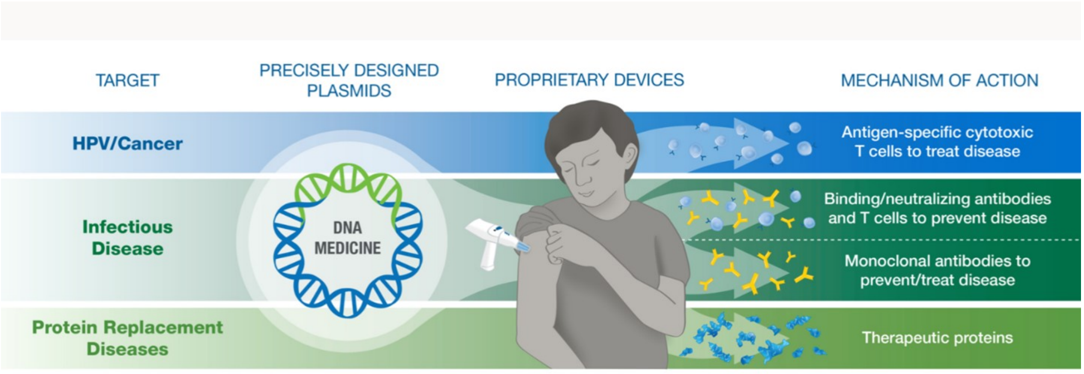
CELLECTRA® Delivery Technology

DNA medicines need a pathway into the cell to work effectively. To help DNA plasmids, which are relatively large molecules, pass through the cell membrane, we use our proprietary CELLECTRA delivery technology. After injecting the DNA medicine either intramuscularly (IM) or intradermally (ID), CELLECTRA devices use electroporation (EP), or brief electrical pulses, to reversibly open small pores in the cell membrane, allowing DNA plasmids to enter. Through this process, the cellular uptake of the DNA plasmids can be substantially increased compared to the *in vivo* injection of DNA plasmids alone. This improved cellular uptake has enabled the immune responses and efficacy results observed in our clinical trials to date.

Our CELLECTRA device portfolio currently consists of two models (CELLECTRA 5PSP AND CELLECTRA 3PSP) designed for late-stage clinical use and potentially for eventual commercial use, and one device (CELLECTRA 2000) that we primarily utilize in earlier-stage clinical trials. These devices have been designed to optimize delivery of our DNA medicine candidates depending on the target disease. Our CELLECTRA 5PSP model provides intramuscular EP and is designed to be used with candidates addressing cancers and HPV related pre-cancers. It uses a prefilled drug cartridge, delivers both the DNA medicine and the EP to the patient and is designed for commercial use. CELLECTRA 5PSP was used in our Phase 3 trials (REVEAL1/REVEAL2) for cervical HSIL and will be used in our planned confirmatory trial for INO-3107, our DNA medicines candidate for RRP. Our CELLECTRA 3PSP model was developed with support from the U.S. Department of Defense, the Center for Epidemic Preparedness Innovations, and the Bill & Melinda Gates Foundation for intradermal EP delivery. The small, handheld design is intended for mass administration and commercial use and will mainly be used with candidates addressing infectious disease. CELLECTRA 3PSP only delivers EP, after a separate DNA medicine injection into the skin. The EP is delivered around the intradermal injection site.

CELLECTRA devices are validated and manufactured under Current Good Manufacturing Practices (cGMP). We have used CELLECTRA devices in global human clinical trials. The CELLECTRA 5PSP model has received CE mark certification in the EU.

The process for administration of our DNA medicines is illustrated in the following graphic.



DNA Medicines and HPV-related Diseases

HPV can lead to a persistent viral infection. Approximately 90% of all HPV infections clear naturally and do not result in disease. However, for those not able to clear the virus naturally, persistent infection can lead to cancer and other debilitating, life-threatening diseases affecting quality of life.

In general, HPV types fall into two groups. Low-risk HPV (e.g., HPV 6 and HPV 11) may lead to benign growths (warts or papillomas) that can develop into conditions such as RRP. High-risk (HR) HPV (e.g., HPV 16 and HPV 18) may lead to cell changes and lesions (i.e., precancerous dysplasia) that can become malignant and lead to cervical cancer. HPV causes nearly all cervical cancers and many cancers of the vagina, vulva, penis, anus, rectum, and oropharynx.

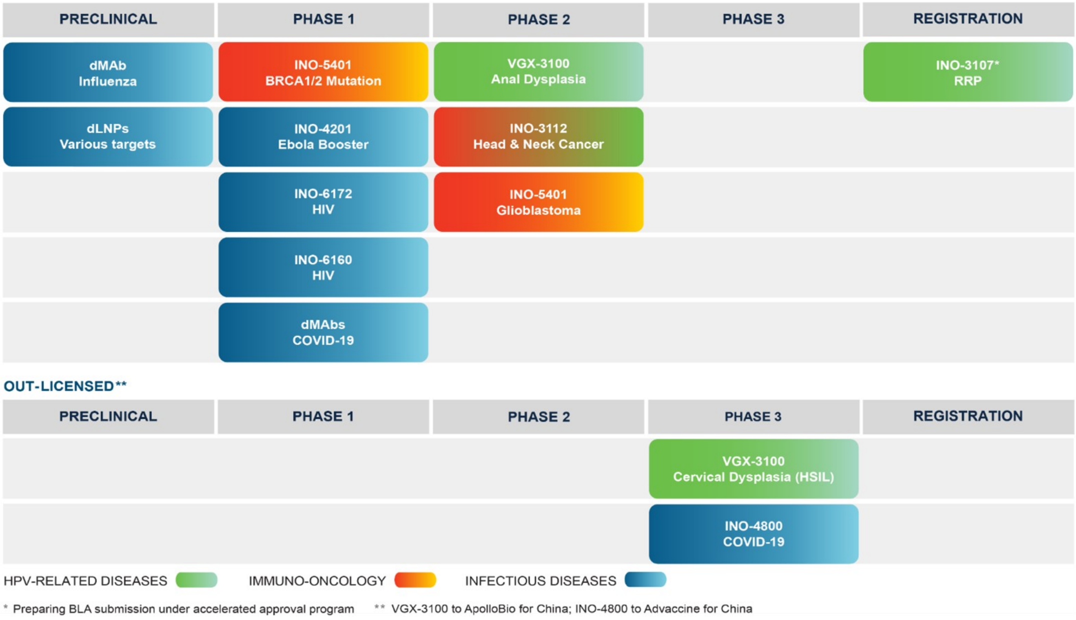
While there are currently vaccines available to prevent HPV infection, challenges with acceptance, accessibility, and patient compliance have resulted in many vaccine-eligible people remaining unvaccinated and at risk. It is estimated that even in the United States, only 50-60% of the eligible population has been vaccinated against HPV. In addition, current preventive HPV vaccines cannot treat or protect those already infected with the same HPV genotypes. As a result, there is still an urgent need for the development of HPV therapies that can treat existing infections and prevent the development of HPV-related diseases. The current standard of care for many HPV-related diseases, including RRP and many cancers, is surgery. These surgeries can be invasive and may be needed repeatedly because the underlying HPV infection is not eliminated. In addition to surgery, other options are being explored to treat HPV-related diseases, including the usage of immune checkpoint inhibitors and other immunotherapies.

A summary of the key characteristics of DNA medicines that we believe are important for the treatment of HPV-related diseases are listed in the following table:

Topic	Attribute	Effect
Immunogenicity	Generates antibody, helper T cell, and killer T cell responses	Induction of antigen-specific long-lived memory, helper, and killer T cells
	Antigen expression optimized based on INOVIO's proprietary technology	Potential for enhanced immunogenicity
Safety & Tolerability	Does not contain whole or weakened HPV virus	Cannot cause HPV infection
	Repeat administrations have been well-tolerated	Booster doses possible
	Substantial clinical trial experience	Favorable adverse event profile across programs

Our DNA Medicines in Development

The chart below provides an overview of our DNA medicines pipeline. In 2023, we reprioritized our pipeline to focus our efforts and resources on those product candidates that we believe have the greatest potential to reach the market. The programs identified in the chart are described in more detail below.



INO-3107 for HPV-related RRP

RRP is a life-long, rare disease characterized by the growth of small tumors, or papillomas, in the respiratory tract primarily caused by HPV-6 and/or HPV-11 genotypes. Although mostly benign, these papillomas can cause severe, sometimes life-threatening airway obstruction and respiratory complications. A distinguishing aspect of RRP is the tendency for the papillomas to recur after surgical procedures to remove them. If RRP develops in the lungs, affected individuals can potentially experience recurrent pneumonia, chronic lung disease (bronchiectasis) and, ultimately, progressive pulmonary failure. In extremely rare cases (approximately 2%), RRP can develop into squamous cell carcinoma. Additional symptoms of RRP can include a hoarse voice, difficulty in sleeping and swallowing, and chronic coughing. RRP symptoms are usually more severe in children than in adults. The standard of care for RRP is surgery. The most widely cited U.S. epidemiology data, published in 1995, estimated that there were 14,000 active cases for both adults and juveniles, and about 1.8 new cases per 100,000 adults each year.

We are developing our lead product candidate, INO-3107, for the treatment of HPV-6 and HPV-11-associated RRP. INO-3107 is composed of plasmids encoding for HPV-6 and HPV-11 antigens, as well as human interleukin-12 (IL-12). In May 2023, results from an open-label, multicenter Phase 1/2 trial (NCT:04398433) evaluating the efficacy, safety, tolerability and immunogenicity of our lead product candidate INO-3107 in 32 patients with HPV 6 and/or HPV 11-associated RRP were presented at the American Broncho-Esophagological Association (ABEA) program at the Combined Otolaryngology Spring Meetings (COSM) in Boston, Massachusetts. The trial included a first cohort of 21 patients dosed with a standard injection needle and a second cohort of 11 patients dosed with an exploratory side port injection needle. We plan to use the standard needle in our planned confirmatory trial and for delivery of the commercial product, should it be approved. In both cohorts of the trial, our proprietary CELLECTRA 2000 electroporation device was used to deliver the product candidate.

The trial evaluated the reduction in the number of surgical interventions in the year following initial administration of INO-3107 compared to the year prior to treatment. For this trial, adult patients first underwent surgical removal of their papillomas and then received up to four doses of INO-3107, once every three weeks. The primary endpoint of this trial was safety and tolerability. At the outset of the study (Day 0), patients could have RRP tissue surgically removed, but any surgery performed after Day 0 during the dosing window was counted against the efficacy endpoint.

In the trial, 81.3% (26/32) of patients had a decrease in number of surgical interventions in the year after INO-3107 administration compared to the prior year, including 28.1% (9/32) that required no surgical intervention during or after the dosing window. Patients in the trial had a median range of 4 surgeries (overall range of 2-8) in the year prior to dosing. After dosing, there was a statistically significant median decrease of 3 surgical interventions (95% confidence interval: -3 to -2). Treatment with INO-3107 generated a strong immune response in the trial, inducing activated CD4 T cells and activated CD8 T cells with lytic potential. T-cell responses were also observed at Week 52, indicating a persistent cellular memory response. INO-3107 was well tolerated by participants in the trial, resulting in mostly low-grade (Grade 1) treatment-emergent adverse effects such as injection site pain and fatigue. These results were published in a scientific journal, The Laryngoscope, in 2023.

The FDA granted INO-3107 Orphan Drug Designation (ODD) in July 2020 and Breakthrough Therapy Designation in August 2023. The European Commission has also granted INO-3107 Orphan Drug Designation, and our CELLECTRA 5PSP device has received CE marking, a regulatory standard that certifies that a product has met the European Union’s safety, health and environmental standards ensuring consumer safety.

INO-3112 for the Treatment of HPV-related Oropharyngeal Squamous Cell Carcinoma, or OPSCC

INO-3112 is a DNA medicine candidate targeting HPV 16/18 combined with a DNA plasmid encoding for human IL-12 as an immune activator. Results from a Phase 1/2a trial of INO-3112 alone in 22 HPV-positive head and neck squamous cell carcinoma (HNSCC) patients, published in Clinical Cancer Research in 2019, included the observation of T cell responses and infiltration of CD8+ T cells into the head and neck tumors. In early 2023, updated results were published in Clinical Cancer Research from a Phase 1b/2a trial of INO-3112 in combination with AstraZeneca’s PD-L1 immune checkpoint inhibitor, durvalumab, showing an overall response rate, or ORR, of 27.6% (4 complete responses (CR) and 4 partial responses (PR)) in 29 evaluable patients and increased peripheral HPV-specific T cells and tumoral CD8+ T cells. Further, the efficacy of the combination of INO-3112 with durvalumab resulted in a median overall survival, or OS, of more than 29 months. This is an improvement over historical data for immune-checkpoint blockade therapy alone, or in combination with other HPV therapeutic vaccines. Further, this is almost three times that of historical OS data for monotherapy durvalumab in a similar patient population. Objective responses, including CRs, occurred independently of PD-L1 expression, which contrasts with historical data for durvalumab.

In January 2024, we announced a clinical collaboration and supply agreement with Coherus BioSciences, Inc. to evaluate the combination of INO-3112 and LOQTORZI™ (toripalimab-tpzi) as a potential treatment for patients with locoregionally advanced, high-risk, HPV16/18 positive oropharyngeal squamous cell carcinoma, or OPSCC, a type of head and neck cancer commonly known as throat cancer. Under the terms of the supply agreement, Coherus will provide LOQTORZI™, for a planned Phase 3 clinical trial to be conducted by INOVIO, pending alignment with the FDA on study design.

VGX-3100 for the Treatment of HPV-related Cervical HSIL

In August 2023, we announced the discontinuance of our U.S. development program of VGX-3100 for the treatment of HPV-related cervical HSIL. This decision followed final analysis of the data from our Phase 3 trial known as REVEAL2. In this trial, statistical significance was not achieved in the investigational biomarker-selected population for the endpoint of lesion regression and viral clearance. However, statistical significance was achieved in the all-participants population for the endpoint of lesion regression and viral clearance.

REVEAL2 was our second Phase 3 trial with VGX-3100. In March 2021, we announced results from our first Phase 3 trial, known as REVEAL1, indicating that VGX-3100 did not meet its primary endpoint. In April 2022, the trial protocol for REVEAL2 was amended to utilize a biomarker-selected population as the primary population, based on prior analysis of REVEAL1 results suggesting that this investigational biomarker had the potential to identify women more likely to respond to treatment with VGX-3100. We announced that this trial would no longer be considered a pivotal trial and would not lead to a BLA filing for a biomarker-selected population, as the FDA had advised us that the results from the biomarker-positive population would not be sufficient to support approval of a potential marketing application for VGX-3100. The FDA recommended using REVEAL2 as an exploratory trial and that conducting one or two additional well-controlled trials in the biomarker-selected population would be more likely to provide evidence to support approval of a potential marketing application.

Trial participants in REVEAL2 included 203 women, 18 years of age or older, who had histologically confirmed cervical HSIL associated with HPV-16 and/or HPV-18, but who were otherwise healthy. Participants received either VGX-3100 or placebo at 0, 4 and 12 weeks (randomized 2:1). The primary endpoint, as amended, was the percentage of biomarker-selected participants with regression of cervical HSIL and virologic clearance of HPV-16 and/or HPV-18 in the cervix. A secondary endpoint was the percentage of all participants with regression and virologic clearance.

The percentage of participants in the investigational biomarker-selected population meeting the endpoint was 28.6% (6/21) in the treatment group, versus 0% (0/4) in the placebo group (p=0.115; 95% confidence interval: -24.6% to 50.4%), which was not statistically significant.

The result of the all-participants population of 203 participants (134 participants in the treatment group, 69 in the placebo group) was statistically significant, with 27.6% (37/134) of the participants meeting the endpoint in the treatment group, versus 8.7% (6/69) in the placebo group (p=0.001; 95% confidence interval: 7.8% to 28.6%).

In particular, in the all-participants population of REVEAL2, viral clearance was observed in 37.3% (50/134) in the treatment group versus 8.7% (6/69) in the placebo group. Given the importance of viral clearance in removing the underlying cause of the HPV-related diseases, this data may have positive implications in our other HPV-related programs. We plan to submit the data for publication in a peer-reviewed journal.

An ad hoc integrated efficacy analysis of the results for both REVEAL1 and REVEAL2 showed statistical significance in the biomarker-selected and all-participants populations for lesion regression and viral clearance. For the combined biomarker-selected population of 92 participants (68 participants in the treatment group, 24 in the placebo group), the percentage of participants meeting the primary endpoint was 54.4% (37/68 in the treatment group, versus 12.5% (3/24) in the placebo group (p=<0.001; 95% confidence interval: 20.4% to 57.0% difference in percentage). For the combined all-participants population of 404 participants (272 participants in the treatment group, 132 in the placebo group), the percentage of participants meeting the primary endpoint was 25.0% (68/272 in the treatment group, versus 9.8% (13/132) in the placebo group (p=<0.001; 95% confidence interval: 7.4% to 22.1% difference in percentage).

In both REVEAL1 and REVEAL2, VGX-3100 delivered by the CELLECTRA 5PSP device was well tolerated. There were no treatment-related serious adverse events and most adverse events were considered to be mild to moderate.

This combined data set will be used as supportive data in any future regulatory interactions involving VGX-3100. Our collaborator ApolloBio Corporation is conducting a Phase 3 clinical trial of VGX-3100 for cervical HSIL in China and plans to seek regulatory approval for and potentially commercialize the candidate in that jurisdiction.

VGX-3100 for the Treatment of Anal or Perianal HSIL

HPV-16 and HPV-18 can cause precancerous lesions of the anus (anal HSIL). Left untreated, anal HSIL may progress to cancer. Spontaneous regression of anal HSIL is observed in approximately 20% of patients. Persistent infection with one or more high-risk HPV genotypes is responsible for a large portion of anal cancer. In the United States, about 55% to 80% of anal HSIL cases are associated with HPV-16/18, and worldwide about 80% of anal HSIL cases are associated with HPV-16/18. In the United States, over 90% of anal cancer is attributable to HPV, and about 87% of those HPV anal cancers are attributable to HPV-16/18 specifically.

There are no validated screening tests or a general consensus for screening recommendations for anal HSIL. Treatment usually consists of repeated ablation, most commonly radiofrequency ablation (RFA), resections or laser therapy. However, recurrence rates are high, up to 49% one year after treatment, as ablation does not clear the underlying HPV infection, resulting in an unmet medical need.

We conducted a Phase 2 clinical trial (HPV-203) to evaluate VGX-3100 in participants who were HIV-negative with histologically confirmed anal or perianal HSIL, or anal intraepithelial neoplasia (AIN), associated with HPV-16 and/or HPV-18. This open-label trial enrolled 24 participants who received three doses of VGX-3100 delivered by our CELLECTRA 5PSP device. The primary endpoint of the trial was histologic clearance of the high-grade lesions and virologic clearance of the HPV-16/18 virus in anal/perianal tissue samples. In December 2020, we announced Phase 2 efficacy results from this trial.

One-half of participants treated with VGX-3100 (11/22) showed resolution of HPV-16/18-associated anal HSIL at six months following the start of treatment. VGX-3100 delivered by CELLECTRA-5PSP device was well tolerated in the trial.

In addition to the Phase 2 anal HSIL trial described above, a separate Phase 2 trial sponsored by the AIDS Malignancy Consortium (AMC-103 study) is evaluating VGX-3100 in participants with histologically confirmed anal or perianal HSIL associated with HPV-16 and/or HPV-18 who are HIV-positive. This open-label single-arm trial plans to enroll approximately 90 participants who will receive up to four doses of VGX-3100 delivered by CELLECTRA 5PSP. The primary endpoint of the trial is histological regression of high-grade anal lesions to low-grade SIL or normal histology. This study is ongoing.

VGX-3100 for the Treatment of Vulvar HSIL

In 2023, as part of the reprioritization of our pipeline, we discontinued the development of VGX-3100 as a potential treatment for vulvar HSIL.

INO-5401 for the Treatment of Glioblastoma Multiforme (GBM)

Glioblastoma multiforme, or GBM, is the most common aggressive type of brain cancer. In the United States, the median age at diagnosis is 65 years, and the incidence rate increases thereafter. Prognosis is extremely poor, and a limited number of new therapies have been approved over the last 10 years; average survival for U.S. patients has been reported as low as 8 months with a five-year survival rate of 6.9% for all ages combined. The overall incidence of GBM varies worldwide and is highest in North America, Australia and Northern and Western Europe. In the United States, the average age-adjusted incidence rate of GBM is 3.19 cases per 100,000 persons.

Our product candidate INO-5401 is an immunotherapy consisting of three DNA plasmids encoding for three tumor-associated antigens: human Telomerase Reverse Transcriptase (hTERT), Wilms Tumor gene-1 (WT1) and Prostate-Specific Membrane Antigen (PSMA).

We have completed a Phase 1/2 immuno-oncology trial of INO-5401 and INO-9012 (an IL-12 plasmid) in participants with newly diagnosed GBM, in combination with cemiplimab (Libtayo®), a PD-1 immune checkpoint inhibitor developed by Regeneron Pharmaceuticals. This open-label trial began in 2018 and enrolled 52 newly diagnosed GBM participants. The primary endpoint was safety and tolerability, and the trial also evaluated immunogenicity as well as efficacy based on overall survival, or OS, rates.

In May 2022, we presented OS data at the 2022 American Society of Clinical Oncology (ASCO) from the trial. Median OS duration in patients with an unmethylated MGMT promoter (Cohort A) was 17.9 months, which compared favorably to historical comparisons (between 14.6 and 16 months). Median OS data in patients with an MGMT methylated promoter (Cohort B) was 32.5 months, which also compared favorably to historical comparisons (between 23.2 and 25 months). Overall, administration of INO-5401 + INO-9012 with Libtayo and RT/TMZ (radiation and temozolomide) was well tolerated by newly diagnosed GBM patients. Administration of treatment was also observed to be immunogenic, eliciting antigen-specific T cells that may infiltrate GBM tumors. As of the end of 2023, two GBM patients in the trial remained on drug treatment. We are currently completing the study reports and discussing the further development of INO-5401 with our collaborator Regeneron.

INO-5401 for the Prevention of Cancer for People with BRCA1/2 Mutation

INOVIO is partnering with the University of Pennsylvania to conduct a Phase 1b investigator-sponsored trial to evaluate the tolerability and immunogenicity of INO-5401 alone or INO-5401 in combination with INO-9012 delivered with CELLECTRA in adult cancer and non-cancer patients with BRCA1 or BRCA2 mutations. This trial is ongoing.

All humans have BRCA1 and BRCA2 genes, but some people are born with an error, or mutation, in one of these genes. People with a gene mutation in either BRCA1 or BRCA2 are at heightened risk for certain cancers, including breast, ovarian, prostate, and pancreatic cancers. These gene mutations can be passed on to children by either men or women.

Infectious Disease Product Candidates

INO-4800 for COVID-19

Phase 2/3 Clinical Trial – SOLIDARITY TRIAL VACCINES (STV)

INO-4800 is one of two initial COVID-19 vaccine candidates included in the World Health Organization (WHO) sponsored Solidarity Trial Vaccines, or STV, which is designed to evaluate the efficacy and safety of vaccine candidates selected by an independent vaccine prioritization advisory group composed of leading scientists and experts. The conduct of the STV is wholly under the WHO’s control and any announcement regarding that trial will be made by the WHO.

INO-4800 in China

Our collaborator Advaccine has completed enrollment of its 200-participant homologous and 267-participant heterologous booster vaccine trials in China. The trials are designed to evaluate safety, tolerability and immunogenicity of INO-4800 as a homologous booster where INO-4800 was administered as the primary vaccine and as a heterologous booster where an inactivated vaccine was administered as the primary vaccine.

COVID-19 DNA-encoded Monoclonal Antibodies (dMAb®)

Using our GOAL algorithm technology, we are able to create precisely designed DNA plasmids that encode for specific monoclonal antibodies (mAbs). We refer to these DNA plasmids as our dMAb product candidates to differentiate them from infused recombinant monoclonal antibodies. We deliver the plasmid directly into cells of the body using our CELLECTRA delivery system, enabling the electroporated cells to manufacture those DNA-encoded mAbs in vivo (i.e. by the body itself), unlike conventional recombinant mAb technology that requires manufacture outside of the body. We believe this approach provides potentially significant advantages in terms of design simplicity, rapidity of execution and lower production costs. We expect to design dMAb product candidates not only for new disease targets that are not currently addressable with conventional recombinant mAbs, but also targets of existing, commercially available mAb products.

In December 2020, we, along with a team of scientists from The Wistar Institute, AstraZeneca, the University of Pennsylvania, and Indiana University, received a $37.6 million grant from the U.S. Defense Advanced Research Projects Agency (DARPA), a research and development agency of the DoD and the JPEO-CBRND, to use our dMAb technology to develop anti-SARS-CoV-2-specific dMAbs that function as both a therapeutic and preventive treatment for COVID-19.

In July 2022, Wistar announced the dosing of the first participant in a Phase 1, open-label, single-center, dose escalation trial to evaluate the safety, tolerability and pharmacokinetic profile of two of our mAb product candidates, administered IM followed immediately by electroporation using our CELLECTRA 2000 device in a 1- and 2-dose regimen (Days 0 and 3) in healthy adults (NCT05293249). The study is ongoing.

INO-4201 for Ebola Virus Disease

The Ebola virus causes one of the most virulent viral diseases, with case fatality rates averaging approximately 50% but approaching up to 90% in past outbreaks in areas with no or under-developed health care. Ebola can spread through human-to-human transmission by direct contact with the blood, secretions, organs or bodily fluids of an infected individual and with surfaces or materials that contain the contaminated fluids of an infected person, such as bedding and clothing. It is capable of causing death within 2 to 21 days of exposure. In November 2019, the first conditional approval was issued for a preventive vaccine against Ebola virus. This approval was from the European Medicines Agency (EMA) for the vaccine ERVEBO®. That same month, the WHO pre-qualified that vaccine for use in high-risk countries. In the next month, the FDA approved that vaccine. However, ERVEBO has not been approved for repeat dosing and there are no approved booster vaccines yet available in the United States.

In December 2021, we announced complete enrollment of a 46-participant Phase 1b trial (NCT04906629) in which our DNA medicine candidate INO-4201 was assessed as a heterologous booster in healthy volunteers previously vaccinated with ERVEBO. In February 2023, we announced results from the Phase 1b trial. INO-4201 was well tolerated and boosted humoral responses in 100% (36 of 36) of treated participants. We and our collaborators plan to publish the data in a peer-reviewed journal and provide updates on the next steps for INO-4201.

INO-6160 for HIV

INO-6160 is a DNA medicine candidate being developed as a prophylactic vaccine against human immunodeficiency virus, or HIV. INO-6160 is composed of one plasmid encoding for an HIV trimer and one encoding for human IL-12. INO-6160 is being evaluated in a Phase 1 trial that is externally sponsored and funded by the National Institute of Allergy and Infectious Diseases, or NIAID. The trial is a randomized, 20-participant, open-label Phase 1 trial to examine the safety and immunogenicity of INO-6160.

DNA-Launched Nanoparticles (dLNPs)

INOVIO and our collaborators at the Wistar Institute are applying our experience in DNA vaccine development toward the development of the next generation of DNA medicine technology, by investigating DNA-launched nanoparticles, or dLNPs, initially targeting infectious diseases vaccines. INO-6172, INOVIO's first dLNP to enter clinical trials, is in a Phase 1 trial sponsored and funded by NIAID. INO-6172 contains two plasmids, one encoding for the dLNP and one encoding for human IL-12. The trial is a randomized, 45-participant, open-label Phase 1 trial that is examining the safety and immunogenicity of INO-6172 in adults without HIV. The trial is ongoing, as is additional preclinical work with dLNP technology and additional vaccine candidates.

Collaboration and Alliances

In addition to our current collaboration with ApolloBio Corporation described below, our other partners and collaborators include Advaccine Biopharmaceuticals Suzhou Co, AstraZeneca, The Bill & Melinda Gates Foundation (Gates), Coalition for Epidemic Preparedness Innovations (CEPI), Coherus Biosciences, Defense Advanced Research Projects Agency (DARPA), The U.S. Department of Defense (DoD), HIV Vaccines Trial Network, International Vaccine Institute (IVI), Kaneka

Eurogentec, National Cancer Institute (NCI), National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), Plumbline Life Sciences (PLS), Regeneron Pharmaceuticals, Richter-Helm BioLogics, Thermo Fisher Scientific, the University of Pennsylvania, the Walter Reed Army Institute of Research, and The Wistar Institute.

In December 2017, we entered into an Amended and Restated License and Collaboration Agreement with Beijing Apollo Saturn Biological Technology Limited, a corporation organized under the laws of China, or ApolloBio, which was amended on June 14, 2023 (as so amended, the “License and Collaboration Agreement”). Under the terms of this License and Collaboration Agreement, we granted to ApolloBio the exclusive right to develop and commercialize VGX-3100, our DNA immunotherapy product candidate designed to treat pre-cancers caused by HPV, within Greater China (defined as China, Hong Kong, Macao and Taiwan). As part of the collaboration, ApolloBio will fund all clinical development costs within the licensed territory.

We are entitled to receive up to an aggregate of $20.0 million, less required income, withholding or other taxes, upon the achievement of specified milestones related to the regulatory approval of VGX-3100 in accordance with the License and Collaboration Agreement. In the event that VGX-3100 is approved for marketing in Greater China, we will be entitled to receive royalty payments based on a tiered percentage of annual net sales, with such percentage being in the low- to mid-teens, subject to reduction in the event of generic competition in a particular territory. ApolloBio’s obligation to pay royalties will continue for 10 years after the first commercial sale in a particular territory or, if later, until the expiration of the last-to-expire patent covering the licensed products in the specified territory. After marketing approval in a territory, the License and Collaboration Agreement, will continue in force until ApolloBio has no remaining royalty obligations. In December 2021, ApolloBio dosed its first participant in a separate Phase 3 trial in China (HPV-303CHN).

Competition

As we develop and seek to ultimately commercialize our product candidates, we face and will continue to encounter competition with an array of existing or development-stage drug and immunotherapy approaches targeting diseases we are pursuing. We are aware of various established enterprises, including major bio-pharmaceutical companies, broadly engaged in vaccine/immunotherapy research and development. These include AbbVie, AstraZeneca, BioNTech, Bristol-Myers Squibb, GlaxoSmithKline, Janssen Pharmaceuticals (part of J&J), Merck, Moderna, Novartis, Pfizer, Roche, and Sanofi-Aventis. There are also various development-stage biotechnology companies involved in different vaccine and immunotherapy technologies, including but not limited to Agenus, AIVITA, Barinthus Biotherapeutics (formerly Vaccitech), BL Corp, Entos Pharma, Frantz Viral Therapeutics, Immunocore, Imunon, ImVax, Iovance, Gritstone Bio, Genexine, Hookipa, Mimivax, Nektar, Northwest Therapeutics, Novavax, Nykode, Precigen, and PapiVax. If these companies are successful in developing their technologies, it could materially and adversely affect our business and our future growth prospects.

Merck and GlaxoSmithKline have commercialized preventive vaccines against HPV to protect against cervical cancer. Some companies are also seeking to treat early HPV infections. For RRP, which is caused by HPV subtypes 6 and 11, Precigen is developing a product candidate, PRG-2012, based on a Gorilla adenovirus-based vector. Precigen has publicly stated they expect to file a BLA in 2024 based on their Phase 1/2 trial of PRG-2012 for the treatment of RRP and that no additional randomized, placebo-controlled trial will be required to support their submission of a BLA. Other companies have started to explore RRP as a disease target, including Nykode, Merck and Cytovation. For head and neck cancers, AstraZeneca is developing a bispecific antibody targeting PD-1 and TIGIT for locaregionally advanced head and neck squamous cell carcinoma, while the National Cancer Institute is conducting a Phase 3 study with the immunotherapy nivolumab (Bristol-Myers Squibb’s Opdivo) in HPV-positive oropharynx cancer. Other companies are pursuing different approaches to pre-cancers and cancers we are targeting.

We also compete more specifically with companies seeking to utilize antigen-encoding DNA delivered with electroporation or other delivery technologies such as viral vectors or lipid delivery to induce in vivo generated antigen production and immune responses to prevent or treat various diseases. These competitive technologies have shown promise, but they each also have their own unique obstacles to overcome.

Viral Vector-based Vaccine Delivery

This technology utilizes a virus as a carrier, or vector, to deliver genetic material into target cells. The method is efficient for delivering immunotherapy antigens and has the advantage of mimicking real viral infection so that the recipient will mount a broad immune response against the immunotherapy. The potential limitation of the technology stems from problems with unwanted immune responses against components of the viral vector itself, making repeated administration difficult.

Lipid Nanoparticle DNA/RNA Delivery

A number of lipid formulations have been developed that increase the effect of DNA/RNA immunotherapies, most notably with COVID-19 mRNA vaccines. These work by either increasing uptake of the DNA/RNA into cells or by acting as an adjuvant, alerting the immune system.

DNA Immunotherapy Delivery with Electroporation

There are other companies with electroporation intellectual property and devices. We believe we have competitive advantages over other companies focused on electroporation for multiple reasons:

- We have an extensive history and experience in developing the methods and devices that optimize the use of electroporation in conjunction with DNA medicine. This experience has been validated with multiple sets of data from clinical trials assessing DNA medicine against cancers and infectious disease.
- We have a broad product line of electroporation instruments designed to enable DNA delivery, including our intradermal and intramuscular devices.
- We have been proactive in filing for patents, as well as acquiring and licensing additional patents, to expand our global patent estate.

If any of our competitors develop products with efficacy or safety profiles significantly better than our product candidates, we may not be able to commercialize our products, and sales of any of our commercialized products could be harmed. Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to ours.

Our competitive position will be affected by the disease indications addressed by our product candidates versus those of our competitors, the timing of market introduction for these products and the stage of development of other technologies to address these disease indications. For us and our competitors, proprietary technologies, the ability to complete clinical trials on a timely basis and with the desired results, and the ability to obtain timely regulatory approvals to market these product candidates are likely to be significant competitive factors. Other important competitive factors will include efficacy, safety, ease of use, reliability, availability and price of products and the ability to fund operations during the period between technological conception and commercial sales.

The FDA and other regulatory agencies may expand current requirements for public disclosure of DNA-based product development data, which may harm our competitive position with foreign and United States companies developing DNA-based products for similar indications.

Commercialization and Manufacturing

Because of the broad potential applications of our technologies, we intend to develop and commercialize products both on our own and through our collaborators and licensees. We intend to develop and commercialize products in well-defined specialty markets, such as HPV-related diseases, infectious diseases, and cancer. Where appropriate, we intend to rely on strategic marketing and distribution alliances. In 2023, we began accelerating the development of our commercialization plans for INO-3107 in the United States following notice from the FDA that the data from our completed Phase 1/2 trial in patients with RRP could be used to submit a BLA under the accelerated approval program.

We believe our plasmids can be produced in commercial quantities through uniform methods of fermentation and processing that are applicable to all plasmids. We believe we will be able to obtain sufficient supplies of plasmids for all foreseeable clinical investigations.

Intellectual Property

Patents and other proprietary rights are essential to our business. We file patent applications to protect our technologies, inventions and improvements to our inventions that we consider important to the development of our business. We file for patent registration extensively in the United States and in key foreign markets. Although our patent filings include claims covering various features of our products and product candidates, including composition, methods of manufacture and use, our patents do not provide us with complete protection, or guarantee, against the development of competing products. In addition, some of our know-how and technology are not patentable. We thus also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We also require employees, consultants, advisors and collaborators to enter into confidentiality agreements, but such agreements may provide limited protection for our trade secrets, know-how or other proprietary information.

As of December 31, 2023, our patent portfolio included approximately 120 issued U.S. patents and approximately 100 U.S. patent applications as well as approximately 1,100 issued foreign counterpart patents and approximately 800 counterpart foreign patent applications. These are comprised, in part, of:

- one U.S. patent, 4 U.S. patent applications and approximately 40 counterpart foreign patent applications directed to treatment of RRP;

- seven issued U.S. patents and four U.S. patent applications, as well as approximately 80 issued foreign counterpart patents and approximately 30 counterpart foreign patent applications, directed to treatment of GBM;
- approximately 100 issued U.S. patents and approximately 80 U.S. patent applications, as well as approximately 850 issued foreign counterpart patents and approximately 590 counterpart foreign patent applications, directed to our other earlier-stage product candidates; and
- 4 issued U.S. patents and 6 U.S. patent applications, as well as approximately 160 issued foreign counterpart patents and approximately 50 counterpart foreign patent applications, directed to our device delivery systems.

Our pending patent applications directed to treatment of RRP, if issued, would expire between about 2040 and 2043. Our issued patents directed to treatment of GBM expire between about 2027 and 2037 and our pending patent applications, if issued, would expire between about 2027 and 2040. Our issued patents directed to our other product candidates expire between about 2027 and 2036 and our pending patent applications, if issued, would expire between about 2027 and 2042. Our issued patents directed to our device delivery systems expire between about 2024 and 2036 and our pending patent applications, if issued, would expire between about 2024 and 2042.

Individual patent terms extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. In most countries in which we file patent applications, including the United States, the patent term is 20 years from the date of filing of the first non-provisional patent application to which priority is claimed. In some instances, a patent term can be extended under certain circumstances, such as patent term extension or patent term adjustment; alternatively, a patent term may be shortened, for example in the United States, if a patent is terminally disclaimed over an earlier-filed patent. Protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

If we fail to protect our intellectual property rights adequately our competitors might gain access to our technology and our business would thus be harmed. In addition, defending our intellectual property rights might entail significant expense. Any of our intellectual property rights may be challenged by others or invalidated through administrative processes or litigation through the courts. In addition, our patents, or any other patents that may be issued to us in the future, may not provide us with any competitive advantages, or may be challenged by third parties. Furthermore, legal standards relating to the validity, enforceability and scope of protection of intellectual property rights are uncertain. Effective patent, trademark, copyright and trade secret protection may not be available to us in each country where we operate. The laws of some foreign countries may not be as protective of intellectual property rights as those in the United States, and domestic and international mechanisms for enforcement of intellectual property rights in those countries may be inadequate. Accordingly, despite our efforts, we may be unable to prevent third parties from infringing upon or misappropriating our intellectual property or otherwise gaining access to our technology. We may be required to expend significant resources to monitor and protect our intellectual property rights. We may initiate claims or litigation against third parties for infringement of our proprietary rights or to establish the validity of our proprietary rights. Any such litigation, whether or not it is ultimately resolved in our favor, would result in significant expense to us and divert the efforts of our technical and management personnel.

There may be rights we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us, and that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or biologic drug candidate that is the subject of the suit. As a result of patent infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also impact our collaborators, which would also impact the success of the collaboration and therefore us.

Important legal issues remain to be resolved as to the extent and scope of available patent protection for biologic products, including vaccines, and processes in the United States and other important markets outside the United States, such as Europe and Japan. Foreign markets may not provide the same level of patent protection as provided under the United States patent system. We recognize that litigation or administrative proceedings may be necessary to determine the validity and scope of certain of our and others' proprietary rights. Any such litigation or proceeding may result in a significant commitment of resources in the future and could force us to interrupt our operations, redesign our products or processes, or negotiate a license agreement, all of which would adversely affect our revenue. Furthermore, changes in, or different interpretations of, patent laws in the United States and other countries may result in patent laws that allow others to use our discoveries or develop and commercialize our products.

We cannot guarantee that the patents we obtain or the unpatented technology we hold will afford us significant commercial protection.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological products, or biologics, and medical devices, such as our product candidates. Generally, before a new biologic or medical device can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority. These requirements are continually updated by regulatory authorities to address changes in science, manufacturing and potential new threats, such as cybersecurity concerns.

Review and Approval of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, device, or biological packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Our product candidates are combination products comprising an electroporation device for delivery of a biologic. Under the Federal Food, Drug, and Cosmetic Act, or FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the “primary mode of action” of the combination product, which means the mode of action expected to make the greatest contribution to the overall intended therapeutic effects. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biologic product, that is, if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, the FDA center responsible for premarket review of the biologic product would have primary jurisdiction for the combination product. We believe that all of our product candidates will have a biologic primary mode of action.

U.S. Biological Product Development

In the United States, the FDA regulates biologics under FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. Biologics are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. 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 to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates must be approved by the FDA through the Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed product candidate for its proposed indication;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

The data required to support a BLA is generated in two distinct development stages: pre-clinical and clinical. The pre-clinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the pre-clinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the pre-clinical studies, 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. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the product candidate to healthy participants under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research participants provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, participant selection and exclusion criteria, and the parameters to be used to monitor participant safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items 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 informed consent form that must be provided to each clinical trial participant or his or her legal representative and must monitor the clinical trial until completed.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. The FDA requires sponsors to disclose the results of most, but not all, trials after completion.

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase 1, Phase 2 and Phase 3 clinical trials. Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a product candidate. The primary purpose of these clinical trials is to assess the action, side effect tolerability and safety of the product candidate and, if possible, to gain early evidence on effectiveness. Phase 2 clinical trials typically involve studies in patients to determine the dose required to produce the desired benefits. At the same time, safety and preliminary evaluation of efficacy is assessed. Phase 3 clinical trials generally involve large numbers of patients at multiple sites, in multiple countries (from several hundred to several thousand participants) and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may grant conditional approval of a BLA on the sponsor's agreement to conduct additional clinical trials, such as these post-approval trials, to further assess the biologic's safety and effectiveness after BLA approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important rate increase of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research participants are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product 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, must develop methods for testing the identity, strength, quality 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.

BLA and FDA Review Process

Following trial completion, trial data is analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the product candidate, and other relevant information. The BLA is a request for approval to market the biologic in combination with the device, if applicable, for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application includes positive findings from pre-clinical and clinical trials as well as ambiguous or negative results. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. PDUFA also imposes an annual program fee for approved 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 or a waiver of fee based on orphan drug status.

Once a BLA has been accepted for filing, which occurs, if at all, 60 days after the BLA's submission, the FDA's goal is to review BLAs within ten months of the filing date for standard review or six months of the filing date for priority review, if the application is for a product intended for a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness. The review process is often significantly extended by FDA requests for additional information or clarification. If not accepted for filing, the sponsor must resubmit the BLA and begin the FDA's review process again, including the initial 60-day review to determine if the application is sufficiently complete to permit substantive review.

The FDA may also accept the submission of a BLA under its Accelerated Approval Program, which was instituted to allow for earlier approval of drugs that treat serious conditions and fill an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but may not it itself be the final measure of clinical benefit. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval. Companies are still required to conduct studies to confirm the anticipated clinical benefit. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA would grant provisional approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to the removal of the drug from the market.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with cGMP to assure and preserve the product candidate's identity, strength, quality, purity and potency. The FDA may refer applications for novel drug product candidates or drug product candidates which 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. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of a BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and an applicant may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product 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 specifications. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it 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 indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States and applicants may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Post-Marketing Requirements

Following approval of a new product, a manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved labeling, also known as off-label use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. Moreover, the constituent parts of a combination product retain their regulatory status, for example, as a biologic or device, and as such, we may be subject to additional requirements in the Quality System Regulation, or QSR, applicable to medical devices, such as design controls, purchasing controls, and corrective and preventive action. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved 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. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, REMS and post-marketing surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product’s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA’s policies may change, which could delay or prevent regulatory approval of our products under development.

Coverage and Reimbursement

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs and vaccines. Accordingly, a pharmaceutical company’s ability to commercialize its products successfully depends in part on the extent to which private health insurers, other third-party payors, and governmental authorities, including Medicare and Medicaid, establish appropriate coverage and reimbursement levels for its product candidates and related treatments. As a threshold for coverage and reimbursement, third-party payors generally require that products be approved for marketing by the FDA.

Coverage decisions may not favor new products when more established or lower cost therapeutic alternatives are available. The process for obtaining coverage for a product or service is separate from the process to obtain the associated reimbursement. Reimbursement levels can affect the adoption of products and services by physicians and patients. Additionally, products used in connection with medical procedures may not be reimbursed separately, but their cost may instead be bundled as part of the payment received by the provider for the procedure only. Separate reimbursement for a product or the treatment or procedure in which the product is used may not be available.

Coverage and reimbursement policies for drug products and vaccines can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly which may require the provision of scientific and clinical support for the use of the product to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained.

A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and services. Third-party payors are increasingly challenging the effectiveness of and prices charged for medical products and services. Moreover, the U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs.

Healthcare Reform

In both the United States and certain foreign jurisdictions there have been, and continue to be, a number of legislative and regulatory changes to the healthcare system that impact the ability to sell pharmaceutical products profitably. In the United States, the federal government enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA. The ACA, among other things, increased the minimum level of

Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new 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 expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at the Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry qualifying health insurance coverage for all or part of a year. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax, and, effective January 1, 2021, also eliminated the health insurer tax. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or 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 and by creating a newly established manufacturer discount program. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business. In addition, other legislative changes have been proposed and adopted since the ACA was enacted.

In August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect until 2032 unless additional Congressional action is taken. 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. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent 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, 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, the U.S. Department of Health and Human Services, or 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 to advance these principles. In addition, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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.

Healthcare Laws

Certain federal, state, local and foreign healthcare laws and regulations pertaining to fraud and abuse, transparency, patients' rights, and privacy are applicable to the business of a pharmaceutical company. The laws that may affect a pharmaceutical company's ability to operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, people from soliciting, receiving or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the purchasing, ordering, or leasing of an item, good, facility or service, for which payment may be made by a federal healthcare program such as Medicare or Medicaid;
- Federal civil and criminal false claims laws, including the civil False Claims Act, 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on certain individuals and entities;
- the Physician Payments Sunshine Act, created under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- the FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;
- the U.S. Foreign Corrupt Practices Act, which, among other things, prohibits companies issuing stock in the U.S. from bribing foreign officials for government contracts and other business;
- state 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 and local laws requiring the registration of pharmaceutical sales and medical 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 often are not preempted by HIPAA, thus complicating compliance efforts; and
- additional state and local laws such as laws in California and Massachusetts, which mandate implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other state and local laws, such as laws in Vermont, Maine, and Minnesota which require reporting to state governments of gifts, compensation, and other remuneration to physicians.

A pharmaceutical company will need to spend substantial time and money to ensure that its business arrangements with third parties comply with applicable healthcare laws and regulations. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, which require strict compliance in order to offer protection, it is possible that governmental authorities may conclude that its business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If a pharmaceutical company's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity and/or other oversight obligations, contractual damages, reputational harm and the curtailment or restructuring of operations.

Other Regulations

We also are subject to various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted.

Significant Customers and Research and Development

During the year ended December 31, 2023, we derived 29% of our revenue from ApolloBio. During the year ended December 31, 2022, we derived 94% of our revenue from the procurement contract with the DoD that we entered into in June 2020. During the year ended December 31, 2021, we derived 43% of our revenue from the procurement contract with the DoD and 14% of our revenue from our collaborator Plumbline Life Sciences, a company of which we are an approximately 19% stockholder.

Since our inception, virtually all of our activities have consisted of research and development efforts related to developing our electroporation technologies and immunotherapies. Research and development expense consists of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Our research and development expense was $86.7 million in 2023, $187.7 million in 2022 and $249.2 million in 2021.

Geographic Information

All of our revenue for the years ended December 31, 2023, 2022 and 2021 was earned in the United States. All of our long-lived assets are located in the United States.

Corporate Information

Our corporate headquarters are located at 660 W. Germantown Pike, Suite 110, Plymouth Meeting, Pennsylvania 19462, and our main telephone number is (267) 440-4200.

Available Information

Our Internet website address is www.inovio.com. In addition to the information contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

We make our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or the Exchange Act, available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

Information regarding our corporate governance, including the charters of our audit committee, our nomination and corporate governance committee and our compensation committee, our Code of Business Conduct and Ethics, our Corporate Governance Guidelines, and information for contacting our board of directors is available on our website.

Our Code of Business Conduct and Ethics includes our Code of Ethics applicable to our Chief Executive Officer and Chief Financial Officer, who also serves as our principal accounting officer. Any amendments to or waivers of the Code of Ethics will be promptly posted on our website or in a report on Form 8-K, as required by applicable law.

Employees and Human Capital Resources

As of February 14, 2024, we employed 122 people on a full-time basis. Of the total, 90 were in product research, which includes research and development, quality assurance, clinical, engineering and manufacturing, and 32 were in general and administrative functions, which includes corporate development, information technology, legal, commercial, investor relations, finance and corporate administration. Approximately one-half of our workforce is comprised of women and approximately one-half is comprised of individuals with ethnically diverse backgrounds. In addition, four of the eight members of our board of directors are women. None of our employees are subject to collective bargaining agreements. We consider our relationship with our employees to be good.

We compete in the highly competitive biotechnology industry. Attracting, developing and retaining talented people in research, quality assurance, clinical, engineering, manufacturing and other positions is crucial to executing our strategy and our ability to compete effectively. Our ability to recruit and retain such talent depends on several factors, including compensation and benefits, talent development and career opportunities, and work environment. To that end, we invest in our employees to be an employer of choice.

Employee Engagement

As we work to make an impact on how healthcare is delivered, we believe it is critical that our employees are informed and engaged. We communicate frequently and transparently with our employees through a variety of communication methods, including video and written communications, town hall meetings, employee surveys and our company intranet, and acknowledge individual contributions to our company's success through several rewards and recognition initiatives. We believe these engagement efforts keep employees informed about our strategy, culture and purpose and motivated to do their best work.

Health, Safety and Wellness

The physical health, financial well-being, life balance and mental health of our employees is vital to our success. We have a company-wide comprehensive wellness program inclusive of financial, physical, and mental well-being.

Our environmental, health and safety team stays abreast of local, regional and global concerns and trends and ensures safety procedures are in place to mitigate workplace injuries and safety risks. Employees are required to complete training in various safety procedures for the laboratories and manufacturing facilities and specialized safety training based on particular job duties. Designated Safety Officers and response teams oversee safety-related initiatives and a safety committee provides input on safety procedures, practices, and policies. Employees are required to wear personal protective equipment relevant for their particular job duties. Occupational injuries at our workplace have historically been very low and are always investigated to determine if any environmental or other changes need to be implemented.

ITEM 1A. RISK FACTORS

You should carefully consider the following factors regarding information included in this Annual Report. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, financial condition and operating results could be materially adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses in recent years, expect to incur significant net losses in the foreseeable future and may never become profitable.

We have experienced significant operating losses over the last several years. As of December 31, 2023 our accumulated deficit was $1.6 billion. We have generated limited revenues, primarily consisting of license revenue, grant funding and interest income. We expect to continue to incur substantial additional operating losses for at least the next several years as we advance our clinical trials and research and development activities. We may never successfully commercialize our DNA medicine candidates or proprietary device technology and thus may never have any significant future revenues or achieve and sustain profitability.

We have limited sources of revenue and our success is dependent on our ability to develop our DNA medicines and proprietary device technology.

We do not currently generate any revenue from the commercial sale of products. Our ability to generate future revenues depends heavily on our success in:

- developing and securing United States and/or foreign regulatory approvals for our DNA medicine candidates, including securing regulatory approval for conducting clinical trials with DNA medicine candidates;
- developing our proprietary device technology; and
- commercializing any products for which we receive approval from the FDA and foreign regulatory authorities.

Our proprietary device and DNA medicine candidates will require extensive additional clinical study and evaluation, regulatory approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote our proprietary device and DNA medicine candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. If we do not receive regulatory approval for and successfully commercialize any products, we will not generate any revenues from sales of proprietary devices and DNA medicine products, and we may not be able to continue our operations.

A small number of licensing partners and government contracts have accounted for a substantial portion of our revenue.

In the past we have derived a significant portion of our revenue from a limited number of licensing partners and government grants and contracts, and we expect that a significant portion of our revenue will continue to be derived from a limited number of licensing partners and/or government grants and contracts unless and until we are able to commercialize our product candidates. Revenue can fluctuate significantly depending on the timing of upfront and event-based payments and work performed. If we fail to sign additional future contracts with major licensing partners and the government, if a contract is delayed or deferred, or if an existing contract expires or is canceled and we fail to replace the contract with new business, our revenue would be adversely affected.

We will need substantial additional capital to develop our DNA medicines and proprietary device technology, which may prove difficult or costly to obtain.

Conducting the costly and time-consuming research, pre-clinical studies and clinical testing necessary to obtain regulatory approvals and bring our DNA medicine candidates and proprietary device technology to market will require a commitment of substantial funds in excess of our current capital. Our future capital requirements will depend on many factors, including, among others:

- the progress of our current and new product development programs;
- the progress, scope and results of our pre-clinical and clinical testing;
- the time and cost involved in obtaining regulatory approvals;
- the cost of manufacturing our DNA medicine candidates;
- the cost of prosecuting, enforcing and defending against patent infringement claims and other intellectual property rights;
- debt service obligations;
- competing technological and market developments; and

- our ability and the related costs to establish and maintain collaborative and other arrangements with third parties to assist in potentially bringing our products to market.

Additional financing may not be available on acceptable terms, or at all. Domestic and international capital markets have from time to time experienced heightened volatility, particularly in light of geopolitical turmoil, inflation and rising interest rates, making it more difficult in many cases to raise capital through the issuance of equity securities. Volatility in the capital markets can also negatively impact the cost and availability of credit, creating illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases cease to provide, funding to borrowers. To the extent we are able to raise additional capital through the sale of equity securities, or we issue securities in connection with another transaction in the future, the ownership position of existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock and may involve significant fees, interest expense, restrictive covenants and the granting of security interests in our assets. Rising interest rates could also increase the costs of any debt financing we may obtain. Raising capital through a licensing or other transaction involving our intellectual property could require us to relinquish valuable intellectual property rights and thereby sacrifice long-term value for short-term liquidity.

Our failure to successfully address ongoing liquidity requirements would have a substantially negative impact on our business. If we are unable to obtain additional capital on acceptable terms when needed, we may need to take actions that adversely affect our business, our stock price and our ability to achieve cash flow in the future, including possibly surrendering our rights to some technologies or product opportunities, delaying our clinical trials or curtailing or ceasing operations.

Risks Related to Product Development, Manufacturing and Regulatory Approval

If we are unable to obtain FDA approval of our product candidates, we will not be able to commercialize them in the United States.

We need FDA approval prior to marketing our proprietary device and DNA medicine candidates in the United States. If we fail to obtain FDA approval to market our proprietary device and DNA medicine candidates, we will be unable to sell our products in the United States, which will significantly impair our ability to generate any revenues.

This regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of our products as well as the evaluation of our manufacturing processes and our third-party contract manufacturers' facilities, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that our proprietary device and DNA medicine candidates are both safe and effective for each indication for which approval is sought. To the extent that our DNA medicine candidates are manufactured at multiple sites or using different processes, we will also need to demonstrate comparability across the manufacturing batches in order to obtain regulatory approval. Satisfaction of the approval requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the product. We do not know if or when we might receive regulatory approvals for our proprietary device and any of our DNA medicine candidates currently under development. Moreover, any approvals that we obtain may not cover all of the clinical indications for which we are seeking approval, or could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use. In such event, our ability to generate revenues from such products would be greatly reduced and our business would be harmed.

The FDA has substantial discretion in the approval process and may either refuse to consider our application for substantive review or may form the opinion after review of our data that our application is insufficient to allow approval of our proprietary device and DNA medicine candidates. If the FDA does not consider or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our applications for approval, which might significantly harm our business and prospects.

It is possible that none of our product candidates or any product we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us or our collaborators to commence product sales. Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our products, generating revenues and achieving and sustaining profitability.

Furthermore, because our product candidates are combination products comprising an electroporation device for delivery of a biologic, additional time may be required to obtain regulatory approval for our product candidates because of the complexity involved with co-packaging a drug-device combination product. In addition, if the FDA and similar regulatory agencies do not approve our delivery devices, then we will not be able to bring to market our DNA medicines that rely on delivery by such a device. Such delays or failure to obtain approval of our devices would result in significant harm to our business.

If we pursue accelerated approval for INO-3107 or any of our other product candidates, it may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We plan to pursue accelerated approval for our product candidate INO-3107 and may in the future decide to pursue accelerated approval for one or more of our other product candidates. Under the FDA's accelerated approval program, the FDA may approve a drug or biologic for a serious or life-threatening disease or condition that provides a meaningful advantage over available therapies based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. For drugs or biologics granted accelerated approval, post-marketing confirmatory trials are required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence, and the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval.

If we pursue accelerated approval for INO-3107 for the treatment or RRP, or a future product candidate for another disease or condition, we would do so on the basis that there is no available therapy for that disease or condition or that our product candidate provides a benefit over available therapy. If standard of care were to evolve or if any of our competitors were to receive full approval on the basis of a confirmatory trial for a drug or biologic for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, the disease or condition would no longer qualify as one for which there is no available therapy, and accelerated approval of our product candidate would not occur without a showing of benefit over available therapy. The treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials.

We have received feedback from the FDA that data from our completed Phase 1/2 clinical trial of INO-3107 for the treatment of RRP can be used to support the submission of a BLA for review under the accelerated approval program; however, whether any trial is sufficient to receive FDA approval under the accelerated approval pathway will depend on the safety and efficacy results of such trial and will only be determined by the FDA upon review of a submitted BLA.

Moreover, the FDA may withdraw approval of INO-3107 or any future product candidate approved under the accelerated approval pathway if, for example:

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

In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs.

Even if our products receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States, and the same risk applies for products approved outside the United States, with respect to regulatory approval in the United States.

In order to market any proprietary device and DNA medicine candidates outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval, and the regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Furthermore, regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our DNA medicine candidates may not be approved for all indications requested, which could limit the uses of our DNA medicine candidates and have an adverse effect on their commercial potential or require costly, post-marketing follow-up studies.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Results from one study may not be reflected or supported by the results of similar studies. Results of an animal study may not be indicative of results achievable in human studies. Human-use equipment and DNA medicine candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing. The time required to obtain approval by the FDA and similar foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials, depending upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change. We have not obtained regulatory approval for any human-use products.

Our product candidates could fail to complete the clinical trial process for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our proprietary device or product candidate is safe and effective for any indication;
- the results of clinical trials may not meet the level of clinical or statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may not be successful in enrolling a sufficient number of participants in clinical trials;
- we may be unable to demonstrate that our proprietary device or DNA medicine candidates' clinical and other benefits outweigh their safety risks;
- we may be unable to demonstrate that our proprietary device or product candidate presents an advantage over existing therapies, or over placebo in any indications for which the FDA requires a placebo-controlled trial;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our DNA medicine candidates may not be sufficient to support the submission of a new drug application or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or that of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Delays in the commencement, conduct or completion of clinical testing could result in increased costs to us and delay or limit our ability to generate revenues.

Delays in the commencement, conduct or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. In addition, ongoing clinical trials may not be completed on schedule, or at all, and could be placed on a hold by the regulators for various reasons. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory approval to commence a clinical trial;
- adverse results from third-party clinical trials involving gene-based therapies and the regulatory response thereto;
- reaching agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- future bans or stricter standards imposed on clinical trials of gene-based therapy;
- manufacturing sufficient quantities of our proprietary device and DNA medicine candidates for use in clinical trials;
- obtaining Internal Review Board, or IRB, approval to conduct a clinical trial at a prospective site;
- slower than expected recruitment and enrollment of patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for similar indications;
- conducting clinical trials with sites internationally due to regulatory approvals and meeting international standards;

- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up;
- collecting, reviewing and analyzing our clinical trial data; and
- global unrest, including geopolitical risks emanating from countries such as Russia and China, global pathogen outbreaks or pandemics, terrorist activities, the conflict between Israel and Hamas, bank failures and other economic and other external factors beyond our control.

With respect to clinical trials of product candidates for rare diseases, such as our planned confirmatory trial of INO-3107 for the treatment of recurrent respiratory papillomatosis, or RRP, we may encounter difficulties in recruiting a sufficient number of patients to enroll in the trial due to the small number of patients with the disease. Because RRP is caused by specific HPV types, 6 and 11, and there is currently no standard protocol for diagnostic/screening of RRP patients unless there are symptoms of dysphonia, respiratory distress or other symptoms related to the presence of papillomas, it may be difficult to identify and diagnose patients for whom INO-3107 may be a potential treatment.

Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; and
- lack of adequate funding to continue the clinical trial.

If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our proprietary device and our DNA medicine candidates may be harmed and our ability to generate product revenues will be delayed or eliminated altogether. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Further, delays in the commencement, conduct or completion of clinical trials may adversely affect the trading price of our common stock.

None of our DNA medicine candidates have been approved for sale, and we may never develop commercially successful DNA medicine products.

Our DNA medicines programs are in various stages of research and development, and currently include DNA medicine candidates in discovery, preclinical studies and Phase 1, 2 and 3 clinical trials. There are limited data regarding the efficacy of DNA medicine candidates compared with conventional vaccines, and we must conduct a substantial amount of additional research and development before the FDA or any comparable foreign regulatory authority will approve any of our DNA medicine candidates. The success of our efforts to develop and commercialize our DNA medicine candidates could be delayed or fail for a number of reasons. For example, we could experience delays in product development and clinical trials. Our DNA medicine candidates could be found to be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances to proceed with further clinical development or to be approved for marketing. Our products, even if they are deemed to be safe and effective by regulatory authorities, could be difficult to manufacture on a large scale or uneconomical to market, or our competitors could develop superior products more quickly and efficiently or more effectively market their competing products.

In addition, adverse events, or the perception of adverse events, relating to vaccine and immunotherapy candidates and delivery technologies may negatively impact our ability to develop commercially successful products. For example, pharmaceutical companies have been subject to claims that the use of some pediatric vaccines has caused personal injuries, including brain damage, central nervous system damage and autism. These and other claims may influence public perception of the use of vaccine and immunotherapy products and could result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential products.

We previously expended significant resources on the development of a COVID-19 vaccine candidate. We are now only pursuing development in collaboration with third parties, as both a primary and heterologous booster vaccine, but there can be no assurance that our candidate will ever receive regulatory approval as a primary vaccine or a booster in any country, whether by Emergency Use Authorization or otherwise.

Beginning in 2020, we expended significant resources on the clinical development of a COVID-19 vaccine candidate, INO-4800. We were previously conducting a Phase 2/3 clinical trial of INO-4800 called INNOVATE. Based on regulatory feedback and the competitive landscape for COVID-19 vaccines, in 2022 we discontinued the INNOVATE trial and pursued a strategy to develop our COVID-19 vaccine as a potential heterologous booster following administration of other primary vaccines. Following an assessment of the current global demand for COVID-19 vaccines, changes in regulatory timelines and requirements, diminishing government financial support, and the overall growing uncertainty related to opportunities for heterologous booster vaccines, in the fourth quarter of 2022 we discontinued our internally funded efforts to develop INO-4800 as a COVID-19 heterologous booster vaccine.

We are no longer conducting any active clinical trials of INO-4800 and do not expect that it will ever receive regulatory approval in the United States. Our collaborator Advaccine has completed enrollment of its 200-participant homologous and 267-participant heterologous booster vaccine trials in China. They may seek an Emergency Use Authorization, or EUA, from regulatory authorities in China and other countries in Asia for the use of INO-4800 as a heterologous booster. However, any such decision would be made by Advaccine, and there is no guarantee that Advaccine will apply for an EUA or other similar authorization or, if it does apply, that Advaccine will be able to obtain such authorization. An EUA may not be available if countries are no longer in a state of public health emergency, in which case full approval would need to be sought.

We await the results of our COVID-19 vaccine candidate's participation in the World Health Organization’s Solidarity Trial Vaccines. Depending on the results of that trial, we could also pursue a strategy of seeking EUA for the vaccine candidate in other countries outside of the United States. Even if an EUA or other authorization is ultimately granted, we will rely on the applicable regulatory authority policies and guidance governing vaccines authorized in this manner in connection with the marketing and sale of our vaccine candidate. If these policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of our product could be adversely impacted. Regulatory authorities may also terminate an EUA if safety issues or other concerns about our product arise or if we or Advaccine fail to comply with the conditions of authorization. If we or Advaccine apply for an EUA or similar authorization from regulatory authorities outside of the United States, the failure to obtain such authorization or the termination of such an authorization, if obtained, would adversely impact our and Advaccine’s ability to market and sell our COVID-19 vaccine.

DNA medicines are a novel approach to treating and preventing disease, and our CELLECTRA ® delivery devices are a novel approach to administering medicines, and negative perception of the efficacy, safety, or tolerability of any investigational medicines we develop or our devices could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals.

No DNA medicines have been granted EUA or have been approved to date by the FDA. Adverse events in clinical trials of our investigational medicines or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of DNA medicine, or other products that are perceived to be similar to DNA medicines, such as those related to other nucleic acid based vaccines such as mRNA vaccines, gene therapy or gene editing, could result in a decrease in the perceived benefit of one or more of our programs, increased regulatory scrutiny, decreased confidence by patients and clinical trial collaborators in our investigational medicines, and less demand for any product that we may develop. Our pipeline of DNA medicine candidates could result in a greater quantity of reportable adverse events, including suspected unexpected serious adverse reactions, other reportable negative clinical outcomes, manufacturing reportable events or material clinical events that could lead to clinical delay or hold by the FDA or applicable regulatory authority or other clinical delays, any of which could negatively impact the perception of one or more of our programs, as well as our business as a whole. In addition, responses by U.S., state, or foreign governments to negative public perception may result in new legislation or regulations that could limit our ability to develop any investigational medicines or commercialize any approved products, obtain or maintain regulatory approval, or otherwise achieve profitability. More restrictive statutory regimes, government regulations, or negative public opinion would have an adverse effect on our business, financial condition, results of operations, and prospects and may delay or impair the development of our investigational medicines and commercialization of any approved products or demand for any products we may develop.

In addition, the novelty of our CELLECTRA ® delivery devices may make it difficult to demonstrate to physicians and third-party payors that this delivery system is an appropriate approach for DNA medicines and provides advantages compared to the current standards of care. Further, if we or our commercialization and collaboration partners are not successful in conveying to physicians, patients and third-party payors that our CELLECTRA® delivery devices provide useful patient outcomes, we or our commercialization and collaboration partners may experience reluctance, or refusal, on the part of physicians to order and use, and third-party payors to cover and provide adequate reimbursement for,our DNA medicines.

If we and the contract manufacturers upon whom we rely fail to produce our proprietary devices and DNA medicine candidates in the volumes that we require on a timely basis, or at all, or if these contractors fail to comply with their obligations to us or with stringent regulations, we may face delays in the development and commercialization of our proprietary device and DNA medicine candidates.

We manufacture some components of our proprietary devices and utilize the services of contract manufacturers to manufacture the remaining components of these devices. We also rely on third party contract manufacturers to produce our DNA medicine candidates for use in our clinical trials and potentially for commercial distribution, if any product candidate is approved by regulatory authorities. The manufacture of these devices and our DNA medicine candidates requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers often encounter difficulties in production, particularly in scaling up for commercial production.

These problems include difficulties with production costs and yields, quality control, including stability of the equipment and DNA medicine candidates and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations.

If we or our manufacturers were to encounter any of these difficulties or our manufacturers otherwise fail to comply with their obligations to us, our ability to provide our proprietary device to our partners and to supply DNA medicine candidates for clinical trials or to commercially launch a product would be jeopardized. For example, we previously relied on VGXI to manufacture DNA plasmids for our DNA medicine candidates before they became unable to produce the necessary plasmids due to a lack of manufacturing capacity. As a result, we had to engage several additional third-party contract manufacturers. However, there can be no assurance that we will be able to secure adequate additional manufacturing capacity for any of our DNA medicine candidates on commercially reasonable terms. Our inability to secure sufficient manufacturing capacity, or our inability to transfer necessary manufacturing know-how to third parties, would adversely affect our commercialization plans and could also harm our reputation.

Furthermore, any delay or interruption in the supply of clinical trial supplies for our DNA medicine candidates could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial program and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

In addition, all manufacturers of our products must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the generation and maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product is compromised due to our or our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our products, entail higher costs or result in our being unable to effectively commercialize our products. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis, pursuant to provided specifications and at commercially reasonable prices, we may be unable to meet demand for our products and would lose potential revenues.

Our product candidates are combination products regulated under both the biologic and device regulations of the Public Health Service Act and Federal Food, Drug, and Cosmetic Act. Third-party manufacturers may not be able to comply with cGMP regulations, regulations applicable to biologic/device combination products, including applicable provisions of the FDA’s drug cGMP regulations, device cGMP requirements embodied in the quality system regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates.

We are dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, our product candidates and investigational medicines.

We currently depend on single-source suppliers for some of the components and materials used in, and manufacturing processes required to develop and commercialize, our product candidates and investigational medicines. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that may not be interested in continuing to work with us. Our use of single-source suppliers of raw materials, components, key processes, and finished goods exposes us to several risks, including disruptions in supply, price increases, or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials, and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations, and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates or investigational medicines could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in our product candidates or investigational medicines, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source components and materials used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to supply our investigational medicines.

Our reliance on these suppliers, service providers, and manufacturers subjects us to a number of risks that could harm our reputation, business, and financial condition, including, among other things:

- delays to the development timelines for our development candidates or investigational medicines;
- interruption of supply resulting from modifications to or discontinuation of a supplier’s operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier’s variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of components from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers’ prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted.

Even if our products receive regulatory approval, they may still face future development and regulatory difficulties.

Even if United States regulatory approval is obtained, regulators may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. This governmental oversight may be particularly strict with respect to gene-based therapies. Our products will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, record keeping and submission of safety and other post-market information. For example, the FDA strictly regulates the promotional claims that may be made about medical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product’s approved labeling. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician’s choice of drug treatment made in the physician’s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may in certain circumstances share truthful and not misleading information that is otherwise consistent with the product’s FDA approved labeling. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our DNA medicine candidates, or the manufacturing facilities for our DNA medicine candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue Warning Letters or untitled letters;
- impose civil or criminal penalties;
- suspend regulatory approvals;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

We are developing some of our investigational DNA medicines using new endpoints or methodologies for the treatment of diseases in which there is little clinical experience. As a result, the FDA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.

There are no pharmacologic therapies approved to treat the underlying causes of many diseases that we currently attempt to address or may address in the future. There has been limited clinical trial experience for the development of pharmaceuticals to treat these rare diseases in general, and we are not aware of a registrational trial that led to approval of a drug to treat these diseases. There have been some historical trials with other agents which may have utilized clinical endpoints that are less applicable to our efforts that address the underlying defect. As a result, the design and conduct of clinical trials of investigational medicines for the treatment of these disorders and other disorders may take longer, be more costly, or be less effective as part of the novelty of development in these diseases. For example, our product candidate INO-3107 is being developed for RRP, a rare condition for which there are no approved non-surgical treatments.

Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we or our strategic collaborators may conduct for our programs. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA also could give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that endpoint, if we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of licensure. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints.

We have obtained Orphan Drug Designation for one of our DNA medicine candidates. As part of our business strategy, we may continue to seek Orphan Drug Designation for additional DNA medicine candidates, and we may be unsuccessful in obtaining new designations or may be unable to obtain or maintain the benefits associated with Orphan Drug Designation, including the potential for orphan drug exclusivity.

We have obtained Orphan Drug Designation from the FDA for INO-3107 for the treatment of RRP. We have sought and may continue to seek Orphan Drug Designation for one or more of our other DNA medicine candidates, although we may be unsuccessful in doing so. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as tax advantages and user fee waivers. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs for rare diseases, regardless of whether the drugs are designated for the orphan use. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease 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 product for the same indication for seven years, except in limited circumstances.

Although we have obtained Orphan Drug Designation for INO-3107 for the treatment of RRP, and even if we obtain Orphan Drug Designation for our other DNA medicine candidates in specific indications, we may not be the first to obtain marketing approval of these DNA medicine candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. If a competitor with a product that is determined by the FDA to be the same as one of our DNA medicine candidates obtains marketing approval before us for the same indication we are pursuing and obtains orphan drug exclusivity, our product candidate may not be approved until the period of exclusivity ends unless we are able to demonstrate that our product candidate is clinically superior. Even after obtaining approval, we may be limited in our ability to market our product. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different principal molecular structural features can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same principal molecular structural features for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for some of our DNA medicine candidates, we may never receive such designations.

A breakthrough therapy designation or fast track designation by the FDA for a drug may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the drug will receive marketing approval.

We have received breakthrough therapy designation for INO-3107 and may seek this designation for one or more of our other investigational medicines. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the regulatory submission.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our investigational medicines meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. Even if we are successful in obtaining accelerated approval in the United States or under comparable pathways in other jurisdictions, we may face requirements and limitations that will adversely affect our prospects. For example, we may be approved only for a very limited indication, we may not successfully complete required post-approval trials, such trials may not confirm the clinical benefit of our drug, or approval of the drug may be withdrawn. In addition, even if one or more of our investigational medicines qualify as breakthrough therapies, the FDA may later decide that the investigational medicine no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

Risks Related to Reliance on Third Parties

If we lose or are unable to secure collaborators or partners, or if our collaborators or partners do not apply adequate resources to their relationships with us, our product development and potential for profitability will suffer.

We have entered into, and may continue to enter into, distribution, co-promotion, partnership, sponsored research and other arrangements for development, manufacturing, sales, marketing and other commercialization activities relating to our products. For example, in the past we have entered into license and collaboration agreements to develop, obtain regulatory approval for and commercialize our DNA medicine candidates for specified indications, including in jurisdictions outside of the United States. The amount and timing of resources applied by our collaborators are largely outside of our control.

If any of our current or future collaborators breaches or terminates our agreements, or fails to conduct our collaborative activities in a timely manner, our commercialization of products could be diminished or blocked completely. We may not receive any event-based payments, milestone payments or royalty payments under our collaborative agreements if our collaborative partners fail to develop products in a timely manner or at all. It is possible that collaborators will change their strategic focus, pursue alternative technologies or develop alternative products, either on their own or in collaboration with others. Further, we may be forced to fund programs that were previously funded by our collaborators, and we may not have, or be able to access, the necessary funding. The effectiveness of our partners, if any, in marketing our products will also affect our revenues and earnings.

We desire to enter into new collaborative agreements. However, we may not be able to successfully negotiate any additional collaborative arrangements and, if established, these relationships may not be scientifically or commercially successful. Our success in the future depends in part on our ability to strategically enter into agreements with other organizations. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate, implement and execute a collaboration. Once news of discussions regarding possible collaborations are known in the medical community, regardless of whether the news is accurate, failure to announce a collaborative agreement or the entity's announcement of a collaboration with another entity may result in adverse speculation about us, resulting in harm to our reputation and our business.

Disputes could also arise between us and our existing or future collaborators, as to a variety of matters, including financial and intellectual property matters or other obligations under our agreements. These disputes could be both expensive and time-consuming and may result in delays in the development and commercialization of our products or could damage our relationship with a collaborator.

We have agreements with government agencies that are subject to termination and uncertain future funding. Termination or cessation of funding would have a negative impact on our ability to develop certain of our pipeline candidates and/or require us to seek alternative funding sources to advance product candidates.

We have entered into agreements with government agencies, such as the National Institutes of Health’s National Institute of Allergy and Infectious Diseases, DARPA, Medical CBRN Defense Consortium and the Department of Defense (DoD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, and we intend to continue entering into these types of agreements with government agencies in the future. Our business is partially dependent on the continued performance by these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal and which generally may be terminated by the government agencies at any time. For example, in 2021 the DoD discontinued funding for the planned Phase 3 trial of our COVID-19 product candidate, which resulted in increased expenditures by us.

Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies. In addition, we may fail to perform our responsibilities under these agreements. Many of our government agreements are subject to audits, which may occur several years after the period to which the audit relates. If an audit identifies significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful entering, or ineligible to enter, into future government agreements.

We and our collaborators rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we and our collaborators may not be able to obtain regulatory approval for or commercialize our DNA medicine candidates.

We and our collaborators have entered into agreements with CROs to provide monitors for and to manage data for our on-going clinical programs. We and the CROs conducting clinical trials for our proprietary device and DNA medicine candidates are required to comply with current good clinical practices, or GCPs, regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or the CROs conducting clinical trials of our DNA medicine candidates fail to comply with applicable GCPs, the clinical data generated in the clinical trials may be deemed unreliable and the FDA may require additional clinical trials before approving any marketing applications.

If any relationships with CROs terminate, we or our collaborators may not be able to enter into arrangements with alternative CROs. In addition, these third-party CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our on-going clinical programs or perform trials efficiently. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could harm our competitive position. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our DNA medicine candidates. As a result, our financial results and the commercial prospects for our DNA medicine candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. Cost overruns by or disputes with our CROs may significantly increase our expenses.

We enter into various contracts in the normal course of our business in which we agree to indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically agree to indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sub licensees' exercise of rights under the agreement. With respect to our commercial agreements, we have agreed to indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we typically agree to indemnify them from claims arising from the good faith performance of their services.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage or not covered by insurance, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator or other third party to indemnify us and the collaborator or other third party is denied insurance coverage or otherwise does not have assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Risks Related to Commercialization of Our DNA Medicine Candidates

We currently have only a small marketing organization and no sales organization. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, if approved, we may not be able to generate product revenues.

We currently have only a small commercial organization to support pre-commercial activities for our proprietary device and DNA medicine candidates, if approved, and we do not currently have a sales organization. In order to successfully commercialize INO-3107 or any other products that may receive regulatory approval, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We contemplate establishing our own sales force or seeking third-party partners to sell our products. The establishment and development of a sales force, either on our own or in conjunction with third parties, will be expensive and time-consuming and could delay any product launch, and we may not be able to successfully develop or acquire this capability. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. To the extent we rely on third parties to commercialize our approved products, if any, we will receive lower revenues than if we commercialized these products ourselves. In the event we are unable to successfully develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize our DNA medicine candidates which would negatively impact our ability to generate product revenues.

If products for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial success of our proprietary device and DNA medicine candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by both the medical community and patient population. Coverage and reimbursement of our DNA medicine candidates by third-party payors, including government payors, generally is also necessary for optimal commercial success. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the relative convenience and ease of administration, including the acceptance and usage of our proprietary device by the medical community;
- the prevalence and severity of any actual or perceived adverse side effects;
- limitations or warnings contained in a product's FDA-approved labeling, including, for example, potential “black box” warnings;
- availability of alternative treatments;
- pricing and cost effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- the potential public perception of new therapies and the reputational challenges that the industry is facing related to drug costs;
- our ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the willingness of patients to pay out of pocket in the absence of third-party coverage.

If our proprietary device and DNA medicine candidates are approved but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our DNA medicine candidates may require significant resources and may never be successful.

We are subject to uncertainty relating to coverage and reimbursement policies which, if not favorable to our DNA medicine candidates, could hinder or prevent our products' commercial success.

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs and medical treatments. Accordingly, our ability to commercialize our proprietary device and DNA medicine candidates successfully will depend in part on the extent to which governmental authorities, including Medicare and Medicaid, private health insurers and other third-party payors establish appropriate coverage and reimbursement levels for our DNA medicine candidates and related treatments. As a threshold for coverage and reimbursement, third-party payors in the United States generally require that drug products and vaccines have been approved for marketing by the FDA.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. Coverage decisions may not favor new products when more established or lower cost therapeutic alternatives are already available. Even if we obtain coverage for a given product, co-payments may be required that patients find unacceptably high. Patients are unlikely to use our products unless reimbursement is adequate to cover all or a significant portion of the cost of our drug products. Even if we obtain coverage for our products, the revenue generated may not be adequate to cover our costs, including research, development, intellectual property, manufacture, sale and distribution.

Additionally, some of our products, if approved, will be provided under the supervision of a physician. When used in connection with medical procedures, our DNA medicine candidates may not be reimbursed separately but their cost may instead be bundled as part of the payment received by the provider for the procedure only. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or separately reimburse for our DNA medicine candidates or procedures using our DNA medicine candidates, could reduce physician utilization of our products once approved.

Coverage and reimbursement policies for products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our products.

A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and services. Third-party payors are increasingly challenging the effectiveness of and prices charged for medical products and services. Moreover, the U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. We may not be able to obtain third-party payor coverage or reimbursement for our products in whole or in part.

Risks Related to Employee and Operational Matters

Our operating results may be harmed if our corporate restructuring plans and cost reduction efforts do not achieve the anticipated results or cause undesirable consequences.

Between July 2022 and January 2023, we undertook a corporate restructuring that resulted in a total reduction in headcount of more than 25% of our employees and a significant majority of our contractors. In August 2023 we announced a further headcount reduction of approximately 30%. As a result, our full-time employee headcount has declined from more than 300 employees in early 2022 to approximately 122 currently. Restructuring plans may yield unintended consequences, such as attrition beyond our intended reduction in workforce and reduced employee morale, which may cause our employees who were not affected by the reduction in workforce to seek alternate employment. During the second half of 2022, we experienced increased voluntary attrition after conducting the first reduction in force. Additional attrition could impede our ability to meet our operational goals, which could have a material adverse effect on our financial performance. In addition, as a result of the reductions in our workforce, we may face an increased risk of employment litigation.

Furthermore, employees whose positions have been or will be eliminated in connection with these restructuring plans may seek future employment with our competitors. Although all our employees are required to sign a confidentiality agreement with us at the time of hire, we cannot be certain that the confidential nature of our proprietary information will be maintained in the course of such future employment. We cannot be certain that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our current or any future restructuring plans. In addition, if we continue to reduce our workforce, it may adversely impact our ability to respond rapidly to any new growth or revenue opportunities. Any restructuring activities we undertake may take longer than expected and may require changes to our business that we are unable to implement. If we are unsuccessful in implementing our cost saving initiatives and restructuring plans or if we do not achieve our expected results, our results of operations and cash flows could be adversely affected.

We are currently subject to litigation and may become subject to additional litigation, which could harm our business, financial condition and reputation.

We may have actions brought against us by stockholders relating to past transactions, changes in our stock price or other matters. For example, numerous purported shareholder class action and shareholder derivative complaints were filed against us beginning in 2020, naming us and our directors and executive officers as defendants, alleging that we made materially false and misleading statements in violation of federal securities laws. Although we have resolved these actions, there can be no guarantee that we will not become subject to similar claims in the future.

We may also become party to litigation with third parties as a result of our business activities. In 2020, we filed a lawsuit against one of our contract manufacturers, who then filed a counterclaim against us alleging that we had breached our contract with them, among other claims. There can be no assurance that we will ultimately prevail in the ongoing litigation matters described in this report or in future litigation matters. These and any potential future actions against us could give rise to substantial damages, which could have a material adverse effect on our financial position, liquidity or results of operations. Even if an action is not resolved against us, the uncertainty and expense associated with litigation could harm our business, financial condition and reputation, as litigation is often costly, time-consuming and disruptive to business operations. The defense of our existing and potential future lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business.

We depend upon key personnel who may terminate their employment with us at any time and we may need to hire additional qualified personnel in order to obtain financing, pursue collaborations or develop or market our DNA medicine candidates.

The success of our business strategy will depend to a significant degree upon the continued services of key management, technical and scientific personnel and our ability to attract and retain additional qualified personnel and managers, including personnel with expertise in clinical trials, government regulation, manufacturing, marketing and other areas. Competition for qualified personnel is intense among companies, academic institutions and other organizations. If we are unable to attract and retain key personnel and advisors, it may negatively affect our ability to successfully develop, test, commercialize and market our products and DNA medicine candidates.

Our business could be adversely affected by the effects of health epidemics.

In response to the COVID-19 pandemic, in 2020 a number of governmental orders and other public health guidance measures were implemented across much of the United States, including in the locations of our offices, laboratories, clinical trial sites and third parties on whom we rely. As a result, our expected clinical development timelines were negatively impacted. Similar events could result in future business and manufacturing disruption, or in reduced operations, any of which would materially affect our business, financial condition and results of operations. The COVID-19 pandemic also caused supply chain disruptions and supply shortages globally. As a result, we experienced delays and disruptions in obtaining clinical supplies, manufacturing supplies and components, and had to secure new vendors for certain supplies and components at higher prices. There can be no assurance that we will not encounter similar difficulties in the future.

Future health epidemics could adversely affect our clinical trial operations, including our ability to initiate and conduct our planned trials on their expected timelines and to recruit and retain participants and principal investigators and site staff who, as healthcare providers, may have heightened exposure if an outbreak occurs in their geography. Trial participants may not be able to or may not feel safe going into healthcare facilities, which is necessary for the collection and completion of data samples for our clinical trials. Further, future epidemics could also result in delays in our clinical trials due to prioritization of hospital resources toward the disease, restrictions in travel, potential unwillingness of participants to enroll in trials, participants withdrawing from trials following enrollment as a result of contracting disease or other health conditions. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us.

We face intense and increasing competition and steps taken by our competitors such as the introduction of a new, disruptive technology may impede our ability to develop and commercialize our DNA medicines.

If any of our competitors develop products with efficacy or safety profiles significantly better than our product candidates and introduce new, disruptive technology, we may not be able to complete the development of or commercialize our product candidates, and sales of any commercialized products could be harmed. Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technologies or product candidates obsolete or non-competitive, or result in treatments or cures superior to ours.

Our competitors and potential competitors include large pharmaceutical companies broadly engaged in vaccine/immunotherapy research and development, such as Janssen Pharmaceuticals (part of J&J), Sanofi-Aventis, GlaxoSmithKline, Merck, Pfizer, Roche, AbbVie, Novartis, Bristol-Myers Squibb, and AstraZeneca, as well as various development-stage biotechnology companies involved in different vaccine and immunotherapy technologies, such as CureVac, Dynavax, Genexine, Hookipa, Iovance, Nektar, Nykode, Precigen, Zydus, and Vir Biotechnology. These companies have significantly greater financial and other resources and greater expertise than us in research and development, securing government contracts and grants to support research and development efforts, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing. This may make it easier for them to respond more quickly than us to new or changing opportunities, technologies or market needs. Many of these competitors operate large, well-funded research and development programs and have significant products approved or in development.

Merck and GlaxoSmithKline have commercialized preventive vaccines against HPV to protect against cervical cancer. Some companies are seeking to treat early HPV infections or low-grade cervical dysplasia. Loop Electrosurgical Excision Procedure, commonly known as LEEP, is a surgical procedure and is the current standard of care for treating high-grade cervical dysplasia. In RRP caused by HPV subtypes 6 and 11, Precigen is developing a potential treatment for RRP based on a gorilla adenovirus vector and has publicly stated its plans to submit a BLA in 2024 based on a completed Phase 1/2 study. As a result, Precigen could receive marketing approval for its RRP product candidate before we can obtain regulatory approval for INO-3107, which could put us at a competitive disadvantage in this indication. Advaxis, Genexine, and Gilead Sciences have therapeutic cervical cancer product candidates under development. Many companies are pursuing different approaches to pre-cancers and cancers we are targeting.

We also compete more specifically with companies seeking to utilize antigen-encoding DNA delivered with electroporation or other delivery technologies such as viral vectors or lipid vectors to induce in vivo generated antigen production and immune responses to prevent or treat various diseases.

Small biotechnology companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical companies or through acquisition or development of intellectual property rights. Our potential competitors also include academic institutions, governmental agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for product and clinical development and marketing. Research and development by others may seek to render our technologies or products obsolete or noncompetitive.

Our failure to successfully acquire, develop and market additional product candidates or approved products would impair our ability to grow.

We may acquire, in-license, develop and/or market additional products and product candidates. The success of these actions depends partly upon our ability to identify, select and acquire promising product candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Changes in funding for the FDA and other government agencies could prevent new products 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, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA 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.

If our information technology systems or those of third parties upon which we rely or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to, regulatory

investigations and actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue and profits; and other adverse consequences.

We rely to a large extent upon sophisticated information technology systems to operate our businesses, some of which are managed, hosted provided and/or used for third-parties or their vendors. We collect, store and transmit large amounts of confidential, proprietary or otherwise sensitive information (including personal information and pseudonymized information), and we deploy and operate an array of technical and procedural controls designed to maintain the confidentiality, availability and integrity of such information as appropriate. A significant breakdown, invasion, corruption, destruction, interruption, or unavailability of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. Hardware, software, or applications we develop or obtain from third parties may contain defects in design or manufacture or other supply chain problems that could unexpectedly compromise our information and network security.

The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the compromise of information stored in our or our third-party providers' systems, portable media or storage devices. Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten our information and information technology systems and those of third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources such as traditional computer “hackers,” threat actors, “hactivists,” organized criminal threat actors, personnel (such as through error or malfeasance), sophisticated national states and nation-state support actors (for example, in conjunction with military conflicts). During times of war and other major conflicts, we may be vulnerable to a heightened risk of these attacks. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to: business interruption, loss of information, theft of information or reputational damage from industrial espionage attacks, malware or other cyber-attacks (including ransomware), social-engineering attacks (including through deep fakes and phishing attacks), malicious code (such as viruses and worms), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, telecommunications failures, natural disasters, and other similar threats, any of which may compromise our system infrastructure or lead to data compromise. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of data, reputational harm and diversion of funds. Extortion payments may alleviate some of the negative impact of a ransomware attack but we may be unwilling or unable to make such payments. Remote work has also become more common and increased risks to our information technology systems and data. 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 resent in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during diligence of such acquired or integrated entities and it may be difficult to integrate such entities into our programs.

We rely on service providers and third-party technologies to operate critical business systems to process sensitive information in a variety of contexts, including without limitation, cloud-based infrastructure, personnel email, data hosting, and other functions. Our ability to monitor these third parties’ information security practices is limited and these service providers may not have adequate information security measures in place. If our service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our service providers fail to satisfy their privacy or security-related obligations to us, any aware may be insufficient or we may be unable to recover such award.

While we have implemented measures designed to protect our data and information technology systems, there can be no assurance that our efforts will be effective (including, without limitation prevent service interruptions or security incidents). We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities on a timely or effective basis. Vulnerabilities could be exploited and result in a security incident. Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us. In addition, as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, with new and constantly changing requirements applicable to our business, compliance with those requirements could also result in additional costs. 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 or reasonable security measures.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, regulators, and other 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, such as 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; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

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.

The use of our proprietary device and DNA medicine candidates in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. For example, pharmaceutical companies have been subject to claims that the use of some pediatric vaccines has caused personal injuries, including brain damage, central nervous system damage and autism, and these companies have incurred material costs to defend these claims. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our DNA medicine candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- inability to commercialize our products.

We have obtained product liability insurance coverage for our clinical trials, but our insurance coverage 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. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our business.

Healthcare reform measures could hinder or prevent our products' commercial success.

In both the United States and certain foreign jurisdictions there have been, and we anticipate there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell any of our products profitably. In the United States, the federal government enacted healthcare reform legislation, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs, implemented a new 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 expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial, and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties for not complying with the ACA’s individual mandate to carry qualifying health insurance coverage for all or part of a year. In addition, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage was eliminated, along with the health insurer tax. 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. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or 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 and creating a new manufacturer discount program. It is unclear how such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and our business. 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 addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011 included reductions to Medicare payments to providers of 2% per fiscal year, which, due to subsequent legislative amendments to the statute will remain in effect until 2032, unless Congressional action is taken. The American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has also been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent 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. For example, at the federal level, 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, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration’s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to make and implement healthcare reforms may adversely affect:

- our ability to set a price we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the availability of capital; and
- our ability to obtain timely approval of our products.

If we fail to comply with applicable healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Certain federal, state, local and foreign healthcare laws and regulations pertaining to fraud and abuse, transparency, patients' rights, and privacy are applicable to our business. The laws that may affect our ability to operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, people from soliciting, receiving or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or ordering, or leasing of an item, good, facility or service, for which payment may be made by a federal healthcare program such as Medicare or Medicaid. The intent standard under the federal healthcare program Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, the ACA codified case law that a claim including items or services resulting from a violation of the federal healthcare program Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- federal civil and criminal false claims laws, including the civil False Claims Act, 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;
- HIPAA, which prohibits, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal healthcare program Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and related regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on certain individuals and entities;
- the Physician Payments Sunshine Act, created under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with certain exceptions, to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- the FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;
- the U.S. Foreign Corrupt Practices Act, which, among other things, prohibits companies issuing stock in the U.S. from bribing foreign officials for government contracts and other business;
- state 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 and local laws requiring the registration of pharmaceutical sales and medical 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 often are not preempted by HIPAA, thus complicating compliance efforts; and
- additional state and local laws such as laws in California and Massachusetts, which mandate implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other state and local laws, such as laws in Vermont, Maine, and Minnesota which require reporting to state governments of gifts, compensation, and other remuneration to physicians.

The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and/or reporting requirements, increases the possibility that a company may run afoul of one or more laws.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, which require strict compliance in order to offer protection, it is possible that governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity and/or other oversight obligations, contractual damages, reputational harm, and the curtailment or restructuring of our operations. Any such penalties could adversely affect our ability to operate our business and our financial results. 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.

Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our and our third-party manufacturers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our DNA medicine candidates and other hazardous compounds. We and our manufacturers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In the event of an accident, state or federal authorities may curtail the use of these materials and interrupt our business operations. If we are subject to any liability as a result of our or our third-party manufacturers' activities involving hazardous materials, our business and financial condition may be adversely affected.

We have entered into collaborations with Chinese companies and rely on clinical materials manufactured in China for our development efforts. Uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, a trade war, political unrest or unstable economic conditions in China could materially adversely affect our business, financial condition and results of operations.

We are party to a license and collaboration agreement with a China-based company, ApolloBio, pursuant to which ApolloBio has the exclusive right to develop and commercialize VGX-3100 in China, Hong Kong, Macao and Taiwan. The Chinese legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. In addition, the Chinese legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation. Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Because Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems.

Furthermore, we are exposed to the possibility of disruption of our research and development activities in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, China's "zero COVID" policy caused delays in Advaccine’s conduct of clinical trials for INO-4800 in China under our collaboration with them, which in turn resulted in delays in obtaining clinical data to evaluate the safety and potential efficacy of INO-4800. In addition, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on ApolloBio or Advaccine, which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China’s public health, economic, political, and social conditions and the uncertainty around China’s relationship with other governments, including the threat of a trade war between the United States and China, could lead to supply chain disruptions or increased costs for clinical materials manufactured in China that are necessary for our development efforts. These interruptions or failures could then impede commercialization of our DNA medicine candidates and impair our competitive position. We may also be exposed to fluctuations in the value of the local currency in China. These uncertainties may impede our ability to enforce the contracts we have entered into and our ability to continue our research and development activities and could materially and adversely affect our business, financial condition and results of operations.

Our employees, principal investigators, and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions; provide accurate information to the FDA, the EMA, and other regulatory authorities; comply with healthcare fraud and abuse laws and regulations in the United States and abroad; or report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. 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, and prospects, including the imposition of significant fines or other sanctions.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile work place, discrimination, wage and hour disputes, sexual harassment, or other employment issues. In recent years there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment-related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related claims, our business could be negatively affected.

Risks Related to Our Intellectual Property

It is difficult and costly to generate and protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent, trademark, trade secret, and other intellectual property protection relating to our proprietary device and DNA medicine candidates, as well as successfully defending these intellectual property rights against third-party challenges.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. The laws and regulations regarding the breadth of claims allowed in biotechnology patents have evolved over recent years and continues to undergo review and revision, both in the United States and abroad. The biotechnology patent situation outside the United States can be even more uncertain depending on the country. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our licensed patents, our patents or in third-party patents, nor can we predict the likelihood of our patents surviving a patent validity challenge.

The degree of future protection for our intellectual property rights is uncertain, because legal decision-making can be unpredictable, thereby often times resulting in limited protection, which may not adequately protect our rights or permit us to gain or keep our competitive advantage, or resulting in an invalid or unenforceable patent. For example:

- we, or the parties from whom we have acquired or licensed patent rights, may not have been the first to file the underlying patent applications or the first to make the inventions covered by such patents;
- the named inventors or co-inventors of patents or patent applications that we have licensed or acquired may be incorrect, which may give rise to inventorship and ownership challenges;
- others may develop similar or alternative technologies, or duplicate any of our products or technologies that may not be covered by our patents, including design-arounds;
- pending patent applications may not result in issued patents;
- the issued patents covering our products and technologies may not provide us with any competitive advantages or have any commercial value;
- the issued patents may be challenged and invalidated, or rendered unenforceable;
- governments in the United States or abroad may prevent us from enforcing patents on our vaccines, which could prevent us from excluding competitors from those markets;
- the issued patents may be subject to reexamination, which could result in a narrowing of the scope of claims or cancellation of claims found unpatentable;
- we may not develop or acquire additional proprietary technologies that are patentable;
- our trademarks may be invalid or subject to a third party's prior use; or
- our ability to enforce our patent rights will depend on our ability to detect infringement, and litigation to enforce patent rights may not be pursued due to significant financial costs, diversion of resources, and unpredictability of a favorable result or ruling.

We depend, in part, on our licensors and collaborators to protect a portion of our intellectual property rights. In such cases, our licensors and collaborators may be primarily or wholly responsible for the maintenance of patents and prosecution of patent applications relating to important areas of our business. If any of these parties fail to adequately protect these products with issued patents, our business and prospects would be harmed significantly.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our trade secrets to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we or our licensors fail to obtain or maintain patent protection or trade secret protection for our DNA medicine candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

From time to time, U.S. and other policymakers have proposed reforming the patent laws and regulations of their countries. In September 2011 the America Invents Act (the Act) was signed into law. The Act changed the current “first-to-invent” system to a system that awards a patent to the “first-inventor-to-file” for an application for a patentable invention. The Act also created a procedure to challenge newly issued patents in the patent office via post-grant proceedings and new inter parties reexamination proceedings. These changes may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our product sales, business and results of operations. The changes may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Other companies may have or may acquire intellectual property rights that could be enforced against us. If they do so, we may be required to alter our technologies, pay licensing fees or cease activities. If our products or technologies infringe the intellectual property rights of others, they could bring legal action against us or our licensors or collaborators claiming damages and seeking to enjoin any activities that they believe infringe their intellectual property rights.

Because patent applications can take many years to issue, and there is a period when the application remains undisclosed to the public, there may be currently pending applications unknown to us or reissue applications that may later result in issued patents upon which our products or technologies may infringe. There could also be existing patents of which we are unaware that our products or technologies may infringe. In addition, if third parties file patent applications or obtain patents claiming products or technologies also claimed by us in pending applications or issued patents, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office to determine priority or derivation of the invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of our filed foreign patent applications.

If a third party claims that we infringe its intellectual property rights, it could cause our business to suffer in a number of ways, including:

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit, the third party's patent is invalid or we have not infringed;
- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a third party's patent;
- we may be enjoined by a court to stop making, selling or licensing our products or technologies without a license from a patent holder, which may not be available on commercially acceptable terms, if at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our products so that they do not infringe upon others' patent rights, which may not be possible or could require substantial investment or time.

If any of these events occur, our business could suffer and the market price of our common stock may decline.

We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.

Our trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are 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 do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Risks Related to an Investment in Our Common Stock

An active trading market for our common stock may not be sustained.

Although our common stock is listed on the Nasdaq Capital Market, we cannot be certain that an active trading market for our shares will continue to be sustained. If an active market for our common stock is not sustained, it may be difficult for investors in our common stock to sell shares without depressing the market price for the shares or to sell the shares at all.

The price of our common stock has been and may continue to be volatile, and an investment in our common stock could decline substantially in value.

In light of our small size and limited resources, as well as the uncertainties and risks that can affect our business and industry, our stock price has been and may continue to be highly volatile and has been and may in the future be subject to substantial drops, with or even in the absence of news affecting our business. Period to period comparisons are not indicative of future performance. The following factors, which are not exhaustive, in addition to the other risk factors described in this report, and the potentially low volume of trades in our common stock, may have a significant impact on the market price of our common stock, some of which are beyond our control:

- developments concerning any research and development, clinical trials, manufacturing, and marketing efforts or collaborations;
- fluctuating public or scientific interest in the potential for our vaccines or other DNA medicine candidates;
- our announcement of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- fluctuations in our operating results;
- announcements of technological innovations;
- new products or services that we or our competitors offer;
- changes in the structure of healthcare payment systems;
- the initiation, conduct and/or outcome of intellectual property and/or litigation matters;
- changes in financial or other estimates by securities analysts or other reviewers or evaluators of our business;
- conditions or trends in bio-pharmaceutical or other healthcare industries;
- regulatory developments in the United States and other countries;
- perceptions of gene-based therapy;
- changes in the economic performance and/or market valuations of other biotechnology and medical device companies;
- additions or departures of key personnel;
- sales or other transactions involving our common stock;
- changes in our capital structure;
- sales or other transactions by executive officers or directors involving our common stock;
- changes in accounting principles;
- global unrest including geopolitical risks emanating from countries such as Russia and China, terrorist activities, the conflict between Israel and Hamas, bank failures, and other economic and other external factors; and
- catastrophic weather and/or global disease pandemics.

The stock market in general can experience relatively large price and volume fluctuations from time to time. In particular, the market prices of securities of smaller biotechnology and medical device companies have experienced dramatic fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. In addition, price volatility may increase if the trading volume of our common stock remains limited or declines.

We have broad discretion in the use of our cash, cash equivalents, and investments, and may not use them effectively.

Our management has broad discretion in the application of our cash, cash equivalents, and investments, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. For example, our operating expenses increased significantly from 2020 to 2022 due to development and manufacturing activities for our COVID-19 vaccine program, for which we discontinued internal funding in the fourth quarter of 2022. We may not deploy our current capital resources effectively. The failure by our management to apply our funds effectively could result in financial losses that could have a material adverse impact on our business, cause the price of our common stock to decline, and delay the development of our product candidates. Pending their use, we may invest our cash, cash equivalents, and investments in a manner that does not produce income or that loses value.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock.

Our amended and restated certificate of incorporation contains provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- the authority of our board of directors to issue shares of undesignated preferred stock and to determine the rights, preferences and privileges of these shares, without stockholder approval;
- all stockholder actions must be effected at a duly called meeting of stockholders and not by written consent; and
- the elimination of cumulative voting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors, including to delay or impede a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We have never paid cash dividends on our common stock and we do not anticipate paying dividends in the foreseeable future.

We have paid no cash dividends on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude or limit our ability to pay any dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of potential gain for the foreseeable future.

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

Under Sections 382 and 383 of the revised Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity by certain significant shareholders over a rolling three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our share ownership, some of which would be outside our control. If our ability to use our net operating losses and other tax attributes is limited by ownership changes, we may be unable to utilize a material portion of our net operating losses and other tax attributes to offset our future taxable income. In addition, there is also a risk that due to changes in laws and regulations, such as alternative minimum taxes or suspensions on the use of net operating losses, or other unforeseen reasons, our existing net operating losses could expire or otherwise become unavailable to offset future income tax liabilities.

General Risk Factors

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our proprietary device, DNA medicine candidates or future development programs;
- expenses related to corporate transactions, including ones not fully completed;
- addition or termination of clinical trials or funding support;
- any intellectual property infringement lawsuit in which we may become involved;
- any legal claims that may be asserted against us or any of our officers;
- regulatory developments affecting our proprietary device and DNA medicine candidates or those of our competitors;
- debt service obligations;
- changes in the fair value of our investments, including investments in affiliated entities;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- if any of our DNA medicine candidates receive regulatory approval, the levels of underlying demand for our products.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our results of operations and liquidity needs could be materially affected by market fluctuations and general economic conditions.

Our results of operations could be materially affected by economic conditions generally, both in the United States and elsewhere around the world. Concerns over inflation, rising interest rates, energy costs, geopolitical issues, global pathogen outbreaks or pandemics, and the availability and cost of credit have in the past and may continue to contribute to increased volatility and diminished expectations for the economy and the markets going forward. Market upheavals may have an adverse effect on us. In the event of a market downturn, our results of operations could be adversely affected. Our future cost of equity or debt capital and access to the capital markets could be adversely affected, and our stock price could decline. There may be disruption or delay in the performance of our third-party contractors and suppliers. If our contractors, suppliers and partners are unable to satisfy their contractual commitments, our business could suffer. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits, and we may experience losses on these deposits.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, could adversely impact our business, financial condition and results of operations.

Actual events involving limited liquidity or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in 2023, several banking institutions were closed or seized by the Federal Deposit Insurance Corporation, leading to significant liquidity concerns in the broader financial services industry.

While we did not have any deposits at any of the banks impacted by the adverse developments in 2023, we maintain deposits at financial institutions as a part of doing business that could be at risk if another similar event were to occur. Our ongoing cash management strategy is to maintain the majority of our deposit accounts in large financial institutions, but there can be no assurance this strategy will be successful. Increasing concerns regarding the U.S. or international financial systems, including bank failures and bailouts, and their potential broader effects and potential systemic risk on the banking sector generally, may adversely affect our access to capital. Any decline in available funding or access to our cash and liquidity resources could, among other risks, limit our ability to meet our capital needs and fund future growth or fulfill our other obligations, or result in breaches of our financial and/or contractual obligations. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our business, financial condition and results of operations.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business, and we have limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

The issuance of additional stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

Our certificate of incorporation authorizes us to issue up to 600,000,000 shares of common stock and up to 10,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our stock incentive plans or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

We incur significant costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant legal, accounting and other costs that could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and stock exchanges, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

Changes in tax laws could adversely affect our business and financial condition.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. In 2017, tax legislation commonly known as the Tax Cuts and Jobs Act, or Tax Act, was enacted, which significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, resulted in significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 percent to a flat rate of 21 percent, limitation of the tax deduction for interest expense to 30 percent of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80 percent of current-year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). It is uncertain if and to what extent various states will conform to the federal tax law. The issuance of additional regulatory or accounting guidance related to the Tax Act, or legislative changes proposed or implemented, could materially affect our tax obligations and effective tax rate.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our research, development candidates, investigational medicines, and the diseases our development candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, participants may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our development candidates and investigational medicines. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, 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 (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, and financial information (collectively, sensitive data).

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and 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, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA"), applies to personal data of consumers, business representatives, and employees who are California residents, and requires certain businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data. For example, under GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally 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 the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), 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 the EEA, the UK, 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 (such as Europe) 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, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. 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 us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: 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 substantial changes to our business model or operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data (including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and clinical trial data) (collectively, "Information Systems and Data").

Our Information Technology department ("IT Department") (including its Senior Director), with support from service providers, helps identify, assess and manage the Company's cybersecurity threats and risks. The IT Department identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company's risk profile using various methods. For example, the methods include manual and automated tools; subscriptions to reports and services that identify cybersecurity threats; analysis of threat and threat actor reports; threat environment scans; law enforcement coordination; audits; threat assessments; and vulnerability assessments.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: security incident response strategies; tools designed to detect and respond to security incidents; data encryption strategies; access controls; physical security controls; asset management strategies; systems monitoring; personnel training; penetration testing; and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, the IT Department works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business and our management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example: professional services firms (including legal counsel); cybersecurity consultants; cybersecurity software providers; managed cybersecurity service providers; and penetration testing firms.

We use service providers to perform a variety of functions throughout our business, such as application providers; hosting providers; and contract research organizations. Depending on the nature of the services provided, in order to analyze the cybersecurity processes of certain vendors we review their internal security assessment reports and certifications, if available.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including in particular under the caption "if our information technology systems or those of third parties upon which we rely or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to, regulatory investigations and actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue and profits; and other adverse consequences."

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of our management, including the Senior Director of the IT Department. This individual has previously held roles as a head of cybersecurity, cybersecurity consultant and information security specialist for other organizations. This individual holds several certifications related to cybersecurity including as a Certified Information Systems Security Professional.

The IT Department reports to our Chief Financial Officer (CFO) who is responsible for helping the IT Department hire appropriate personnel, integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. The Senior Director of the IT Department is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the CFO. The Senior Director of IT and the CFO work with our incident response team to help mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response and vulnerability management processes include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

As indicated above, the audit committee receives reports from the Senior Director of IT or other designee concerning significant cybersecurity threats and risk and the processes we have implemented to address them. The audit committee also receives various written reports, summaries or presentations related to cybersecurity threats, risk and mitigation. In turn, the audit committee routinely provides reports to the board on cybersecurity matters.

ITEM 2. PROPERTIES

We own no real property and have no plans to acquire any real property in the future.

San Diego Leases

In November 2023, we entered into a lease agreement, or the New San Diego Lease, for research and development space in San Diego, California. The total space under the New San Diego Lease is approximately 5,563 square feet. The term of the New San Diego Lease commenced on February 10, 2024 and the initial term is 4.3 years.

The base rent adjusts periodically throughout the term of the New San Diego Lease. Rent payments under the New San Diego Lease will include base rent with an annual increase of approximately three percent, and additional monthly fees to cover our share of certain facility expenses, including utilities, property taxes, insurance and maintenance. In addition, we have paid a security deposit of $33,000.

In 2013, we entered into a lease, or the First San Diego Lease, for office space in San Diego, California. The initial term of the First San Diego Lease was through November 2023. In June 2015, we amended the First San Diego Lease to increase the total leased space to 31,207 square feet and occupy the entire building. In November 2023, we extended the term of the First San Diego Lease until February 29, 2024.

In 2016, we entered into an office lease, or the Second San Diego Lease, for a second property in San Diego, California. The total space under the Second San Diego Lease is approximately 51,000 square feet. We are using the facility for office, manufacturing and research and development purposes. The term of the Second San Diego Lease commenced in June 2017 and continues through May 2027.

The base rent adjusts periodically throughout the term of the Second San Diego Lease. As of December 31, 2023, rent payments under the Second San Diego Lease include base rent with an annual increase of approximately three percent, and additional monthly fees to cover our share of certain facility expenses, including utilities, property taxes, insurance and maintenance. In addition, we have paid a security deposit of $95,000.

Plymouth Meeting Lease

In 2014, we entered into a lease, or the Plymouth Meeting Lease, for our corporate headquarters in Plymouth Meeting, Pennsylvania. We have amended the Plymouth Meeting Lease on multiple occasions to increase the total leased space to 57,361 square feet and extend the lease term through December 31, 2029.

The base rent adjusts periodically throughout the term of the Plymouth Meeting Lease. As of December 31, 2023, rent payments under the Plymouth Meeting Lease include base rent with an annual increase of approximately two percent, and additional monthly fees to cover our share of certain facility expenses, including utilities, property taxes, insurance and maintenance. In addition, we have paid security deposits totaling $124,000.

We have entered into four agreements to sublease a total of approximately 25,000 square feet in our Plymouth Meeting headquarters, with one sublease term through March 31, 2025, two terms through December 31, 2026, and one month-to-month.

We believe our current and future planned facilities will be adequate to meet our operating needs for the foreseeable future. Should we need additional space, we believe we will be able to secure additional space at commercially reasonable rates.

ITEM 3. LEGAL PROCEEDINGS

Securities Litigation

Securities Class Action Litigation

In March 2020, a purported shareholder class action complaint, McDermid v. Inovio Pharmaceuticals, Inc. and J. Joseph Kim, was filed in the United States District Court for the Eastern District of Pennsylvania, naming the Company and its former President and Chief Executive Officer as defendants. The lawsuit alleged that the Company made materially false and misleading statements in violation of certain federal securities laws. The plaintiffs sought unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including reasonable attorneys' fees. The plaintiffs' complaint was later amended to include certain of the Company's other officers as defendants. After additional motions were filed in the case, in June 2022 the parties negotiated an agreement in principle to settle the shareholder class action complaint, which was approved by the court in January 2023. Under the settlement, we agreed to pay $30.0 million in cash and $14.0 million in shares of its common stock to settle all outstanding claims. Our insurance carriers paid the $30.0 million cash component of the settlement. During the three months ended March 31, 2023, we issued 760,083 shares of common stock pursuant to the securities class action settlement.

Shareholder Derivative Litigation

In April 2020, a purported shareholder derivative complaint, Behesti v. Kim, et al., was filed in the United States District Court for the Eastern District of Pennsylvania, naming eight current and former directors of the Company as defendants. The lawsuit asserted state and federal claims and was based on the same alleged misstatements as the shareholder class action complaint described above. The lawsuit accused the Company's board of directors of failing to exercise reasonable and prudent supervision over our management, policies, practices, and internal controls. The plaintiff sought unspecified monetary damages on behalf of the Company as well as governance reforms. Between June 2020 and August 2020, additional shareholder derivative complaints were filed and later consolidated by the court.

In March 2022, an additional shareholder derivative complaint was filed in the Delaware Court of Chancery, asserting substantially similar claims as those in the consolidated derivative action. In May 2022, the Delaware Court of Chancery entered a stay of the litigation.

In March 2023, the parties submitted a joint status report to the Court of Chancery reporting that the parties agreed to a settlement in principle, which also provided for the resolution of the consolidated derivative action and certain stockholder demands.

In April 2023, the plaintiffs in the consolidated derivative action filed a motion for preliminary approval of settlement with the United States District Court for the Eastern District of Pennsylvania. The proposed settlement provided for resolution of the consolidated derivative action, the derivative action pending in the Delaware Court of Chancery, and certain stockholder demands.

In June 2023, the court entered an order preliminarily approving the proposed settlement of the derivative claims, in accordance with a Stipulation of Settlement. The Stipulation of Settlement contemplated that, following the settlement hearing and the final approval of the settlement by the court, we would implement certain corporate governance reforms described in the Stipulation of Settlement. The preliminary order also approved the form and manner of the notice of the Settlement. As part of the Settlement, in July 2023 we paid $1.2 million to plaintiffs' counsel for their fees and expenses. In October 2023, the court entered an order and final judgment approving the Settlement, which became effective in November 2023. The Company has implemented the corporate governance reforms in response to the provisions of the Stipulation of Settlement.

VGXI Litigation

In June 2020, we filed a complaint in the Court of Common Pleas of Montgomery County, Pennsylvania against VGXI, Inc. and GeneOne Life Science, Inc., or GeneOne, and together with VGXI, Inc. collectively referred to as VGXI, alleging that VGXI had materially breached our supply agreement with them. The complaint seeks declaratory judgments, specific performance of the agreement, injunctive relief, an accounting, damages, attorneys' fees, interest, costs and other relief from VGXI. In June 2020, the Company filed a petition for preliminary injunction, which was denied.

Following our appeal, in July 2020 VGXI filed counterclaims against us, alleging that we had breached the supply agreement, as well as misappropriation of trade secrets and unjust enrichment. The counterclaims seek injunctive relief, damages, attorneys' fees, interest, costs and other relief from us. VGXI also filed a third-party complaint against Ology Bioservices, Inc., a contract manufacturing organization that we had engaged to provide services similar to those that were being provided by VGXI. We filed an answer to VGXI's counterclaims, disputing the allegations and the claims raised in VGXI's filing. In October 2020, we filed a notice of discontinuance of appeal with the Pennsylvania Superior Court. A trial date for the litigation has not been set.

We intend to aggressively prosecute the claims set forth in its complaint against VGXI and to vigorously defend ourselves against VGXI's counterclaims.

GeneOne Litigation

In December 2020, GeneOne filed a complaint in the Court of Common Pleas of Montgomery County, Pennsylvania against us, alleging that we had breached the CELLECTRA Device License Agreement, or the Agreement, between us and GeneOne. We terminated the Agreement in October 2020. The complaint asserts claims for breach of contract, declaratory judgment, unfair competition, and unjust enrichment. The complaint seeks injunctive relief, an accounting, damages, disgorgement of profits, attorneys' fees, interest, and other relief from us. We filed preliminary objections to the complaint, which were overruled. In September 2021, we filed an answer to the complaint, new matter, and counterclaims. Our counterclaims allege that GeneOne breached the Agreement, and assert claims for breach of contract and declaratory judgment. The counterclaims seek damages, interest, expenses, attorney's fees, and costs. On October 18, 2021, GeneOne filed its answer to our counterclaims and new matter. A trial date for this litigation has not been set.

We intend to aggressively prosecute the claims set forth in our counterclaims against GeneOne and to vigorously defend ourselves against the claims in GeneOne's complaint.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock, par value $0.001 per share, began trading on the Nasdaq Global Select Market on September 15, 2014 under the symbol "INO," having previously traded on the NYSE MKT exchange. On November 2, 2023, the listing of our common stock was transferred to the Nasdaq Capital Market.

On January 24, 2024, we implemented a 1-for-12 reverse stock split of our common stock. As of March 1, 2024, we had approximately 58 common stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

The closing price per share of our common stock on March 1, 2024 was $9.55, as reported on the Nasdaq Capital Market.

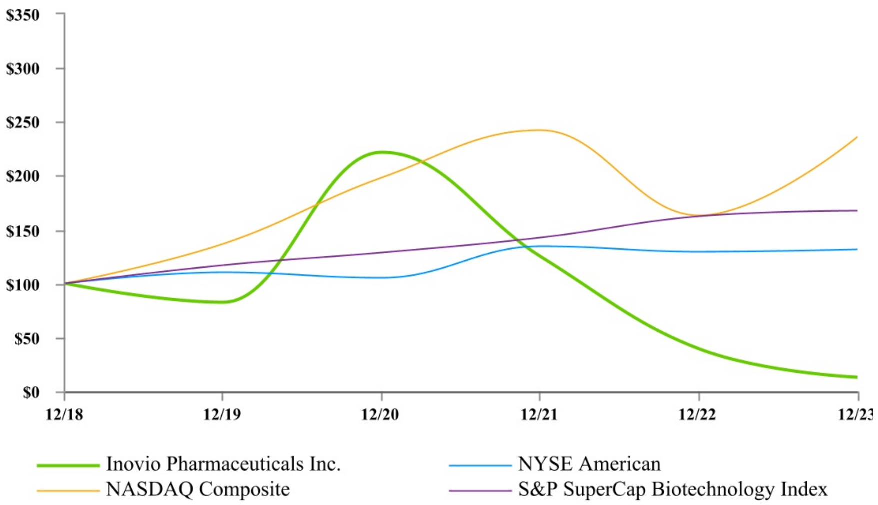
Dividends

The payment of any dividends on our common stock is within the discretion of our board of directors. We have never paid cash dividends on our common stock and the board of directors does not expect to declare cash dividends on the common stock in the foreseeable future.

Performance Graph

The graph below compares the performance of our common stock with the performance of the NYSE American Index, the S&P SuperCap Biotechnology index and the Nasdaq Composite Index for the five years ended December 31, 2023. The graph assumes a $100 investment on December 31, 2018 in our common stock and in each index, with the reinvestment of all dividends, if any.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Inovio Pharmaceuticals Inc., the NYSE American Index, the NASDAQ Composite Index, and S&P SuperCap Biotechnology Index



*$100 invested on 12/31/18 in stock or index, including reinvestment of dividends.
Fiscal year ended December 31.

	12/18	12/19	12/20	12/21	12/22	12/23
Inovio Pharmaceuticals, Inc.	100.00	82.50	221.25	124.75	39.00	12.75
NYSE American	100.00	110.19	104.83	134.55	129.34	131.60
Nasdaq Composite	100.00	136.69	198.10	242.03	163.28	236.17
S&P SuperCap Biotechnology Index	100.00	116.98	128.56	142.49	161.98	167.26

The stock price performance included in this graph is not necessarily indicative of future stock price performance. The performance graph is furnished solely to accompany this Form 10-K annual report and shall not be deemed to be incorporated by reference by means of any general statement incorporating by reference this Form 10-K into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate such information by reference, and shall not otherwise be deemed filed under such acts.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This report contains forward-looking statements, as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of such terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

Although we believe that the expectations reflected in the forward-looking statements are reasonable based on our current expectations and projections, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we, nor any other person, assume responsibility for the accuracy and completeness of the forward-looking statements. We are under no obligation to update any of the forward-looking statements after the filing of this Annual Report to conform such statements to actual results or to changes in our expectations.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes and other financial information appearing elsewhere in this Annual Report. Readers are also urged to carefully review and consider the various disclosures made by us which attempt to advise interested parties of the factors which affect our business, including without limitation the disclosures made in Item 1A of Part I of this Annual Report under the caption "Risk Factors."

Risk factors that could cause actual results to differ from those contained in the forward-looking statements include but are not limited to: our history of losses; our lack of products that have received regulatory approval; uncertainties inherent in clinical trials and product development programs, including but not limited to the fact that pre-clinical and clinical results may not be indicative of results achievable in other trials or for other indications, that the studies or trials may not be successful or achieve desired results, that preclinical studies and clinical trials may not commence, have sufficient enrollment or be completed in the time periods anticipated, that results from one study may not necessarily be reflected or supported by the results of other similar studies, that results from an animal study may not be indicative of results achievable in human studies, that clinical testing is expensive and can take many years to complete, that the outcome of any clinical trial is uncertain and failure can occur at any time during the clinical trial process, and that our proprietary device technology and DNA medicine candidates may fail to show the desired safety and efficacy traits in clinical trials; the availability of funding; the ability to manufacture our DNA medicine candidates; the availability or potential availability of alternative therapies or treatments for the conditions targeted by us or our collaborators, including alternatives that may be more efficacious or cost-effective than any therapy or treatment that we and our collaborators hope to develop; our ability to receive development, regulatory and commercialization event-based payments under our collaborative agreements; whether our proprietary rights are enforceable or defensible or infringe or allegedly infringe on rights of others or can withstand claims of invalidity; and the impact of government healthcare laws and proposals.

Overview

We are a clinical-stage biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from diseases associated with human papillomavirus (HPV), cancer, and infectious diseases. Our platform harnesses the power of in vivo protein production, featuring optimized design and delivery of DNA medicines that teach the body to manufacture its own disease-fighting tools.

We use proprietary technology to design DNA plasmids which are small circular DNA molecules that work like software the body's cells can download to produce specific proteins to target and fight disease. Our proprietary investigational CELLECTRA® delivery devices help our DNA medicines enter the body's cells for optimal effect.

Our lead candidate is INO-3107 for the treatment of recurrent respiratory papillomatosis, or RRP, a rare and debilitating disease of the respiratory tract caused by HPV infection. In our completed Phase 1/2 clinical trial of INO-3107 for the treatment of HPV-6 and HPV-11-associated RRP, 81.3% of patients experienced a reduction in the number of surgical interventions in the year following administration of INO-3107, when compared with the year prior to treatment.

In February 2023, we announced data from the second cohort of our Phase 1/2 clinical trial, which followed the announcement of the first cohort in October 2022. In the second cohort of 11 patients who were administered INO-3107 via an exploratory side port injection needle, 10 of the 11 patients (91%) saw a reduction in surgical interventions in the year following initial treatment, with the measurement beginning on Day 0, the start of trial therapy. Of these 10 patients, four did not require surgery. There was a statistically significant median decrease of three surgical interventions when comparing the year following treatment to the year prior to treatment. INO-3107 was well-tolerated and immunogenic among patients in the second cohort. The safety and efficacy results for the second cohort were consistent with results announced for the first cohort in October 2022.

In the fourth quarter of 2023, we received feedback from the U.S. Food and Drug Administration, or FDA, that the data from this completed trial could be used to support the submission of a Biologic License Application, or BLA, for review under the FDA's accelerated approval program. As part of submitting our BLA under the accelerated program, we will need to satisfy all FDA filing requirements and initiate a confirmatory clinical trial prior to BLA submission.

In addition to our development efforts with INO-3107, we are actively developing or planning to develop DNA medicines for other indications, including HPV-related anal dysplasia and oropharyngeal squamous cell carcinoma, or OPSCC; glioblastoma multiforme, or GBM, a deadly form of brain cancer; and a potential vaccine booster to protect against the Ebola virus. We were previously conducting clinical trials of a DNA medicine candidate for the treatment of HPV-related cervical high-grade squamous intraepithelial lesions, or HSIL, but announced in August 2023 that we were ceasing development for this indication in the United States. However, our collaborator ApolloBio Corporation continues to conduct a Phase 3 clinical trial of this candidate in China and plans to seek regulatory approval for and potentially commercialize the candidate in that jurisdiction.

Our partners and collaborators include Advaccine Biopharmaceuticals Suzhou Co, ApolloBio Corporation, AstraZeneca, The Bill & Melinda Gates Foundation (Gates), Coalition for Epidemic Preparedness Innovations (CEPI), Coherus Biosciences, Defense Advanced Research Projects Agency (DARPA), The U.S. Department of Defense (DoD), HIV Vaccines Trial Network, International Vaccine Institute (IVI), Kaneka Eurogentec, National Cancer Institute (NCI), National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), Plumbline Life Sciences, Regeneron Pharmaceuticals, Richter-Helm BioLogics, Thermo Fisher Scientific, the University of Pennsylvania, the Walter Reed Army Institute of Research, and The Wistar Institute.

All of our DNA medicine candidates are in the research and development phase. We have not generated any revenues from the sale of any products, and we do not expect to generate any material revenues unless and until we obtain marketing approval for and successfully commercialize INO-3107 and our other product candidates. We earn revenue from license fees and milestone revenue and collaborative research and development agreements and contracts. Our DNA medicine candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All DNA medicine candidates that we advance to clinical testing will require regulatory approval prior to commercial use, and will require significant costs for commercialization. We may not be successful in our research and development efforts, and we may never generate sufficient product revenue to be profitable.

As of December 31, 2023, we had an accumulated deficit of $1.6 billion. We expect to continue to incur substantial operating losses in the future due to our commitment to our research and development programs, the funding of preclinical studies, clinical trials and regulatory activities and the costs of general and administrative activities.

Critical Accounting Policies and Estimates

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and require management's judgment. Our discussion and analysis of our financial condition and results of operations are based on our audited consolidated financial statements, which have been prepared in accordance with U.S. GAAP. Our significant accounting policies are outlined in Note 2 to the consolidated financial statements included in this report.

The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. We base our estimates on experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements:

Collaboration Agreements and Revenue Recognition

We assess whether our collaboration agreements are subject to Accounting Standards Codification ("ASC") Topic 808: Collaborative Arrangements ("Topic 808") based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of Topic 808 and we conclude that our collaboration partner is not a customer, we present such payments as a reduction of research and development expense. If payments from our collaboration partner to us represent consideration from a customer, then we account for those payments within the scope of Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers ("Topic 606").

Research and Development Expenses - Clinical Trial Accruals

Our activities have largely consisted of research and development efforts related to developing proprietary device technologies, DNA medicine candidates and dMABs. For clinical trial expenses, judgments used in estimating accruals rely on estimates of total costs incurred based on participant enrollment, completion of studies and other events. Accrued clinical trial costs are subject to revisions as trials progress. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development expense; however a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

Recent Accounting Pronouncements

Information regarding recent accounting pronouncements is contained in Note 2 to the consolidated financial statements, included elsewhere in this report.

Results of Operations

The consolidated financial data for the years ended December 31, 2023, 2022 and 2021 is presented in the following table and the results of these periods are used in the discussion thereafter.

	Year Ended December 31,			Increase/(Decrease) 2023 vs. 2022		Increase/(Decrease) 2022 vs. 2021	
	2023	2022	2021	$	%	$	%
Revenue from collaborative arrangements and other contracts, including affiliated entity	$ 832,010	$ 10,262,268	$ 1,774,758	$ (9,430,258)	(92)%	$ 8,487,510	478 %
Operating expenses:							
Research and development	86,676,563	187,650,503	249,240,324	(100,973,940)	(54)	(61,589,821)	(25)
General and administrative	47,582,104	90,185,285	53,752,353	(42,603,181)	(47)	36,432,932	68
Impairment of Goodwill	10,513,371	—	—	10,513,371	100	—	—
Total operating expenses	144,772,038	277,835,788	302,992,677	(133,063,750)	(48)	(25,156,889)	(8)
Loss from operations	(143,940,028)	(267,573,520)	(301,217,919)	123,633,492	46	33,644,399	11
Interest income	8,133,290	4,782,030	3,363,080	3,351,260	70	1,418,950	42
Interest expense	(1,222,789)	(1,253,952)	(1,936,447)	31,163	(2)	682,495	(35)
Gain (loss) on investment in affiliated entity	773,145	(1,899,654)	(553,570)	2,672,799	*	(1,346,084)	*
Net unrealized gain (loss) on available-for-sale equity securities	5,850,626	(7,846,172)	(3,222,838)	13,696,798	*	(4,623,334)	*
Other (expense) income, net	(4,711,596)	(3,861,584)	343,371	(850,012)	*	(4,204,955)	*
Net loss before share in net loss of Geneos	(135,117,352)	(277,652,852)	(303,224,323)	142,535,500	51	25,571,471	8
Share in net loss of Geneos	—	(2,165,213)	(434,387)	2,165,213	*	(1,730,826)	*
Net loss	$ (135,117,352)	$ (279,818,065)	$ (303,658,710)	$ 144,700,713	(52)%	$ 23,840,645	(8)%

*Not meaningful

Comparison of Years Ended December 31, 2023 and 2022

Revenue

Revenue was primarily derived under collaborative arrangements and other contracts, including arrangements with affiliated entities, for the years ended December 31, 2023 and 2022. The $9.4 million decrease in revenue was primarily due to no revenue from our Procurement Contract with the DoD as all performance obligations were satisfied during 2022.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, facilities expenses, overhead expenses, cost of laboratory supplies, clinical trial and related clinical manufacturing expenses, fees paid to contract research organizations and other consultants, and outside expenses. We utilize a labor reporting system to record employee compensation on a project-by-project basis. Unallocated research and development expenses include engineering and device-related expenses that are not allocable to a specific project, as well as stock-based compensation, other employee-related expenses that are not related to a specific project, and facilities and depreciation expenses.

Research and development costs are expensed as incurred. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

The following tables summarize our research and development expense by product candidate for the years ended December 31, 2023 and 2022:

	Years Ended December 31,		Increase (Decrease)	
(dollars in thousands)	**2023**	**2022**	**$**	**%**
INO-4800 and other Covid-19	$ 8,869	$ 93,464	$ (84,595)	(91)%
VGX-3100	4,748	15,989	(11,241)	(70)
INO-3107	17,841	8,133	9,708	119
INO-5401 and other Immuno-oncology	8,372	2,775	5,597	202
Other research and development programs (a)	8,472	6,227	2,245	36
Engineering and device-related	8,863	25,187	(16,324)	(65)
Stock-based compensation	4,606	9,059	(4,453)	(49)
Other unallocated expenses (b)	24,906	26,817	(1,911)	(7)
Research and development expense	$ 86,677	$ 187,651	$ (100,974)	(54)%

(a) Net of contributions received from grant agreements and recorded as contra-research and development expense.

(b) Includes impairment of intangible assets of $2.0 million recorded in the second quarter of 2023.

The $101.0 million overall decrease in research and development expenses year over year was primarily the result of:

- $61.4 million in lower drug manufacturing, clinical study expenses, outside services and expensed inventory related to INO-4800 after we discontinued this program in the fourth quarter of 2022;
- $17.9 million in lower drug manufacturing and clinical study expenses related to other COVID-19 studies that ceased after we discontinued development of INO-4800;
- $15.0 million in lower employee and consultant compensation, including stock-based compensation, primarily due to reductions in headcount in 2023;
- $9.4 million in lower expensed inventory and outside services related to our CELLECTRA 3PSP device and array automation project;
- $8.4 million in lower immunology, clinical study expenses and outside services related to VGX-3100 as we discontinued development of this product candidate in the third quarter of 2023; and
- $4.4 million in lower drug manufacturing related to the sub-grant through Wistar for COVID-19 dMAbs

These decreases were partially offset by:

- $17.7 million of lower contra-research and development expense recorded from grant agreements; and
- $5.8 million of higher other drug manufacturing costs.

Contributions received from current grant agreements and recorded as contra-research and development expense were $6.8 million and $24.5 million for the years ended December 31, 2023 and 2022, respectively. The decrease year over year was primarily due to decreases of $7.7 million earned under the sub-grant through Wistar primarily for DARPA COVID-19 dMAb, $6.1 million from the DoD 3PSP device development grant and $5.0 million earned under the CEPI Lassa and MERS grants. These decreases were offset by an increase of $2.4 million in reimbursements from Advaccine.

General and Administrative Expenses

General and administrative expenses, which include business development expenses, the amortization of intangible assets and patent expenses, were $47.6 million for the year ended December 31, 2023 as compared to $90.2 million in 2022. The $42.6 overall decrease year over year was primarily the result of:

- $14.0 million in net expense related to the class action securities litigation settlement, which was accrued in 2022 but paid in 2023;
- $11.3 million in lower legal expenses, primarily the result of the conclusion of litigation in 2023;
- $6.9 million in one-time severance expenses related to the separation of our former President and Chief Executive Officer in 2022, including $4.2 million of stock-based compensation expense related to equity award modifications, that did not recur in 2023;
- $5.9 million in lower employee compensation, including employee and consultant stock-based compensation, as a result of headcount reductions in 2023;
- $1.9 million in lower insurance expenses; and
- $1.4 million in lower other outside services related to our discontinued INO-4800 and VGX-3100 programs.

Impairment of goodwill

In September 2023, we concluded that our goodwill was impaired due to a sustained decline in our stock price and related market capitalization, and a general decline in equity values in the biotechnology industry. Based on this analysis, we recognized a non-cash, pre-tax goodwill impairment charge of $10.5 million during the three months ended September 30, 2023. For more information, see Note 8 – *Goodwill and Intangible Assets* to the consolidated financial statements included in this report.

Stock-based compensation

Employee stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the employee's requisite service period. Total employee stock-based compensation cost for the years ended December 31, 2023 and 2022 was $10.4 million and $22.2 million, of which $4.5 million and $8.8 million was included in research and development expenses and $5.9 million and $13.4 million was included in general and administrative expenses, respectively.

Interest Income

The $3.4 million increase in interest income for the year ended December 31, 2023 as compared to 2022 was primarily due to higher interest rates earned on our cash balance.

Interest Expense

There was a $31,000 decrease in interest expense for the year ended December 31, 2023 as compared to 2022. We expect interest expense to decrease materially in 2024 due to the maturity and repayment in full of our convertible senior notes on March 1, 2024.

Gain (Loss) on Investment in Affiliated Entity

The gain (loss) on investment in affiliated entity resulted from the change in the fair market value of our investment in PLS of $773,000 and $(1.9) million for the years ended December 31, 2023 and 2022, respectively. We record our investment in PLS at its market value based on the closing price of the shares on the Korea New Exchange Market at each balance sheet date, with changes in fair value reflected in the consolidated statements of operations.

Net Unrealized Gain (Loss) on Available-for-Sale Equity Securities

The net unrealized gain (loss) on available-for-sale equity securities for the years ended December 31, 2023 and 2022 was $5.9 million and $(7.8) million, respectively, which resulted from a change in the fair market value of the investments.

Other (Expense) Income , net.

Other (expense) income, net, for the years ended December 31, 2023 and 2022 was $(4.7) million and $(3.9) million, respectively, related primarily to the realized loss on short-term investments sold during the periods.

Share in Net Loss of Geneos

The share in net loss of Geneos represents our share of Geneos' losses during 2022. As described in Note 15 to the consolidated financial statements in this report, we reduced the carrying value of our investment in Geneos to zero in March 2022 and will not record our share of further net losses of Geneos as we have no obligation to fund its operations.

Income Taxes

Since inception, we have incurred operating losses and accordingly have not recorded a provision for U.S. income taxes for any of the periods presented. Utilization of net operating losses and tax credits are subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986, as amended, or IRC. As of December 31, 2023, we had net operating loss carry forwards for U.S. federal, California and Pennsylvania income tax purposes of $1,013.3 million, $251.4 million and $102.6 million, respectively, net of the net operating losses that will expire due to IRC Section 382 limitations. We also had U.S. federal and state research and development tax credits of $41.6 million and $6.1 million, respectively, net of the federal research and development credits that will expire due to IRC Section 383 limitations. The net operating losses and credits began to expire during 2023.

Comparison of Years Ended December 31, 2022 and 2021

For a comparison of the years ended December 31, 2022 and 2021, you may refer to Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 1, 2023.

Liquidity and Capital Resources

Our primary uses of cash are to finance research and development activities, including clinical trial activities for the advancement of our DNA medicine candidates. We have satisfied our cash requirements principally from proceeds from the sale of equity securities, indebtedness and grants and government contracts.

Working Capital and Liquidity

As of December 31, 2023, we had cash and short-term investments of $145.3 million and working capital of $110.5 million, as compared to $253.0 million and $218.4 million as of December 31, 2022, respectively.

Cash Flows

Operating Activities

Net cash used in operating activities was $124.4 million and $216.2 million for the years ended December 31, 2023 and 2022, respectively. The variance was primarily due to the timing and changes in working capital balances, offset by decreased operating expenses.

Investing Activities

Net cash provided by investing activities was $87.4 million and $109.6 million for the years ended December 31, 2023 and 2022, respectively. The variance was primarily the result of timing differences in short-term investment purchases, sales and maturities.

Financing Activities

Net cash provided by financing activities was $5.0 million and $81.8 million for the years ended December 31, 2023 and 2022, respectively. The variance was primarily due to net proceeds of $5.5 million from the sale of common stock under the Sales Agreement (defined below) in 2023 compared to net proceeds of $83.0 million received during 2022.

Issuances of Common Stock

On November 9, 2021, we entered into an ATM Equity Offering SM Sales Agreement, or the Sales Agreement, with outside sale s agents, or collectively, the Sales Agents, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock with aggregate gross proceeds of up to $300.0 million, through the Sales Agents.

Subject to the terms and conditions of the Sales Agreement, the Sales Agents may sell the common stock by any method permitted by law deemed to be an “at the market" offering. The Sales Agents will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us, including any price, time or size limits or other customary parameters or conditions we may impose. We will pay the Sales Agents a commission of up to three percent (3.0%) of the gross sales proceeds of any common stock sold through the Sales Agents under the Sales Agreement, and we have provided the Sales Agents with certain indemnification rights. During the year ended December 31, 2023, we sold 875,305 shares of our common stock under the Sales Agreement at a weighted average price of $6.33 per share, resulting in aggregate net proceeds of $5.5 million. During the year ended December 31, 2022, we sold 2,870,478 shares of common stock under the Sales Agreement for aggregate net proceeds of $83.0 million. From January 1, 2024 through the date of this report, we sold an additional 543,620 shares of common stock under the Sales Agreement for net proceeds of $5.2 million.

During the year ended December 31, 2023, no stock options were exercised and tax payments of $467,000 were made related to the net sh are settlement of RSU awards. During the year ended December 31, 2022, stock options to purchase 9,891 shares of common stock were exercised for aggregate net proceeds of $283,000, which proceeds were offset by tax payments made related to net share settlement of RSU awards of $1.4 million. During the year ended December 31, 2021, stock options to purchase 109,188 shares of common stock were exercised for aggregate net proceeds of $6.7 million, which proceeds were offset by tax payments made related to net share settlement of RSU awards of $4.6 million.

During the three months ended March 31, 2023, we issued 760,083 shares of common stock pursuant to a securities class action settlement, as described in Note 11 to our consolidated financial statements included in this report.

Funding Requirements

As of December 31, 2023, we had an accumulated deficit of $1.6 billion and we expect to continue to operate at a loss in the near term. The amount of our accumulated deficit will continue to increase, as it will be expensive to continue research and development efforts. Our current cash resources, including amounts that we may be able to obtain through sales of common stock under the Sales Agreement, will not be sufficient to complete the clinical development of any of our product candidates, and we anticipate that additional financing will be required in order to complete the development of and to commercialize and generate revenues from the sale of any product candidates that receive regulatory approval. If these activities are successful and if we receive approval from the FDA to market our DNA medicine candidates, then we will need to raise additional funding to market and sell the approved products and equipment. In addition to the potential issuance of equity or debt securities in order to raise capital, we are also evaluating potential collaborations as an additional way to fund our operations. We believe that our current cash and short-term investments are sufficient to meet our planned working capital requirements for at least the next twelve months from the date of this report.

During 2023, we undertook actions to decrease our expenses, including multiple headcount reductions. Taking into account these actions, as well as the changes to our clinical development plan for INO-3107 as a result of FDA feedback, we expect our cash runway to extend into the second quarter of 2025, without giving effect to any further capital raising activities.

Contractual Obligations

As of December 31, 2023, future minimum payments due under our contractual obligations are set forth in the table below. We expect to be able to satisfy these obligations, both in the short-term and in the longer-term, with cash on hand.

	Payments Due by Period				
	Total	**Less than 1 year**	**1 – 3 years**	**3 – 5 years**	**More than 5 years**
Convertible senior notes (1)	$ 16,948,000	$ 16,948,000	$ —	$ —	$ —
Operating lease obligations (2)	$ 17,665,000	$ 3,247,000	$ 7,021,000	$ 5,265,000	$ 2,132,000
Manufacturing commitments (3)	$ 4,489,000	$ 4,489,000	$ —	$ —	$ —

(1) On March 1, 2024 these Convertible Senior Notes matured and we satisfied the obligation in full from existing cash. See Note 9, Convertible Debt, to the consolidated financial statements in this report for additional information.

(2) We have entered into operating leases for our facilities, which expire from 2024 to 2029, and operating leases for office equipment, which expire in 2024. We have four active subleases for portions of our Plymouth Meeting corporate headquarters facility with periods through March 31, 2025, two through December 31, 2026 and the other month-to-month. As of December 31, 2023, we expect to receive aggregate future minimum lease payments totaling $1.3 million (non-discounted) over the duration of the sublease agreements, which expected payments are not included in the table above.

(3) Purchase obligations from supply agreements with contract manufacturers.

In the normal course of business, we are a party to a variety of agreements pursuant to which we may be obligated to indemnify the other party. It is not possible to predict the maximum potential amount of future payments under these types of agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement. Historically, payments made by us under these types of agreements have not had a material effect on our business, consolidated results of operations or financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in short-term investment-grade securities. During much of 2022 and into the year ended December 31, 2023, there was a pronounced overall increase in prevailing interest rates in the United States compared to the first half of 2022, which contributed to the unrealized loss of $3.9 million in the market value of our investment portfolio as of December 31, 2023.

The interest rate on our indebtedness at December 31, 2023 was fixed and not subject to fluctuations in interest rates. As of March 1, 2024, we have no indebtedness.

Foreign Currency Risk

We operate primarily in the United States and most transactions during the year ended December 31, 2023 were made in United States dollars. Accordingly, we do not have any material exposure to foreign currency rate fluctuations, with the exception of certain cash and cash equivalents held in South Korea that are denominated in South Korean Won and the valuation of our equity investment in PLS, which is denominated in South Korean Won and then translated into United States dollars.

Certain transactions are denominated primarily in foreign currencies, including South Korean Won, Euros, British Pounds and Canadian Dollars. These transactions give rise to monetary assets and liabilities that are denominated in currencies other than the U.S. dollar. The value of these monetary assets and liabilities are subject to changes in currency exchange rates from the time the transactions are originated until settlement in cash. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets where we conduct business.

We do not use derivative financial instruments for speculative purposes and do not engage in exchange rate hedging or hold or issue foreign exchange contracts for trading purposes.

Inflation Risk

Inflation generally affects us by increasing our cost of labor. Although inflation has increased generally in the United States in recent years, we do not believe that inflation has had a material effect on our business, financial condition or results of operations during the year ended December 31, 2023.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item 8 is incorporated by reference to our Consolidated Financial Statements and the Report of Independent Registered Public Accounting Firm beginning at page F-1 of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, which are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosures.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Based on an evaluation carried out as of the end of the period covered by this Annual Report, under the supervision and with the participation of our management, including our CEO and CFO, our CEO and CFO have concluded that, as of the end of such period, our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) were effective as of December 31, 2023 at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting and Attestation Report of Registered Public Accounting Firm

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is a process designed under the supervision of our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with United States generally accepted accounting principles.

As of December 31, 2023, management, with the participation of the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting based on the criteria for effective internal control over financial reporting established in “Internal Control—Integrated Framework,” issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the assessment, management determined that we maintained effective internal control over financial reporting as of December 31, 2023.

This Annual Report does not include an attestation report of our registered public accounting firm regarding the effectiveness of internal control over financial reporting as required by Section 404(b) of the Sarbanes-Oxley Act of 2002. Management’s report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit smaller reporting companies to provide only management’s report in this Annual Report.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting that occurred during the fourth quarter of our fiscal year ended December 31, 2023, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Trading Plans

During the fiscal quarter ended December 31, 2023, none of our officers or directors, as defined in Rule 16a-1(f), adopted , modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Item 408 of Regulation S-K.

Severance Plan and Participation Agreements

On March 4, 2024, our board of directors approved and adopted the Company’s Severance Plan and Summary Plan Description (the “Plan”), which provides severance benefits to certain eligible of our executives (the “Covered Executives”) who become participants in the Plan in the event of termination of a Covered Executive’s employment with us other than for Cause (as defined in the Plan), or as a result of such Covered Executive’s resignation for Good Reason (as defined in the Plan) (any such termination, a “Covered Termination”).

Our Chief Executive Officer, Jacqueline Shea; our Chief Scientific Officer, Laurent Humeau; and our Chief Medical Officer, Michael Sumner, are participants in the Plan and have entered into Participation Agreements. The terms of the Plan described below will generally supersede any severance and change in control benefits set forth in any pre-existing employment agreement that those officers have with us. Our Chief Financial Officer, Peter Kies, is not a participant in the Plan, and the terms of his existing employment agreement will continue to apply.

Under the terms of the Plan, in the event of a Covered Termination, a Covered Executive will be eligible to receive as severance: (a) base salary continuation for the applicable number of months set forth in the Covered Executive’s Participation Agreement (18 months for Dr. Shea and 12 months for Drs. Humeau and Sumner), paid in equal installments on our regular payroll schedule (the “Severance Period”); and (b) Company-paid COBRA premiums for the Covered Executive’s continued coverage under our benefit plans, subject to timely COBRA election, for the number of months set forth in the Covered Executive’s Participation Agreement (or until the Covered Executive secures employment with similar benefits).

In the event such Covered Termination occurs within one (1) year after a Change in Control (as defined in our 2023 Omnibus Incentive Plan), the Covered Executive will be eligible for the following Change in Control severance benefits: (a) base salary continuation for the applicable number of months set forth in the Covered Executive’s Participation Agreement (24 months for Dr. Shea and 18 months for Drs. Humeau and Sumner), paid in equal installments on the Company’s regular payroll schedule; (b) an amount equal to the target annual bonus for the year of such Covered Termination multiplied by the applicable bonus multiple set forth in the Covered Executive’s Participation Agreement (two times for Dr. Shea and 1.5 times for Drs. Humeau and Sumner); (c) each of the Covered Executive’s then-outstanding equity awards, other than performance awards, subject to time-based vesting shall accelerate and become vested and exercisable as to the percentage of the unvested shares subject to the equity award set forth in the Covered Executive’s Participation Agreement (100% for each of Drs. Shea, Humeau and Sumner); and (d) Company-paid COBRA premiums for the Covered Executive’s continued coverage under the Company benefit plans, subject to timely COBRA election, for the number of months set forth in the Covered Executive’s Participation Agreement (24 months for Dr. Shea and 18 months for Drs. Humeau and Sumner) (or until the Covered Executive secures employment with similar benefits).

In the event of the termination of a Covered Executive’s employment due to Disability (as defined in the Plan), such Covered Executive will be eligible to receive: (a) base salary continuation for the applicable number of months set forth in the Covered Executive’s Participation Agreement (18 months for Dr. Shea and 12 months for Drs. Humeau and Sumner), paid in equal installments on the Company’s regular payroll schedule; (b) Company-paid COBRA premiums for the Covered Executive’s continued coverage under the Company benefit plans, subject to timely COBRA election, for the number of months set forth in the Covered Executive’s Participation Agreement (18 months for Dr. Shea and 12 months for Drs. Humeau and Sumner) (or until Covered Executive secures employment with similar benefits); and (c) such Covered Executive’s then-outstanding equity awards, other than performance awards, subject to time-based vesting shall continue to vest on the original vesting dates and any performance awards held by the Covered Executive shall remain outstanding and eligible to vest based on actual performance through the end of the applicable performance period.

In the event of termination of Covered Executive’s employment due to death, such Covered Executive’s then-outstanding equity awards, other than performance awards, subject to time-based vesting shall accelerate and become vested and exercisable as to the percentage of the unvested shares subject to the equity award set forth in the Covered Executive’s Participation Agreement and any performance awards held by the Covered Executive shall remain outstanding and eligible to vest based on the Company’s actual performance through the end of the applicable performance period.

As a condition to any Covered Executive receiving any severance benefits under the Plan, such Covered Executive must sign, and allow to become effective, a separation agreement containing among other provisions, a release of all claims in favor of us and our subsidiaries and affiliates (the “Release”) and the Covered Executive’s continued compliance with any proprietary information and inventions agreement, and any restrictive covenant agreement between the Covered Executive and us. The benefits provided under the Plan will generally supersede any other change in control, severance benefit plan, or agreement between us and a Covered Executive. Any prior acceleration rights set forth in existing awards between the Covered Executive and us will not be impacted by participating in the Plan.

The foregoing description of the Plan is qualified in its entirety by reference to the full text of the Plan, a copy of which is filed as an exhibit to this Annual Report, and the individual Participation Agreements. The Participation Agreements for Drs. Shea, Humeau and Sumner are also filed as exhibits to this Annual Report.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 is hereby incorporated by reference from our definitive proxy statement, to be filed pursuant to Regulation 14A within 120 days after the end of our 2023 fiscal year, under the captions “Election of Directors” and “Executive Officers and Other Information.”

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is hereby incorporated by reference from our definitive proxy statement, to be filed pursuant to Regulation 14A within 120 days after the end of our 2023 fiscal year, under the captions “Executive Compensation” and “Director Compensation".

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is hereby incorporated by reference from our definitive proxy statement, to be filed pursuant to Regulation 14A within 120 days after the end of our 2023 fiscal year, under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information.”

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Director independence and other information required by this Item 13 is hereby incorporated by reference from our definitive proxy statement, to be filed pursuant to Regulation 14A within 120 days after the end of our 2023 fiscal year, under the captions “Certain Relationships and Related Party Transactions” and “Election of Directors.”

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is hereby incorporated by reference from our definitive proxy statement, to be filed pursuant to Regulation 14A within 120 days after the end of our 2023 fiscal year, under the caption “Ratification of Appointment of Independent Registered Public Accounting Firm.”

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. Financial Statements

   Consolidated financial statements required to be filed hereunder begin on Page F-1 in this report.

2. Financial Statement Schedules

   Schedules not listed herein have been omitted because the information required to be set forth therein is not applicable or is included in the Financial Statements or notes thereto.

3. Exhibits

   The following exhibits are filed as part of this annual report on Form 10-K:

Exhibit Number	Description of Document
3.1	Certificate of Incorporation with all amendments prior to December 31, 2023 (incorporated by reference to Exhibit 3.1 of the registrant's Form S-3 registration statement, filed on July 23, 2014).
3.2	Certificate of Amendment to Certificate of Incorporation, effective as of January 24, 2024 (incorporated by reference to Exhibit 3.1 to the registrant's current report on Form 8-K filed on January 25, 2024).
3.3	Amended and Restated Bylaws of Inovio Pharmaceuticals, Inc. dated August 10, 2011 (incorporated by reference to Exhibit 3.2 to the registrant's Form 8-K current report filed on August 12, 2011).
4.1	Indenture, dated as of February 19, 2019, by and between the registrant and U.S. Bank National Association, as trustee (incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 8-K filed with the SEC on February 20, 2019).
4.2	Form of Note representing the registrant's 6.50% Convertible Senior Notes due 2024 (included as Exhibit A to the Indenture filed as Exhibit 4.1).
4.3	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (incorporated by reference to Exhibit 4.9 to the registrant's annual report on Form 10-K filed with the SEC on March 12, 2020).
10.1†	R&D Alliance Agreement dated December 19, 2005 by and between Ganial Immunotherapeutics, Inc. and VGX Pharmaceuticals, Inc., as amended by Novation and Amendment Agreement by and between VGX Pharmaceuticals, Inc., Ganial Immunotherapeutics, Inc., and Onconox (incorporated by reference to Exhibit 10.31 as filed with the registrant's Registration Statement on Form S-4 (File No. 333-156035) on April 27, 2009).
10.2†	R&D Collaboration and License Agreement dated December 18, 2006 by and between VGX International, Inc. and VGX Pharmaceuticals, Inc., as amended by First Amendment dated October 31, 2007 and as amended by Second Amendment dated August 4, 2008 (incorporated by reference to Exhibit 10.39 as filed with the registrant's Registration Statement on Form S-4 (File No. 333-156035) on April 27, 2009).
10.3†	Patent License Agreement dated April 27, 2007 by and between The Trustees of the University of Pennsylvania and VGX Pharmaceuticals, Inc., as amended by First Amendment dated June 12, 2008 (incorporated by reference to Exhibit 10.50 as filed with the registrant's Registration Statement on Form S-4 (File No. 333-156035) on April 27, 2009).
10.4†	License Agreement dated May 9, 2007 by and between Baylor University and VGX Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.34 as filed with the registrant's registration statement on Form S-4 (File No. 333-156035) on April 27, 2009).
10.5	ATM Equity Offering[SM] Sales Agreement dated November 9, 2021 by and among Inovio Pharmaceuticals, Inc., BofA Securities, Inc., RBC Capital Markets, LLC and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 10.1 as filed with the registrants Form 10-Q quarterly report for the quarter ended September 30, 2021 filed on November 9, 2021).

10.6†	License and Collaboration Agreement dated March 24, 2010 between Inovio Pharmaceuticals, Inc. and VGX International, Inc. (incorporated by reference to Exhibit 10.2 as filed with the registrant's Form 10-Q quarterly report for the quarter ended March 31, 2010 filed on May 17, 2010).
10.7†	Collaborative Development and License Agreement dated October 7, 2011 between VGX International, Inc. and Inovio Pharmaceuticals, Inc., as amended by First Amendment dated August 21, 2013, and Second Amendment dated October 7, 2013 (incorporated by reference to Exhibit 10.1 as filed with the registrant's Form 10-Q quarterly report for the quarter ended September 30, 2011 filed on November 7, 2011).
10.8	Collaborative Research Agreement dated March 14, 2016 by and between The Wistar Institute of Anatomy and Biology, a Commonwealth of Pennsylvania nonprofit corporation, and Inovio Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 as filed with the registrant's Form 10-Q quarterly report for the quarter ended March 31, 2016 filed on May 9, 2016).
10.9	Collaborative Research Agreement dated March 14, 2016 by and between The Wistar Institute of Anatomy and Biology, a Commonwealth of Pennsylvania nonprofit corporation, and Inovio Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 as filed with the registrant's Form 10-Q quarterly report for the quarter ended March 31, 2016 filed on May 9, 2016).
10.10†	Amended and Restated License and Collaboration Agreement, dated December 29, 2017, by and between Inovio Pharmaceuticals, Inc. and Beijing Apollo Saturn Biological Technology Limited (incorporated by reference to Exhibit 10.12 as filed with the registrant's Form 10-K annual report for the year ended December 31, 2017 filed on March 14, 2018).
10.11	First Amendment to the Amended and Restated License and Collaboration Agreement, dated June 14, 2023, by and between Inovio Pharmaceuticals, Inc. and Beijing Apollo Saturn Biological Technology Limited (filed herewith).
10.12	Office Lease Agreement dated October 10, 2016 by and between 6759 Mesa Ridge Road Holdings, LLC and Inovio Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 as filed with the registrant's Form 10-Q quarterly report for the quarter ended September 30, 2016 filed on November 9, 2016).
10.13	Sublease dated June 21, 2017 between Accolade, Inc. and Inovio Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 as filed with the registrant's Form 10-Q quarterly report for the quarter ended June 30, 2017 filed on August 8, 2017).
10.14+	Employment Agreement dated as of December 27, 2010 between Inovio Pharmaceuticals, Inc. and Peter Kies (incorporated by reference to Exhibit 10.5 to the registrant's Form 10-K report for the year ended December 31, 2010 filed on March 16, 2011).
10.15+	First Amendment to Employment Agreement dated as of December 31, 2012 between Inovio Pharmaceuticals, Inc. and Peter Kies (incorporated by reference to Exhibit 10.42 of the registrant's Form 10-K annual report for the year ended December 31, 2012 filed on March 18, 2013).
10.16+	Second Amendment to Employment Agreement dated November 7, 2014 by and between Inovio Pharmaceuticals, Inc. and Peter Kies (incorporated by reference to Exhibit 10.2 of the registrant's Form 10-Q quarterly report for the quarter ended September 30, 2014 filed on November 10, 2014).
10.17+	Inovio Pharmaceuticals, Inc. Severance Plan and Summary Plan Description (filed herewith).
10.18+	Participation Agreement under Severance Plan for Jacqueline Shea (filed herewith).
10.19+	Participation Agreement under Severance Plan for Laurent Humeau (filed herewith).
10.20+	Participation Agreement under Severance Plan for Michael Sumner (filed herewith).
10.21+	Form of Indemnification Agreement for Directors and Officers of Inovio Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the registrant's Form 10-Q quarterly report for the quarterly period ended June 30, 2009, filed on August 19, 2009).

10.22+	Amended and Restated 2007 Omnibus Incentive Plan, as amended (incorporated by reference to Exhibit 10.12 to the registrant's Form 10-K report for the year ended December 31, 2015 filed on March 14, 2016).
10.23+	Form of Incentive and Non-Qualified Stock Option Grants under the 2007 Omnibus Stock Incentive Plan (incorporated by reference to Exhibit 4.4 to the registrant's Registration Statement on Form S-8 filed on May 14, 2007).
10.24+	Inovio Pharmaceuticals, Inc. 2016 Omnibus Incentive Plan, as amended to date (incorporated by reference to Exhibit 10.1 to the registrant's Form 8-K filed on May 10, 2019).
10.25+	Form of Incentive Stock Option Agreement under 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.55 as filed with the registrant's Form 10-K annual report for the year ended December 31, 2016 filed on March 15, 2017.)
10.26+	Form of Nonqualified Stock Option Agreement under 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.56 as filed with the registrant's Form 10-K annual report for the year ended December 31, 2016 filed on March 15, 2017.)
10.27+	Form of Restricted Stock Unit Award Agreement under 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.54 as filed with the registrant's Form 10-K annual report for the year ended December 31, 2016 filed on March 15, 2017.)
10.28+	Inovio Pharmaceuticals, Inc. 2022 Inducement Plan (incorporated by reference to Exhibit 99.1 of the registrant's Form S-8 registration statement, filed on June 30, 2022).
10.29+	Form of Option Grant Package under 2022 Inducement Plan (incorporated by reference to Exhibit 99.2 of the registrant's Form S-8 registration statement, filed on June 30, 2022).
10.30+	Form of RSU Grant Package under 2022 Inducement Plan (incorporated by reference to Exhibit 99.3 of the registrant's Form S-8 registration statement, filed on June 30, 2022).
10.31+	Inovio Pharmaceuticals, Inc. 2023 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed on May 18, 2023).
10.32+	Form of Option Grant Package under 2023 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.2 to the registrant's quarterly report on Form 10-Q filed on August 9, 2023).
10.33+	Form of RSU Grant Package under 2023 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.3 to the registrant's quarterly report on Form 10-Q filed on August 9, 2023).
21.1	Subsidiaries of the registrant (filed herewith).
23.1	Consent of Independent Registered Public Accounting Firm (filed herewith).
24.1	Power of Attorney (included on signature page).
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1^	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
97.1	Incentive Compensation Recoupment Policy, adopted on November 14, 2023 (filed herewith) .
101.INS	XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).

101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

+ Designates management contract, compensatory plan or arrangement.

† Confidential treatment has been granted for certain portions omitted from this exhibit (indicated by asterisks) pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The confidential portions of this exhibit have been separately filed with the Securities and Exchange Commission.

†† Certain confidential portions of this exhibit (indicated by asterisks) were omitted because the identified confidential portions are not material and are of the type that the registrant treats as private or confidential.

^ These certifications are being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 6, 2024.

Inovio Pharmaceuticals, Inc.

By: /s/ JACQUELINE E. SHEA

Jacqueline E. Shea

President, Chief Executive Officer and Director (On Behalf of the Registrant)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jacqueline E. Shea and Peter Kies, and each of them severally, his or her true and lawful attorney-in-fact with power of substitution and resubstitution to sign in his or her name, place and stead, in any and all capacities, to do any and all things and execute any and all instruments that such attorney may deem necessary or advisable under the Securities Exchange Act of 1934 and any rules, regulations and requirements of the United States Securities and Exchange Commission in connection with the Annual Report on Form 10-K and any and all amendments hereto, as fully for all intents and purposes as he or she might or could do in person, and hereby ratifies and confirms all said attorneys-in-fact and agents, each acting alone, and his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JACQUELINE E. SHEA **Jacqueline E. Shea**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2024
/s/ SIMON X. BENITO **Simon X. Benito**	Chairman of the Board of Directors	March 6, 2024
/s/ PETER KIES **Peter Kies**	Chief Financial Officer (Principal Accounting Officer and Principal Financial Officer)	March 6, 2024
/s/ ROGER D. DANSEY **Roger D. Dansey**	Director	March 6, 2024
/s/ ANN C. MILLER **Ann C. Miller**	Director	March 6, 2024
/s/ JAY SHEPARD **Jay Shepard**	Director	March 6, 2024
/s/ DAVID B. WEINER **David B. Weiner**	Director	March 6, 2024
/s/ WENDY L. YARNO **Wendy L. Yarno**	Director	March 6, 2024
/s/ LOTA S. ZOTH **Lota S. Zoth**	Director	March 6, 2024

INOVIO PHARMACEUTICALS, INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Inovio Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the consolidated balance sheets of Inovio Pharmaceuticals, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

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. Those standards require that we plan and perform the audit 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 audits 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrual of Clinical Trial Expenses

Description of the Matter

During 2023, the Company incurred $86.7 million for research and development expenses and as of December 31, 2023 accrued $2.4 million for clinical study costs. A substantial portion of the Company’s ongoing research and development activities are conducted by third-party service providers, including clinical research organizations (“CROs”). External costs to be paid t CROs are accrued and expensed based upon actual work completed in accordance with signec agreements.

Auditing management’s accounting for accrued clinical study costs is especially challengir because the evaluation is dependent upon a high-volume of data and input exchanged betweer clinical personnel and third-party service providers, such as the number of sites activated, the number of patients enrolled, and the number of patient visits, which is tracked in spreadsheets and other end user computing programs.

How We Addressed the Matter in our Audit

We obtained an understanding of the accounting for accrued clinical trial expenses including management’s process for measuring estimated accrued clinical study costs such as patient enrollment and total cost incurred to date from third-parties.

To test the completeness of the Company’s accrued clinical trial expenses, we obtained from third-parties confirmation of patient enrollment and direct service cost to date for significan clinical trials. We attended internal clinical trial and project status meetings with accounting personnel and the clinical project manager to understand the status of significant clinical trial activities. To assess the appropriate measurement of accrued clinical trial expenses, we inspected key terms, timelines of completion, activities and costs for a sample of vendor contracts, including amendments, and compared these to management’s analyses used in tracking the progress of service agreements. We also tested a sample of subsequent payments by agreeing the invoice to the original accrual and the invoice payments to bank statements.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

San Diego, California

March 6, 2024

Inovio Pharmaceuticals, Inc.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,310,862	$ 46,329,359
Short-term investments	130,982,913	206,669,397
Accounts receivable	—	1,701,726
Accounts receivable from affiliated entities	2,405,228	10,036,490
Prepaid expenses and other current assets	5,393,665	50,130,481
Prepaid expenses and other current assets from affiliated entities	20,432	375,227
Total current assets	153,113,100	315,242,680
Fixed assets, net	4,960,986	7,727,997
Investments in affiliated entity	2,780,287	2,007,142
Intangible assets, net	—	2,129,861
Goodwill	—	10,513,371
Operating lease right-of-use assets	9,491,735	10,228,207
Other assets	605,315	684,044
Total assets	$ 170,951,423	$ 348,533,302
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,847,744	$ 79,686,885
Accounts payable and accrued expenses due to affiliated entities	1,070,519	1,220,439
Accrued clinical trial expenses	2,365,382	10,594,073
Operating lease liability	2,406,522	2,803,973
Grant funding liability	87,489	2,475,031
Grant funding liability from affiliated entities	21,918	87,673
Convertible senior notes	16,770,654	—
Total current liabilities	42,570,228	96,868,074
Convertible senior notes	—	16,614,840
Operating lease liability, net of current portion	11,032,066	12,655,586
Deferred tax liabilities	—	32,046
Total liabilities	53,602,294	126,170,546
Commitments and contingencies		
Inovio Pharmaceuticals, Inc. stockholders' equity:		
Preferred stock—par value $ 0.001 ; Authorized shares: 10,000,000 , issued and outstanding shares: 9 at December 31, 2023 and 2022	—	—
Common stock—par value $ 0.001 ; Authorized shares: 600,000,000 at December 31, 2023 and 2022, issued and outstanding: 22,793,075 at December 31, 2023 and 21,090,938 at December 31, 2022 [(1)]	22,792	21,090
Additional paid-in capital	1,740,954,074	1,710,888,191
Accumulated deficit	(1,622,965,136)	(1,487,847,784)
Accumulated other comprehensive loss	(662,601)	(698,741)
Total Inovio Pharmaceuticals, Inc. stockholders' equity	117,349,129	222,362,756
Total liabilities and stockholders' equity	$ 170,951,423	$ 348,533,302

[(1)] The Company effected a reverse stock split of its outstanding shares of common stock on January 24, 2024 where every twelve shares of its common stock issued and outstanding was converted into one share of common stock. Any fractional post-split shares as a result of the reverse split were paid in cash. Shareholders of the Company authorized the Board of Directors to approve the reverse stock split at a special meeting of stockholders held on January 12, 2024. Outstanding share amounts have been restated to reflect the reverse stock split on a retroactive basis for all periods presented.

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

Inovio Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year ended December 31,		
	2023	**2022**	**2021**
Revenue from collaborative arrangements and other contracts, including affiliated entity	$ 832,010	$ 10,262,268	$ 1,774,758
Operating expenses:			
Research and development	86,676,563	187,650,503	249,240,324
General and administrative	47,582,104	90,185,285	53,752,353
Impairment of goodwill	10,513,371	—	—
Total operating expenses	144,772,038	277,835,788	302,992,677
Loss from operations	(143,940,028)	(267,573,520)	(301,217,919)
Other income (expense):			
Interest income	8,133,290	4,782,030	3,363,080
Interest expense	(1,222,789)	(1,253,952)	(1,936,447)
Gain (loss) on investment in affiliated entity	773,145	(1,899,654)	(553,570)
Net unrealized gain (loss) on available-for-sale equity securities	5,850,626	(7,846,172)	(3,222,838)
Other (expense) income, net	(4,711,596)	(3,861,584)	343,371
Net loss before share in net loss of Geneos	(135,117,352)	(277,652,852)	(303,224,323)
Share in net loss of Geneos	—	(2,165,213)	(434,387)
Net loss	$ (135,117,352)	$ (279,818,065)	$ (303,658,710)
Net loss per share			
Basic and diluted [(1)]	$ (6.09)	$ (14.07)	$ (17.45)
Weighted average number of common shares outstanding			
Basic and diluted [(1)]	22,173,662	19,885,182	17,402,483

[(1)] Share and per share amounts have been restated to reflect the 1-for-12 reverse stock split effected in January 2024 on a retroactive basis for all periods presented.

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

Inovio Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	For the Year ended December 31,		
	2023	2022	2021
Net loss	$ (135,117,352)	$ (279,818,065)	$ (303,658,710)
Other comprehensive loss:			
Foreign currency translation	(3,920)	(25,556)	(30,134)
Unrealized (loss) gain on short-term investments, net of tax	40,060	(390,949)	4,048
Comprehensive loss	$ (135,081,212)	$ (280,234,570)	$ (303,684,796)

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

Inovio Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred stock		Common stock [1]				Accumulated	
	Number of shares	Amount	Number of shares	Amount	Additional paid-in capital	Accumulated deficit	other comprehensive loss	Total stockholders' equity
Balance at December 31, 2020	9	—	15,570,957	$ 15,571	$ 1,367,578,149	$ (906,196,812)	$ (256,150)	$ 461,140,758
Issuance of common stock for cash, net of financing costs	—	—	2,275,861	2,276	209,439,134	—	—	209,441,410
Conversion of December 2019 Bonds to common stock	—	—	84,120	84	4,377,808	—	—	4,377,892
Exercise of stock options for cash and vesting of RSUs, net of tax payments	—	—	184,299	184	2,057,209	—	—	2,057,393
Stock-based compensation	—	—	—	—	26,336,764	—	—	26,336,764
Net loss	—	—	—	—	—	(303,658,710)	—	(303,658,710)
Unrealized gain on short-term investments, net of tax	—	—	—	—	—	—	4,048	4,048
Foreign currency translation	—	—	—	—	—	—	(30,134)	(30,134)
Balance at December 31, 2021	9	—	18,115,237	$ 18,115	$ 1,609,789,064	$ (1,209,855,522)	$ (282,236)	$ 399,669,421
Cumulative adjustment from adoption of ASU 2020-06	—	—	—	—	(3,294,019)	1,825,803	—	(1,468,216)
Issuance of common stock for cash, net of financing costs	—	—	2,870,478	2,870	82,952,441	—	—	82,955,311
Exercise of stock options for cash and vesting of RSUs, net of tax payments	—	—	105,223	105	(1,114,714)	—	—	(1,114,609)
Stock-based compensation	—	—	—	—	22,555,419	—	—	22,555,419
Net loss	—	—	—	—	—	(279,818,065)	—	(279,818,065)
Unrealized loss on short-term investments, net of tax	—	—	—	—	—	—	(390,949)	(390,949)
Foreign currency translation	—	—	—	—	—	—	(25,556)	(25,556)
Balance at December 31, 2022	9	$ —	21,090,938	$ 21,090	$ 1,710,888,191	$ (1,487,847,784)	$ (698,741)	$ 222,362,756
Issuance of common stock for legal settlement	—	—	760,083	760	13,999,240	—	—	14,000,000
Issuance of common stock for cash, net of financing costs	—	—	875,305	875	5,460,870			5,461,745
Vesting of RSUs, net of tax payments	—	—	66,749	67	(466,713)	—	—	(466,646)
Stock-based compensation	—	—	—	—	11,072,486	—	—	11,072,486
Net loss	—	—	—	—	—	(135,117,352)	—	(135,117,352)
Unrealized gain on short-term investments, net of tax	—	—	—	—	—	—	40,060	40,060
Foreign currency translation	—	—	—	—	—	—	(3,920)	(3,920)
Balance at December 31, 2023	9	$ —	22,793,075	$ 22,792	$ 1,740,954,074	$ (1,622,965,136)	$ (662,601)	$ 117,349,129

[1] All share amounts in this column, including appropriate reclassifications between common stock and additional paid-in capital, have been restated to reflect the 1-for-12 reverse stock split effected in January 2024 on a retroactive basis for all periods presented.

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

Inovio Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year ended December 31,		
	2023	2022	2021
Cash flows from operating activities:			
Net loss	$ (135,117,352)	$ (279,818,065)	$ (303,658,710)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,621,649	3,656,713	3,040,096
Amortization of intangible assets	145,417	496,494	520,415
Amortization of operating lease right-of-use assets	736,472	1,342,819	1,170,270
Impairment of goodwill	10,513,371	—	—
Impairment of intangible assets	1,984,444	—	—
Deferred taxes	(32,046)	—	—
Non-cash stock-based compensation	11,072,486	22,555,419	26,336,764
Non-cash interest on senior convertible notes	155,814	186,977	858,644
Amortization of (discounts) premiums on investments	(4,686,144)	(1,320,546)	1,633,286
Realized loss on sales of short-term investments	4,805,804	4,029,961	5,397
Gain on remeasurement of investment in Geneos	—	(165,215)	—
Net loss on disposal of fixed assets	317,997	1,074,830	—
(Gain) loss on equity investment in affiliated entity	(773,145)	1,899,654	553,570
Share of net loss in Geneos	—	2,165,213	434,387
Net unrealized (gain) loss on available-for-sale equity securities	(5,850,626)	7,846,172	3,222,838
Unrealized transaction (gain) loss on foreign-currency denominated debt	—	—	(176,927)
Changes in operating assets and liabilities:			
Accounts receivable, including from affiliated entities	9,332,988	(3,706,172)	11,031,705
Prepaid expenses and other current assets, including from affiliated entities	39,020,611	(5,336,525)	(6,343,632)
Other assets	78,729	741,750	24,531,654
Accounts payable and accrued expenses, including due to affiliated entities	(45,989,061)	32,606,581	26,140,970
Accrued clinical trial expenses	(8,228,691)	267,807	375,921
Deferred revenue, including from affiliated entity	—	(85,989)	(39,853)
Operating lease right-of-use assets and liabilities, net	(2,020,971)	(2,603,956)	(2,329,394)
Grant funding liability, including from affiliated entity	(2,453,297)	(2,034,517)	(2,973,089)
Other liabilities	—	(14,826)	(42,837)
Net cash used in operating activities	(124,365,551)	(216,215,421)	(215,708,525)
Cash flows from investing activities:			
Purchases of investments	(203,475,052)	(248,528,843)	(348,953,236)
Proceeds from sale or maturity of investments	284,932,562	361,083,850	174,839,758
Purchases of capital assets	(320,898)	(969,153)	(1,231,006)
Proceeds from sale of capital assets	6,219,263	—	—
Investment in Geneos	—	(1,999,998)	—
Net cash provided by (used in) investing activities	87,355,875	109,585,856	(175,344,484)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net of issuance costs	5,461,745	82,955,311	209,441,410
Proceeds from stock option exercises	—	283,022	6,668,741
Taxes paid related to net share settlement of equity awards	(466,646)	(1,397,631)	(4,611,348)
Net cash provided by financing activities	4,995,099	81,840,702	211,498,803
Effect of exchange rate changes on cash and cash equivalents	(3,920)	(25,556)	(30,134)
Decrease in cash and cash equivalents	(32,018,497)	(24,814,419)	(179,584,340)
Cash and cash equivalents, beginning of period	46,329,359	71,143,778	250,728,118
Cash and cash equivalents, end of period	$ 14,310,862	$ 46,329,359	$ 71,143,778
Supplemental disclosure:			
Amounts accrued for purchases of fixed assets	$ —	$ 108,181	$ 204,815
Interest paid	$ 1,066,975	$ 1,066,975	$ 1,077,803
Change in prepaid expenses and other current assets related to fixed assets	$ —	$ 6,071,000	$ 7,709,337
Issuance of common stock as part of litigation settlement	$ 14,000,000	$ —	$ —

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. The Company

Inovio Pharmaceuticals, Inc. (the “Company” or “INOVIO”) is a clinical-stage biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from diseases associated with human papillomavirus (HPV), cancer, and infectious diseases. INOVIO's platform harnesses the power of in vivo protein production, featuring optimized design and delivery of DNA medicines that teach the body to manufacture its own disease-fighting tools.

INOVIO uses proprietary technology to design DNA plasmids, which are small circular DNA molecules that work like software the body’s cells can download to produce specific proteins to target and fight disease. The Company's proprietary investigational CELLECTRA® delivery devices help its DNA medicines enter the body’s cells for optimal effect.

INOVIO's lead candidate is INO-3107 for the treatment of recurrent respiratory papillomatosis (RRP), a rare and debilitating disease of the respiratory tract caused by HPV infection. In its completed Phase 1/2 clinical trial of INO-3107 for the treatment of HPV-6 and HPV-11-associated RRP, 81.3% of patients experienced a reduction in the number of surgical interventions in the year following administration of INO-3107, when compared with the year prior to treatment.

In addition to its development efforts with INO-3107, INOVIO is actively developing or planning to develop DNA medicines for other indications, including HPV-related anal dysplasia and oropharyngeal squamous cell carcinoma (OPSCC); glioblastoma multiforme (GBM), a deadly form of brain cancer; and a potential vaccine booster to protect against the Ebola virus. The Company was previously conducting clinical trials of a DNA medicine candidate for the treatment of HPV-related cervical high-grade squamous intraepithelial lesions (HSIL) but announced in August 2023 that it was ceasing development for this indication in the United States. However, its collaborator ApolloBio Corporation continues to conduct a Phase 3 clinical trial of this candidate in China and plans to seek regulatory approval for and potentially commercialize the candidate in that jurisdiction.

The Company's partners and collaborators include Advaccine Biopharmaceuticals Suzhou Co, ApolloBio Corporation, AstraZeneca, The Bill & Melinda Gates Foundation (Gates), Coalition for Epidemic Preparedness Innovations (CEPI), Coherus Biosciences, Defense Advanced Research Projects Agency (DARPA), The U.S. Department of Defense (DoD), HIV Vaccines Trial Network, International Vaccine Institute (IVI), Kaneka Eurogentec, National Cancer Institute (NCI), National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), Plumbline Life Sciences, Regeneron Pharmaceuticals, Richter-Helm BioLogics, Thermo Fisher Scientific, the University of Pennsylvania, the Walter Reed Army Institute of Research, and The Wistar Institute.

INOVIO was incorporated in Delaware in 2001 and has its principal executive offices in Plymouth Meeting, Pennsylvania.

2. Summary of Significant Accounting Policies

Basis of Presentation and Liquidity

The Company incurred a net loss of $ 135.1 million for the year ended December 31, 2023. The Company had working capital of $ 110.5 million and an accumulated deficit of $ 1.6 billion as of December 31, 2023. The Company has incurred losses in each year since its inception and expects to continue to incur significant expenses and operating losses for the foreseeable future in connection with the research and preclinical and clinical development of its product candidates. The Company’s cash, cash equivalents and short-term investments of $ 145.3 million as of December 31, 2023 are sufficient to support the Company's operations for a period of at least 12 months from the date it is issuing these financial statements.

In order to continue to fund future research and development activities, the Company will need to seek additional capital. This may occur through strategic alliance and licensing arrangements, grant agreements and/or future public or private debt or equity financings, including under At-the-Market Equity Offering Sales Agreements (“Sales Agreements”). The Company has a history of conducting debt and equity financings, including the receipt of net proceeds of $ 5.5 million, $ 83.0 million and $ 47.7 million from equity offerings under Sales Agreements during the years ending December 31, 2023, 2022 and 2021, respectively, and $ 162.1 million from a January 2021 underwritten public offering of common stock. However, sufficient funding may not be available in the future, or if available, may be on terms that significantly dilute or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available, the Company may need to delay, reduce the scope of or put on hold one or more of its clinical and/or preclinical programs.

The Company is and, from time to time, may in the future be subject to various legal proceedings and claims arising in the ordinary course of business. The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its consolidated financial statements. An estimated loss contingency is accrued in the consolidated financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Legal proceedings, including litigation, government investigations and enforcement actions, could result in material costs, occupy significant management resources and entail civil and criminal penalties, even if the Company ultimately prevails. Any of the foregoing consequences could result in serious harm to the Company’s business, results of operations and financial condition.

Reverse Stock Split

On January 24, 2024, the Company filed with the Secretary of State of the State of Delaware a certificate of amendment to its certificate of incorporation, as previously amended, to effect a 1-for-12 reverse stock split of our common stock (the “Reverse Stock Split”). As a result of the Reverse Stock Split, every 12 issued and outstanding shares of the Company's common stock were automatically combined into one issued and outstanding share of common stock. The reverse stock split was reflected on the Nasdaq Capital Market beginning with the opening of trading on January 25, 2024. Accordingly, an amount equal to the par value of the decreased shares resulting from the reverse stock split was reclassified from "Additional paid-in capital" to "Common stock" on the balance sheet and statement of changes in stockholders’ equity. Any fractional post-split shares as a result of the reverse stock split were eliminated by the payment of cash for the value of such fractional share. As a result of the Reverse Stock Split, proportionate adjustments were made to the number of shares underlying, and the exercise or conversion prices of, the Company's outstanding stock options and outstanding shares of Series C Cumulative Convertible Preferred Stock and to the number of shares of common stock issuable under the Company's equity incentive plans. The reverse stock split did not change the par value of the Company's common stock or the authorized number of shares of the Company's common stock. All share amounts and per share amounts disclosed in this Annual Report on Form 10-K have been restated to reflect the reverse stock split on a retroactive basis for all periods presented.

Consolidation

The consolidated financial statements include the accounts of Inovio Pharmaceuticals, Inc. and its wholly-owned subsidiary Inovio Asia LLC.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one segment operating primarily within the United States.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and short-term investments. The Company limits its exposure to credit loss by placing its cash and investments with high credit quality financial institutions. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities which are designed to maintain principal and maximize liquidity.

The Company has contracts with certain of its customers that have represented more than 10% of the Company's total revenues, as discussed in Note 3.

Fair Value Measurements

The guidance regarding fair value measurements establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets that are accessible at the measurement date; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The Company’s financial instruments include cash equivalents, short-term investments, investments in affiliated entity, accounts receivable, prepaid expenses and other assets, accounts payable and accrued expenses, and convertible senior notes. The carrying amounts of cash equivalents, accounts receivable, prepaid expenses and other assets, accounts payable and accrued expenses approximate the related fair values due to the short-term maturities of these instruments. Short-term investments are recorded at fair value on a recurring basis, based on current market valuations. The Company carries convertible senior notes at face value less unamortized debt discount and issuance costs on its consolidated balance sheet, and it presents the fair value of such convertible notes for disclosure purposes only.

Cash and Cash Equivalents

Cash equivalents are considered by the Company to be highly liquid investments purchased with original maturities of three months or less from the date of purchase. Cash and cash equivalents included certain mutual funds and U.S. treasury securities at December 31, 2023 and 2022.

Short-term Investments

The Company defines investments as income-yielding securities that can be readily converted into cash or equity investments classified as available-for-sale. Investments included mutual funds, U.S. treasury securities, certificates of deposit, U.S. agency mortgage-backed securities and an equity investment in the Company’s affiliated entity, PLS, at December 31, 2023 and 2022.

Short-term investments are recorded at fair value, based on current market valuations. Unrealized gains and losses on the Company's short-term debt investments are excluded from earnings and reported as a separate component of other comprehensive loss until realized. Realized gains and losses and unrealized gains and losses on available-for-sale equity securities are included in non-operating other income (expense) on the consolidated statements of operations and are derived using the specific identification method for determining the cost of the securities sold.

Accounts Receivable

Accounts receivable are recorded at invoiced amounts and do not bear interest. The Company performs ongoing credit evaluations of its customers’ financial condition. Credit is extended to customers as deemed necessary and generally does not require collateral. Management believes that the risk of loss is significantly reduced due to the quality and financial position of the Company's customers. There was no allowance for doubtful accounts for potential credit losses as of December 31, 2023 and 2022.

Fixed Assets

Fixed assets include property and equipment and leasehold improvements. Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful life of the assets, generally three to five years . Leasehold improvements are amortized over the shorter of the remaining term of the related leases or the estimated economic useful lives of the improvements. Repairs and maintenance are expensed as incurred.

The Company evaluates the carrying value of long-lived assets, which includes fixed assets and right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying amounts of the asset may not be fully recoverable. No impairment losses have been recognized related to long-lived assets for the year ended December 31, 2023 and 2022.

Goodwill and Intangible Assets

Goodwill represents the excess of acquisition cost over the fair value of the net assets of acquired businesses. Goodwill is reviewed for impairment at least annually, or more frequently if an event occurs indicating the potential for impairment. The Company evaluates intangible assets for impairment whenever events or changes in circumstances indicate the carrying amounts of the assets may not be recoverable.

During its goodwill impairment review, the Company may assess qualitative factors to determine whether it is likely that the fair value of its reporting unit is less than its carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and market considerations, and the overall financial performance of the Company. If, after assessing the totality of these qualitative factors, the Company determines that it is not likely that the fair value of its reporting unit is less than its carrying amount, then no additional assessment is deemed necessary. Otherwise, the Company will proceed to perform the impairment test in which the fair value of the reporting unit is compared with its carrying amount, and an impairment charge will be recorded for the amount by which the carrying amount exceeds the reporting unit's fair value, if any.

Calculating the fair value of a reporting unit, an asset group and an individual asset involves significant estimates and assumptions. These estimates and assumptions include, among others, projected future cash flows, risk-adjusted discount rates, future economic and market conditions, and the determination of appropriate market comparables. Changes in these factors and assumptions used can materially affect the amount of impairment loss recognized in the period the asset was considered impaired.

During 2023, the Company experienced a decline in its market capitalization as a result of a sustained decrease in the Company’s stock price. This sustained decrease was considered to represent a triggering event requiring management to perform a quantitative goodwill impairment test as of September 30, 2023. The Company first tested its long-lived assets for impairment. The Company determined that all of its long-lived assets, which include property and equipment, leasehold improvements and right-of-use assets, represented one asset group for purposes of its long-lived asset impairment assessment. The Company concluded that the long-lived assets were not impaired, as their carrying values were not in excess of their fair value. Next, the Company determined that the fair value of its reporting unit was less than its carrying value and the Company recorded a loss on impairment of goodwill of $ 10.5 million.

During 2023, the Company also recorded an impairment charge of $ 2.0 million to research and development expense for the remaining book value of intangible assets acquired in 2016 from Bioject Medical Technologies, as the Company had no plans to further develop or utilize this technology.

Refer to Note 8 for further information regarding Goodwill and Intangible Assets .

Income Taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company’s assets and liabilities along with net operating loss and tax credit carry forwards. The Company records a valuation allowance against its deferred tax assets to reduce the net carrying value to an amount that it believes is more likely than not to be realized. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income taxes will increase or decrease, respectively, in the period such determination is made.

Valuation allowances against the Company’s deferred tax assets were $ 327.5 million and $ 299.1 million at December 31, 2023 and 2022, respectively. Changes in the valuation allowances, when they are recognized in the provision for income taxes, are included as a component of the estimated annual effective tax rate.

Collaboration Agreements and Revenue Recognition

The Company assesses whether its collaboration agreements are subject to Accounting Standards Codification ("ASC") Topic 808: Collaborative Arrangements (“Topic 808”) based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of Topic 808 and the Company concludes that its collaboration partner is not a customer, the Company presents such payments as a reduction of research and development expense. If payments from the collaboration partner to the Company represent consideration from a customer, then the Company accounts for those payments within the scope of Accounting Standards Update (“ASU”) 2014-09, Revenue from Contracts with Customers (“Topic 606”).

Grants

The Company accounts for various grant agreements under the contributions guidance under Subtopic 958-605, *Not-for-Profit Entities-Revenue Recognition* , which is outside the scope of Topic 606, as the government agencies granting the Company funds are not receiving reciprocal value for their contributions. All contributions received from current grant agreements are recorded as a contra-research and development expense as opposed to revenue on the consolidated statement of operations.

Foreign Currency Transactions

The functional and presentation currency of the Company is the U.S. dollar. Transactions denominated in a currency other than the functional currency are recorded on the initial recognition at the exchange rate at the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at the end of each reporting period into the functional currency at the exchange rate at that date. The cumulative translation adjustment is included in the accumulated other comprehensive income (loss) within the statement of stockholders' equity. Exchange differences are included in general and administrative expenses in the consolidated statement of operations. Non-monetary assets and liabilities measured at cost are remeasured at the exchange rate at the date of the transaction.

Variable Interest Entities (VIE)

The Company evaluates its ownership, contractual and other interests in entities that are not wholly-owned to determine if these entities are VIEs, and, if so, whether the Company is the primary beneficiary of the VIE. In determining whether the Company is the primary beneficiary of a VIE and therefore required to consolidate the VIE, the Company applies a qualitative approach that determines whether it has both (1) the power to direct the activities of the VIE that most significantly impact the VIE’s economic performance and (2) the obligation to absorb losses of, or the rights to receive benefits from, the VIE that could potentially be significant to that VIE. The Company will continuously perform this assessment, as changes to existing relationships or future transactions may result in the consolidation or deconsolidation of a VIE.

Equity Investments

Under ASC Topic 321, *Investments - Equity Securities,* the Company must measure equity investments (except those accounted for under the equity method, those that result in consolidation of the investee and certain other investments) at fair value and recognize any changes in fair value in the consolidated statement of operations. The Company can elect a measurement alternative for equity investments that do not have readily determinable fair values and do not qualify for the practical expedient in ASC Topic 820, *Fair Value Measurement,* to estimate fair value using the net asset value per share (or its equivalent). The Company's equity investments that do not have readily determinable fair values and do not qualify for the net asset value practical expedient for estimating fair value are measured at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identifiable or similar investments of the same issuer.

Research and Development Expenses - Clinical Trial Accruals

The Company's activities have largely consisted of research and development efforts related to developing its proprietary device technology and DNA medicine candidates. For clinical trial expenses, judgements used in estimating accruals rely on estimates of total costs incurred based on participant enrollment, completion of studies and other events. Accrued clinical trial costs are subject to revisions as trials progress. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Historically, revisions have not resulted in material changes to research and development expense; however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to the Company's results of operations.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss for the year by the weighted average number of shares of common stock outstanding during the year. Diluted net loss per share is calculated in accordance with the treasury stock method for the outstanding stock options and restricted stock units ("RSUs") and reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted to common stock. The dilutive impact of the outstanding Notes issued by the Company (discussed in Note 9) has been considered using the "if-converted" method. The calculation of diluted net loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the options or other securities and the presumed exercise of such securities are dilutive to net loss per share for the period, an adjustment to net loss used in the calculation is required to remove the change in fair value of such securities from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any. For the years ended December 31, 2023, 2022 and 2021, basic and diluted net loss per share are the same, as the assumed exercise or settlement of stock options, RSUs and the potentially dilutive shares issuable upon conversion of the Notes would have been anti-dilutive.

The following table summarizes potential shares of common stock that were excluded from diluted net loss per share calculation because of their anti-dilutive effect:

	Year Ended December 31,		
	2023	**2022**	**2021**
Options to purchase common stock	1,128,864	1,018,095	874,082
Service-based restricted stock units	274,794	212,964	204,005
Performance-based restricted stock units	—	9,328	55,279
Convertible preferred stock	275	275	275
Convertible notes	254,165	254,165	254,165
Total	1,658,098	1,494,827	1,387,806

Leases

For its long-term operating leases, the Company recognized an operating lease right-of-use asset and an operating lease liability on its consolidated balance sheets. The lease liability is determined as the present value of future lease payments using an estimated rate of interest that the Company would pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The right-of-use asset is based on the liability adjusted for any prepaid or deferred rent. The Company determines the lease term at the commencement date by considering whether renewal options and termination options are reasonably assured of exercise.

Fixed rent expense for the Company's operating leases is recognized on a straight-line basis over the term of the lease and is included in operating expenses on the consolidated statements of operations. Variable lease payments including lease operating expenses are recorded as incurred.

Stock-Based Compensation

The Company incurs stock-based compensation expense related to RSUs and stock options. The fair value of restricted stock is determined by the closing price of the Company's common stock reported on the Nasdaq Global Select Market on the date of grant. The Company estimates the fair value of stock options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of subjective assumptions, including the expected stock price volatility and expected option life. The Company amortizes the fair value of the awards on a straight-line basis over the requisite vesting period of the awards. Expected volatility is based on historical volatility. The expected life of options granted is based on historical expected life. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant. The dividend yield is based on the fact that no dividends have been paid historically and none are currently expected to be paid in the foreseeable future. The Company recognizes forfeitures as they occur.

The weighted average assumptions used in the Black-Scholes model for option grants to employees and directors are presented below:

	Year Ended December 31,		
	2023	2022	2021
Risk-free interest rate	4.05 %	2.05 %	0.91 %
Expected volatility	100 %	94 %	93 %
Expected life in years	5.5	5.7	6
Dividend yield	—	—	—

The weighted average assumptions used in the Black-Scholes model for option grants to non-employees are presented below:

	Year Ended December 31,		
	2023	2022	2021
Risk-free interest rate	3.90 %	1.96 %	1.45 %
Expected volatility	89 %	87 %	87 %
Expected life in years	10	10	10
Dividend yield	—	—	—

Recent Accounting Pronouncements

The recent accounting pronouncements below may have a significant effect on the Company's financial statements. Recent accounting pronouncements that are not anticipated to have an impact on or are unrelated to the Company's financial condition, results of operations, or related disclosures are not discussed.

ASU No. 2023-07. 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 ASU expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly reviewed by the Chief Operating Decision Maker (CODM) and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. The ASU also allows, in addition to the measure that is most consistent with U.S. GAAP, the disclosure of additional measures of segment profit or loss that are used by the CODM in assessing segment performance and deciding how to allocate resources. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. The ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, on a retrospective basis, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements and disclosures.

ASU No. 2023-09. In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* ASU 2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

3. Revenue Recognition and Concentration of Credit Risk

During the years ended December 31, 2023, 2022 and 2021, the Company recognized revenue from various license and other agreements. The following table indicates the percentage of total revenues in excess of 10% with any single customer:

Customer	2023 Revenue	% of Total Revenue	2022 Revenue	% of Total Revenue	2021 Revenue	% of Total Revenue
ApolloBio Corporation	$ 245,056	29 %	$ —	— %	$ —	— %
Plumbline Life Sciences, Inc. (affiliated entity)	—	—	33,596	—	245,310	14
U.S. Department of Defense	—	—	9,591,778	94	754,853	43
All other, including affiliated entities	586,954	71	636,894	6	774,595	43
Total revenue	$ 832,010	100 %	$ 10,262,268	100 %	$ 1,774,758	100 %

No revenue recognized during the year ended December 31, 2023 was in deferred revenue as of December 31, 2022. During the year ended December 31, 2022, the Company recognized revenue of $ 14,000 that was included in deferred revenue at December 31, 2021. Performance obligations are generally satisfied within 12 months of the initial contract date.

As of December 31, 2023, the Company had no accounts receivable balance. As of December 31, 2022, all of the Company's accounts receivable was attributable to the CEPI MERS grant. There is minimal credit risk with the Company's customers based upon the short-term nature of the accounts receivable, collection history, their size and financial condition. Accordingly, the Company does not record an allowance for potential credit losses against its accounts receivable.

4. Collaborative Agreements

Advaccine Biopharmaceuticals Suzhou Co., Ltd.

On December 31, 2020, the Company entered into a Collaboration and License Agreement with Advaccine Biopharmaceuticals Suzhou Co., Ltd. (“Advaccine”), which was amended and restated on June 7, 2021 (as amended and restated, the “Advaccine Agreement”). Under the terms of the Advaccine Agreement, the Company granted to Advaccine the exclusive right to develop, manufacture and commercialize the Company’s vaccine candidate INO-4800 within the territories of China, Taiwan, Hong Kong and Macau (referred to collectively as “Greater China”) and 33 additional countries in Asia. The June 2021 amendment related to a collaboration between the Company and Advaccine to jointly conduct a global Phase 3 segment of the Company’s clinical trial of INO-4800 that was planned. The parties were jointly participating in the trial and were to equally share the global development costs for the trial, including the Company’s manufacturing costs to supply INO-4800. Advaccine agreed to be fully responsible for conducting the trial in Greater China, including its costs and expenses incurred. In the fourth quarter of 2022, the Company discontinued its internally funded efforts to develop INO-4800 as a COVID-19 heterologous booster vaccine. Advaccine continues to develop INO-4800 with its own resources under the terms of the Advaccine Agreement.

In connection with the June 2021 amendment, the Company determined that the global Phase 3 trial component of the agreement was a collaboration and not a contract with a customer and therefore accounted for the June 2021 amendment under ASC Topic 808. Reimbursements from Advaccine were recognized as contra-research and development expense on the consolidated statement of operations once earned and collectibility was assured. During the years ended December 31, 2023, 2022 and 2021, the Company received funding of $ 3.6 million, $ 1.2 million and $ 4.5 million, respectively, from Advaccine that was recorded as contra-research and development expense.

ApolloBio Corporation

On December 29, 2017, the Company entered into an Amended and Restated License and Collaboration Agreement (the "ApolloBio Agreement"), with ApolloBio Corporation ("ApolloBio"), which was amended on June 14, 2023. Under the terms of the ApolloBio Agreement, the Company granted to ApolloBio the exclusive right to develop and commercialize VGX-3100, its DNA immunotherapy product candidate designed to treat pre-cancers caused by HPV, within the agreed upon territories.

The Company is entitled to receive up to an aggregate of $ 20.0 million, less required income, withholding or other taxes, upon the achievement of specified milestones related to the regulatory approval of VGX-3100 in accordance with the ApolloBio Agreement. In the event that VGX-3100 is approved for marketing, the Company will be entitled to receive royalty payments based on a tiered percentage of annual net sales, with such percentage being in the low- to mid-teens, subject to reduction in the event of generic competition in a particular territory. ApolloBio’s obligation to pay royalties will continue for 10 years after the first commercial sale in a particular territory or, if later, until the expiration of the last-to-expire patent covering the licensed products in the specified territory.

During the year ended December 31, 2023, the Company received funding of $ 245,000 from the ApolloBio Agreement that was recorded as revenue. For the years ended December 31, 2022 and 2021, there were no significant reimbursable program costs under the ApolloBio Agreement.

Coalition for Epidemic Preparedness Innovations

The Company previously entered into agreements with CEPI, pursuant to which the Company intended to develop vaccine candidates against Lassa fever and MERS. As part of the arrangement between the parties, CEPI agreed to fund up to an aggregate of $ 56 million of costs over a five-year period for preclinical studies, as well as planned Phase 1 and Phase 2 clinical trials, to be conducted by the Company and collaborators, with funding from CEPI based on the achievement of identified milestones. In November 2022, the Company announced that it and CEPI would discontinue the development of these product candidates targeting Lassa fever and MERS, following the initial analysis of data from the studies conducted by the Company and funded by CEPI. During the years ended December 31, 2023, 2022 and 2021, the Company received funding of $ 1.8 million, $ 6.7 million and $ 10.0 million, respectively, related to these grants and recorded those payments as contra-research and development expense. As of December 31, 2023 and 2022, the Company had an accounts receivable balance of $ 0 and $ 1.7 million, respectively, on the consolidated balance sheet related to these CEPI grants. As of December 31, 2023, the Company had $ 2.2 million recorded as an accrued liability, and at December 31, 2022, had $ 0 recorded as deferred grant funding on the consolidated balance sheet related to these CEPI grants.

In January 2020, CEPI awarded the Company a grant of up to $ 9.0 million to support preclinical and clinical development of INO-4800 through Phase 1 human testing in the United States. In April 2020, CEPI awarded the Company a grant of $ 6.9 million to work with the International Vaccine Institute ("IVI") and the Korea National Institute of Health ("KNIH") to conduct clinical trials of INO-4800 in South Korea, a grant of $ 5.0 million to accelerate development of the Company's next-generation intradermal electroporation device, known as CELLECTRA 3PSP, for the intradermal delivery of INO-4800, and a grant of $ 1.3 million to support large-scale manufacturing of INO-4800. During the years ended December 31, 2023, 2022 and 2021, the Company received funding of $ 330,000 , $ 1.1 million and $ 6.9 million, respectively, from CEPI related to these grants for INO-4800 and recorded such amounts as contra-research and development expense. As of December 31, 2023, the Company had $ 2.1 million recorded as an accrued liability, and at December 31, 2022, had $ 2.3 million recorded as deferred grant funding on the consolidated balance sheet related to the CEPI grants related to INO-4800.

Bill & Melinda Gates Foundation

In October 2018, Gates awarded and funded the Company a grant of $ 2.2 million to advance the development of dMAbs to address issues in infectious disease prevention and therapy. This technology has high relevance for the control of influenza and HIV. This next-generation approach to the delivery of monoclonal antibodies would make the technology accessible to low and middle-income countries. In August 2019, Gates funded an additional $ 1.1 million for the project. During the years ended December 31, 2023, 2022 and 2021, the Company recorded $ 70,000 , $ 233,000 and $ 182,000 , respectively, as contra-research and development expense related to the Gates dMAb grant. As of December 31, 2023 and 2022, the Company had $ 87,000 and $ 153,000 , respectively, recorded as deferred grant funding on the consolidated balance sheet related to the grant.

Department of Defense (DoD)

In June 2020, the Company entered into an Other Transaction Authority for Prototype Agreement (the “OTA Agreement”) with the DoD to fund the Company’s efforts in developing the CELLECTRA® 3PSP device and associated arrays to be used for delivery of INO-4800 against COVID-19. The total amount of funding provided to the Company under the OTA Agreement was $ 54.5 million. The Company determined that the OTA Agreement should be considered under Subtopic 958-605, *Not-for-Profit Entities-Revenue Recognition*, which is outside the scope of Topic 606, as the government agency granting the Company funds was not receiving reciprocal value for their contributions. The Company recorded contra-research and development expense on the consolidated statement of operations in the same period that the underlying expenses were incurred. During the years ended December 31, 2023, 2022 and 2021, the Company recorded $ 0 , $ 6.1 million and $ 27.1 million, respectively, as contra-research and development expense related to the OTA agreement.

Additionally, in June 2020, the Company was awarded a fixed-price contract (the “Procurement Contract”) from the DoD for the purchase of the Company’s intradermal CELLECTRA ® 2000 device and accessories. The total purchase price under the Procurement Contract was $ 16.8 million. The Company determined that the Procurement Contract fell under the scope of ASC Topic 606 as the contract was with a customer and the Company was able to satisfy its obligations under the arrangement. Performance obligations under the Procurement Contract consisted of the delivery of a specified number of CELLECTRA ® 2000 devices and accessories. The total transaction price was allocated to the individual performance obligations based on the determined standalone selling price for the devices and accessories. In 2021, the DoD announced that it would discontinue funding for the Phase 3 segment of the Company's clinical trials for INO-4800 and in January 2022, the total purchase price under the Procurement Contract was reduced to $ 10.7 million. During the year ended December 31, 2022, all performance obligations under the Procurement Contract were satisfied. During the years ended December 31, 2023, 2022 and 2021 , the Company recorded revenue of $ 0 , $ 9.6 million and $ 755,000 , respectively, from the Procurement Contract.

5. Short-term Investments and Fair Value Measurements

The following is a summary of available-for-sale securities as of December 31, 2023 and 2022:

	Contractual Maturity (in years)	As of December 31, 2023 Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Mutual funds	---	$ 55,389,289	$ —	$ (3,522,888)	$ 51,866,401
U.S. treasury securities	Less than 1	75,164,782	24,938	—	75,189,720
Certificates of deposit	Less than 1	2,978,917	11,709	(300)	2,990,326
U.S. agency mortgage-backed securities	*	1,340,439	—	(403,973)	936,466
		$ 134,873,427	$ 36,647	$ (3,927,161)	$ 130,982,913

	Contractual Maturity (in years)	As of December 31, 2022 Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Mutual funds	---	$ 117,036,232	$ —	$ (9,373,514)	$ 107,662,718
U.S. treasury securities	Less than 1	95,001,209	7,567	(44,266)	94,964,510
Certificates of deposit	Less than 1	2,977,564	13,664	(320)	2,990,908
U.S. agency mortgage-backed securities	*	1,435,592	—	(384,331)	1,051,261
		$ 216,450,597	$ 21,231	$ (9,802,431)	$ 206,669,397

*No single maturity date.

During the years ended December 31, 2023 and 2022, the Company recorded gross realized gain on investments of $ 1,000 and $ 21,000 , respectively, and gross realized loss on investments of $ 4.8 million and $ 4.1 million, respectively. During the years ended December 31, 2023 and 2022, the Company recorded net unrealized gain (loss) on available-for-sale equity securities of $ 5.9 million and $(7.8) million, respectively. No material balances were reclassified out of accumulated other comprehensive loss for the years ended December 31, 2023, 2022 and 2021. Interest and dividends on investments classified as available-for-sale are included in interest income in the consolidated statements of operations. As of December 31, 2023, the Company had 21 available-for-sale securities in a gross unrealized loss position, of which 20 with an aggregate total unrealized loss of $ 3.9 million were in such position for longer than 12 months.

The Company periodically reviews its portfolio of available-for-sale debt securities to determine if any investment is impaired due to credit loss or other potential valuation concerns. For the debt securities where the fair value of the investment is less than the amortized cost basis, the Company has assessed at the individual security level for various quantitative factors including, but not limited to, the nature of the investments, changes in credit ratings, interest rate fluctuations, industry analyst reports, and the severity of impairment. Unrealized losses on available-for-sale debt securities as of December 31, 2023 were primarily due to changes in interest rates, and not due to increased credit risks associated with specific securities. Based on the credit quality of the available-for-sale debt securities that are in an unrealized loss position, and the Company's estimates of future cash flows to be collected from those securities, the Company believes the unrealized losses are not credit losses. Accordingly, at December 31, 2023, the Company did not record an allowance for credit losses related to its available-for-sale debt securities.

The following table presents the Company's assets that were measured at fair value on a recurring basis, determined using the following inputs as of December 31, 2023:

	Fair Value Measurements at December 31, 2023			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Unobservable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Short-term investments				
Mutual funds	$ 51,866,401	$ 51,866,401	$ —	$ —
U.S. treasury securities	75,189,720	75,189,720	—	—
Certificates of deposit	2,990,326	—	2,990,326	—
U.S. agency mortgage-backed securities	936,466	—	936,466	—
Total short-term investments	130,982,913	127,056,121	3,926,792	—
Investment in affiliated entity	2,780,287	2,780,287	—	—
Total assets measured at fair value	$ 133,763,200	$ 129,836,408	$ 3,926,792	$ —

The following table presents the Company's assets that were measured at fair value on a recurring basis, determined using the following inputs as of December 31, 2022:

	Fair Value Measurements at December 31, 2022			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Unobservable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Short-term investments				
Mutual funds	$ 107,662,718	$ 107,662,718	$ —	$ —
U.S. treasury securities	94,964,510	94,964,510	—	—
Certificates of deposit	2,990,908	—	2,990,908	—
U.S. agency mortgage-backed securities	1,051,261	—	1,051,261	—
Total short-term investments	206,669,397	202,627,228	4,042,169	—
Investments in affiliated entity	2,007,142	2,007,142	—	—
Total assets measured at fair value	$ 208,676,539	$ 204,634,370	$ 4,042,169	$ —

Level 1 assets at December 31, 2023 and 2022 consisted of mutual funds and U.S. treasury securities held by the Company that are valued at quoted market prices, as well as the Company's investment in its affiliated entity, PLS. The Company accounts for its investment in 597,808 common shares of PLS based on the closing price of the shares on the Korea New Exchange Market on the applicable balance sheet date. Unrealized gains and losses on the Company's equity securities are reported in the consolidated statement of operations as unrealized gain or loss on available-for-sale equity securities or as a gain or loss on investment in affiliated entity.

Level 2 assets at December 31, 2023 and 2022 consisted of certificates of deposit and U.S. agency mortgage-backed securities held by the Company that are initially valued at the transaction price and subsequently valued, at the end of each reporting period, typically utilizing market observable data. The Company obtains the fair value of its Level 2 assets from a professional pricing service, which may use quoted market prices for identical or comparable instruments, or inputs other than quoted prices that are observable either directly or indirectly. The professional pricing service gathers quoted market prices and observable inputs from a variety of industry data providers. The valuation techniques used to measure the fair value of the Company's Level 2 financial instruments were derived from non-binding market consensus prices that are corroborated by observable market data, quoted market prices for similar instruments, or pricing models such as discounted cash flow techniques. The Company validates the quoted market prices provided by the primary pricing service by comparing the service's assessment of the fair values of the Company's investment portfolio balance against the fair values of the Company's investment portfolio balance obtained from an independent source.

There were no Level 3 assets held as of December 31, 2023 or 2022.

6. Certain Balance Sheet Items

Prepaid and other current assets at December 31, 2023 and 2022 consisted of the following:

	2023	2022
Insurance recovery (a)	$ —	$ 30,000,000
Prepaid manufacturing expenses	1,486,638	1,401,028
Other prepaid expenses	3,907,027	18,729,453
	$ 5,393,665	$ 50,130,481

Accounts payable and accrued expenses at December 31, 2023 and 2022 consisted of the following:

	2023	2022
Trade accounts payable	$ 3,577,826	$ 19,862,487
Accrued compensation	9,837,104	12,574,921
Accrued litigation settlement (a)	—	44,000,000
Other accrued expenses (b) (c)	6,432,814	3,249,477
	$ 19,847,744	$ 79,686,885

(a) In July 2022, the Company entered into a memorandum of understanding for the proposed settlement of class action securities litigation (see Note 11). The final judicial order for the settlement was issued in January 2023. The settlement consisted of $ 30.0 million in cash and $ 14.0 million in shares of the Company's common stock to settle all outstanding claims. As of December 31, 2022, the Company's insurance carriers had paid the cash component of the proposed settlement, which amounts were being held in escrow. The Company's insurance carriers paid $ 252,000 of other expenses on behalf of the Company, which amounts were offset against the insurers' cash commitment as part of the settlement. During the three months ended March 31, 2023, the cash component of the settlement was released from escrow and the Company issued 760,083 shares of common stock pursuant to the securities class action settlement.

(b) In March 2023, the Company entered into a stipulation of settlement for the proposed settlement of shareholder derivative litigation (see Note 11). In June 2023, the court preliminarily approved the proposed settlement. As part of the settlement, in July 2023, the Company paid $ 1.2 million to plaintiffs' counsel for their fees and expenses. This amount was accrued within "Other accrued expenses" as of December 31, 2022. On October 12, 2023, the court entered an order and final judgment approving the Settlement, which was effective on November 13, 2023.

(c) December 31, 2023 balance includes $ 4.3 million liability for unused grant funding.

7. Fixed Assets

Fixed assets at December 31, 2023 and 2022 consisted of the following:

	Cost	Accumulated Depreciation and Amortization	Net Book Value
As of December 31, 2023			
Leasehold improvements	$ 15,917,596	$ (11,753,081)	$ 4,164,515
Research and development equipment	3,538,698	(3,078,165)	460,533
Office furniture and fixtures	2,827,476	(2,816,577)	10,899
Computer equipment and other	3,529,129	(3,204,090)	325,039
	$ 25,812,899	$ (20,851,913)	$ 4,960,986
As of December 31, 2022			
Leasehold improvements	$ 15,803,108	$ (10,036,080)	$ 5,767,028
Research and development equipment	5,300,104	(4,295,217)	1,004,887
Office furniture and fixtures	2,827,476	(2,803,800)	23,676
Computer equipment and other	5,360,712	(4,428,306)	932,406
	$ 29,291,400	$ (21,563,403)	$ 7,727,997

Depreciation expense for the years ended December 31, 2023, 2022 and 2021 was $ 2.6 million, $ 3.7 million and $ 3.0 million, respectively. The Company determined that the carrying value of its fixed assets was not impaired during the periods presented. During the year ended December 31, 2023, the Company sold fixed assets with no net book value for a gain of $ 148,000 and disposed of fixed assets with a net book value of $ 466,000 . During the year ended December 31, 2022 the Company sold fixed assets with a net book value of $ 6.1 million and disposed of fixed assets with a net book value of $ 1.1 million.

8. Goodwill and Intangible Assets

During the three months ended September 30, 2023, as a result of the sustained decline in the Company's stock price and related market capitalization, and a general decline in equity values in the biotechnology industry, the Company performed an impairment assessment of its goodwill and long-lived assets.

The Company operates as a single reporting unit based on its business and reporting structure. For goodwill, a quantitative impairment assessment was performed using a market approach, whereby the Company's fair value of equity was compared to its carrying value. The fair value of equity was derived using both the market capitalization of the Company and an estimate of a reasonable range of values of a control premium applied to the Company's implied business enterprise value. The control premium was estimated based upon control premiums observed in comparable market transactions. This represented a level 2 nonrecurring fair value measurement. Based on this analysis, the Company recognized a non-cash, pre-tax goodwill impairment charge of $ 10.5 million during the three months ended September 30, 2023. As a result, the goodwill was fully impaired as of September 30, 2023.

Before completing the goodwill impairment assessment, the Company first tested its long-lived assets for impairment. The Company held no indefinite-lived intangible assets as of September 30, 2023. The Company determined that all of its long-lived assets, which included property and equipment, leasehold improvements and right-of-use assets, represented one asset group for purposes of its long-lived asset impairment assessment. The Company concluded that the long-lived assets were not impaired, as their carrying values were not in excess of their fair value.

During the quarter ended June 30, 2023, the Company recorded an impairment charge of $ 2.0 million to research and development expense for the remaining book value of intangible assets acquired in 2016 from Bioject Medical Technologies, as the Company had no plans to further develop or utilize this technology.

The following sets forth goodwill and intangible assets by major asset class:

	Weighted Average Useful Life (Yrs)	December 31, 2023 Gross	Accumulated Amortization	Impairment	Net Book Value	December 31, 2022 Gross	Accumulated Amortization	Net Book Value
Indefinite lived:								
Goodwill		$ 10,513,371	$ —	$ (10,513,371)	$ —	$ 10,513,371	$ —	$ 10,513,371
Definite lived:								
Licenses	10	—	—	—	—	1,323,761	(1,323,761)	—
Bioject	—	5,100,000	(3,115,556)	(1,984,444)	—	5,100,000	(2,988,889)	2,111,111
Other (a)	18	4,050,000	(4,050,000)	—	—	4,050,000	(4,031,250)	18,750
Total intangible assets	11	9,150,000	(7,165,556)	(1,984,444)	—	10,473,761	(8,343,900)	2,129,861
Total goodwill and intangible assets		$ 19,663,371	$ (7,165,556)	$ (12,497,815)	$ —	$ 20,987,132	$ (8,343,900)	$ 12,643,232

(a) Other intangible assets represent the estimated fair value of acquired intellectual property.

Aggregate amortization expense related to intangible assets was $ 145,000 , $ 496,000 and $ 520,000 for the years ended December 31, 2023, 2022 and 2021, respectively.

There were no impairment or impairment indicators present and no losses were recorded during the years ended December 31, 2022 and 2021.

9. Convertible Debt

Convertible Senior Notes

On February 19, 2019 and March 1, 2019, the Company completed a private placement of $ 78.5 million aggregate principal amount of its 6.50 % convertible senior notes due 2024 (the “Notes”). The Notes were sold in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. Net proceeds from the offering were $ 75.7 million.

The Notes were senior unsecured obligations of the Company and accrued interest payable in cash semi-annually in arrears on March 1 and September 1 of each year at a rate of 6.50 % per annum. The Notes matured on March 1, 2024 and the Company paid the then remaining $ 16.9 million obligation in full, including accrued interest.

Initially, in accounting for the issuance of the Notes, the Company separated the Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of similar debt instruments, which do not have an associated convertible feature. The carrying amount of the equity component representing the conversion option for the Notes was $ 16.3 million and was recorded as a debt discount, which was being amortized to interest expense at an effective interest rate of 13.1 %. In addition, the Company allocated $ 592,000 of debt issuance costs to the equity component and the remaining debt issuance costs of $ 2.2 million were allocated to the liability component, which were being amortized to interest expense under the effective interest rate method.

On January 1, 2022, the Company adopted ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity (“ASU 2020-06”). The ASU eliminated the cash conversion feature models in ASC 470-20, Debt with Conversion and Other Options, which required an issuer of certain convertible debt to separately account for embedded conversion features as a component of equity. Instead, the Company accounted for these securities as a single unit of account, unless the conversion feature met certain criteria. The Company adopted the new standard using the modified retrospective method and recorded a net reduction to accumulated deficit of $ 1.8 million, a decrease to additional paid-in capital of $ 3.3 million, and an increase to convertible senior notes of $ 1.5 million to reflect the impact of the accounting change. The Notes were subsequently accounted for as a single liability measured at amortized cost, as no other embedded features required bifurcation and recognition as derivatives.

The balance of the Notes at December 31, 2023 was as follows:

Principal amount	$ 78,500,000
Principal amount converted into common shares	(62,085,000)
Unamortized debt issuance cost	—
Accrued interest	355,654
Net carrying amount	$ 16,770,654

For the years ended December 31, 2023, 2022 and 2021, the Company recognized $ 1.2 million, $ 1.3 million and $ 1.9 million, respectively, of interest expense related to the Notes, of which $ 1.1 million related to the contractual interest coupon in each year.

10. Stockholders' Equity

Preferred Stock

	Shares Authorized	Shares Issued	Shares Outstanding as of December 31, 2023	2022
Series C Preferred Stock, par $ 0.001	1,091	1,091	9	9

The holder of a share or shares of Series C preferred stock has the right at any time, at such holder's option, to convert all or any lesser portion of such holder's shares of the preferred stock into fully paid and non-assessable shares of common stock. As of December 31, 2021, the conversion value was $ 326.40 per share, such that the outstanding shares of Series C preferred stock were convertible into an aggregate of 275 shares of common stock.

Issuances of Common Stock

On November 9, 2021, the Company entered into an ATM Equity Offering SM Sales Agreement (the "2021 Sales Agreement") with outside sales agents (collectively, the "Sales Agents") for the offer and sale of its common stock for an aggregate offering price of up to $ 300.0 million. The 2021 Sales Agreement provides that the Sales Agents will be entitled to compensation in an amount equal to up to 3.0 % of the gross sales proceeds of any common stock sold through the Sales Agents under the 2021 Sales Agreement. During the years ended December 31, 2023 and 2022, the Company sold 875,305 and 2,870,478 shares, respectively, of its common stock under the 2021 Sales Agreement. The sales were made at a weighted average price of $ 6.33 and $ 29.34 per share, respectively, resulting in aggregate net proceeds of $ 5.5 million and $ 83.0 million, respectively. As of December 31, 2023 there was $ 161.8 million of remaining capacity under the 2021 Sales Agreement.

During the three months ended March 31, 2023, the Company issued 760,083 shares of common stock pursuant to the securities class action settlement, as described in Note 11.

Stock Options and Restricted Stock Units

The Company's Board of Directors adopted the 2023 Omnibus Incentive Plan (the "2023 Plan") on March 24, 2023, pursuant to which the Company may grant stock options, restricted stock awards, RSUs and other stock-based awards or short-term cash incentive awards to employees, directors and consultants.

The 2023 Plan was approved by stockholders on May 16, 2023. The aggregate number of shares of the Company's common stock that may be issued under the 2023 Plan will not exceed the sum of 1,166,666 shares plus any shares that may return from time to time from the 2016 Omnibus Incentive Plan (as amended, the "2016 Plan") as a result of expirations, terminations or forfeitures of awards outstanding under the 2016 Plan as of May 16, 2023. At December 31, 2023, the Company had 1,334,012 shares of common stock available for future grant under the 2023 Plan, 1,875 shares underlying outstanding but unvested RSUs and 3,150 shares underlying options outstanding to purchase common stock under the 2023 Plan. The awards granted and available for future grant under the 2023 Plan generally vest over three years and have a maximum contractual term of ten years . The 2023 Plan terminates by its terms on March 24, 2033.

At December 31, 2023, the Company had 262,641 shares underlying outstanding but unvested RSU and options outstanding to purchase 961,499 shares of common stock under the 2016 Plan. The outstanding awards granted under the 2016 Plan generally vest over three years and have a maximum contractual term of ten years . Following adoption of the 2023 Plan, no further awards may be made under the 2016 Plan, but outstanding awards continue to be governed by their existing terms.

On June 24, 2022, the Company's board of directors adopted a stock-based incentive plan (the "2022 Inducement Plan"), which provides for the discretionary grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, RSU awards, performance awards, and other awards to individuals as a material inducement to entering into employment with the Company. The aggregate number of shares of the Company's common stock that may be issued under the 2022 Inducement Plan will not exceed 166,666 shares. At December 31, 2023 the Company had 125,575 shares of common stock available for future grant under the 2022 Inducement Plan, 10,278 shares underlying outstanding but unvested RSUs and options outstanding to purchase 27,759 shares of common stock under the 2022 Inducement Plan. The 2022 Inducement Plan can be terminated by the Company's board of directors at any time.

The Amended and Restated 2007 Omnibus Incentive Plan (the "2007 Incentive Plan") was adopted on March 31, 2007 and terminated by its terms on March 31, 2017. At December 31, 2023, the Company had options outstanding to purchase 136,456 shares of common stock under the 2007 Incentive Plan. The awards granted under the 2007 Incentive Plan generally vest over three years and have a maximum contractual term of ten years .

Total employee and director stock-based compensation expense recognized in the consolidated statements of operations for the years ended December 31, 2023, 2022 and 2021 was $ 10.4 million, $ 22.2 million and $ 25.0 million, respectively, of which $ 4.5 million, $ 8.8 million and $ 13.4 million was included in research and development expenses and $ 5.9 million, $ 13.4 million and $ 11.6 million was included in general and administrative expenses, respectively.

At December 31, 2023 and 2022, there was $ 4.3 million and $ 10.5 million, respectively, of total unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of 1.3 years and 1.6 years, respectively.

At December 31, 2023 and 2022, there was $ 3.5 million and $ 7.2 million, respectively, of total unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of 1.5 years and 1.7 years, respectively.

The fair value of stock options granted to non-employees was estimated using the Black-Scholes pricing model. Total stock-based compensation expense for stock options and RSUs granted to non-employees for the years ended December 31, 2023, 2022 and 2021 was $ 669,000 , $ 1.3 million and $ 1.4 million, respectively. As of December 31, 2023, options to purchase 61,808 shares of common stock granted to non-employees remained outstanding.

The following table summarizes total stock options outstanding at December 31, 2023:

	Options Outstanding			Options Exercisable	
Exercise Price	Shares Underlying Options Outstanding	Weighted-Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Shares Underlying Options Exercisable	Weighted Average Exercise Price
$ 4.32 -$ 18.00	283,472	9.2	$ 14.11	66,918	$ 14.45
$ 18.01 -$ 39.00	264,108	7.3	$ 35.69	141,600	$ 34.99
$ 39.01 -$ 52.00	156,505	4.5	$ 44.93	156,271	$ 44.93
$ 52.01 -$ 90.00	129,681	4.2	$ 76.82	121,124	$ 77.75
$ 90.01 -$ 130.00	136,716	4.2	$ 100.15	131,640	$ 100.00
$ 130.01 -$ 233.28	158,382	5.4	$ 140.27	129,250	$ 141.78
	1,128,864	6.4	$ 58.76	746,803	$ 72.11

At December 31, 2023, the aggregate intrinsic value of options outstanding was $ 2,000 , the aggregate intrinsic value of options exercisable was $ 1,000 , and the weighted average remaining contractual term of options exercisable was 5.5 years.

At December 31, 2023, the aggregate intrinsic value of unvested RSUs was $ 1.7 million and the aggregate intrinsic value of RSUs which vested during the year ended December 31, 2023 was $ 1.3 million.

At December 31, 2023, options to purchase 1,128,864 shares of common stock and 274,794 RSUs were expected to vest.

Stock option activity under the Company's equity incentive plans during the year ended December 31, 2023 was as follows:

	Number of Shares	Weighted-Average Exercise Price
Balance, December 31, 2022	1,018,095	$ 75.32
Granted	339,019	14.23
Exercised	—	—
Cancelled	(228,250)	66.47
Balance, December 31, 2023	1,128,864	$ 58.76

Restricted stock unit activity under the Company's equity incentive plans during the year ended December 31, 2023 was as follows:

	Number of Shares
Balance, December 31, 2022	212,964
Granted	194,747
Vested	(99,420)
Cancelled	(33,497)
Balance, December 31, 2023	274,794

The weighted average exercise price per share was $ 38.86 for the 9,357 options which expired during the year ended December 31, 2023, $ 101.64 for the 6,437 options which expired during the year ended December 31, 2022 and $ 54.72 for the 583 options which expired during the year ended December 31, 2021.

The weighted average grant date fair value per share was $ 11.19 , $ 28.08 and $ 91.32 for options granted during the years ended December 31, 2023, 2022 and 2021, respectively.

The weighted average grant date fair value was $ 10.34 , $ 37.44 and $ 124.44 per share for RSUs granted during the years ended December 31, 2023, 2022 and 2021, respectively.

No stock options were exercised during the year ended December 31, 2023. The Company received $ 283,000 and $ 6.7 million in proceeds from the exercise of stock options during the years ended December 31, 2022 and 2021, respectively. The aggregate intrinsic value of options exercised was $ 81,000 and $ 7.0 million during the years ended December 31, 2022 and 2021, respectively.

11. Commitments and Contingencies

Leases

The Company leases approximately 56,600 square feet of office, laboratory, and manufacturing space in San Diego, California and 57,360 square feet of office space in Plymouth Meeting, Pennsylvania under various non-cancellable operating lease agreements with remaining lease terms as of December 31, 2023 of 3.4 years to 6.0 years, which represent the non-cancellable periods of the leases. The Company has excluded the extension options from its lease terms in the calculation of future lease payments as they are not reasonably certain to be exercised. The Company's lease payments consist primarily of fixed rental payments for the right to use the underlying leased assets over the lease terms as well as payments for common area maintenance and administrative services. The Company has received customary incentives from its landlords, such as reimbursements for tenant improvements and rent abatement periods, which effectively reduce the total lease payments owed for these leases.

In November 2023, the Company amended one of its leases representing 31,207 square feet of office and laboratory space with a lease term expiring in November 2023, to extend the term to February 29, 2024.

In November 2023, the Company entered into a lease agreement for research and development laboratory space in San Diego, California ("New San Diego Lease"). The total space under the New San Diego Lease is approximately 5,563 square feet. The term of the New San Diego Lease commenced on February 10, 2024 and the initial term is 4.3 years.

The base rent adjusts periodically throughout the term of the New San Diego Lease. Rent payments under the New San Diego Lease will include base rent with an annual increase of approximately three percent, and additional monthly fees to cover the Company's share of certain facility expenses, including utilities, property taxes, insurance and maintenance. In addition, the Company has paid a security deposit of $ 33,000 .

The Company performed an evaluation of its contracts with customers and suppliers in accordance with ASC Topic 842 and determined that, except for the real estate leases described above and various copier leases, none of its other contracts contain a right-of-use asset.

Operating lease right-of-use assets and liabilities on the consolidated balance sheet represents the present value of the remaining lease payments over the remaining lease terms. Payments for additional monthly fees to cover the Company's share of certain facility expenses are not included in operating lease right-of-use assets and liabilities. The Company uses its incremental borrowing rate to calculate the present value of its lease payments, as the implicit rates in the leases are not readily determinable.

As of December 31, 2023, the maturities of the Company's operating lease liabilities were as follows:

Year ending December 31,	
2024	$ 3,247,000
2025	3,466,000
2026	3,555,000
2027	2,955,000
2028	2,310,000
Thereafter	2,132,000
Total remaining lease payments	17,665,000
Less: present value adjustment	(4,226,000)
Total operating lease liabilities	13,439,000
Less: current portion	(2,407,000)
Long-term operating lease liabilities	$ 11,032,000
Weighted-average remaining lease term	5.3 years
Weighted-average discount rate	8.9 %

Lease costs included in operating expenses in the consolidated statements of operations for the years ended December 31, 2023, 2022 and 2021 were $ 3.5 million, $ 3.4 million and $ 3.4 million, respectively. Operating lease costs consisting of the fixed lease payments included in operating lease liabilities are recorded on a straight-line basis over the lease terms. Variable lease costs are recorded as incurred.

In the third and fourth quarters of 2023, the Company entered into agreements to sublease a total of approximately 4,400 and 7,000 square feet, respectively, in its Plymouth Meeting headquarters, in each case with sublease terms through December 31, 2026.

In the fourth quarter of 2019, the Company entered into two agreements to sublease a total of approximately 13,500 square feet in its Plymouth Meeting headquarters, with one sublease term through March 31, 2025 and the other month-to-month.

In the normal course of business, the Company is a party to a variety of agreements pursuant to which it may be obligated to indemnify the other party. It is not possible to predict the maximum potential amount of future payments under these types of agreements due to the conditional nature of the Company's obligations and the unique facts and circumstances involved in each particular agreement. Historically, payments made by the Company under these types of agreements have not had a material effect on its business, consolidated results of operations or financial condition.

Legal Proceedings

Securities Litigation

In March 2020, a purported shareholder class action complaint, McDermid v. Inovio Pharmaceuticals, Inc. and J. Joseph Kim, was filed in the United States District Court for the Eastern District of Pennsylvania, naming the Company and its former President and Chief Executive Officer as defendants. The lawsuit alleged that the Company made materially false and misleading statements in violation of certain federal securities laws. The plaintiffs sought unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including reasonable attorneys' fees. The plaintiffs' complaint was later amended to include certain of the Company's other officers as defendants. After additional motions were filed in the case, in June 2022 the parties negotiated an agreement in principle to settle the shareholder class action complaint, which was approved by the court in January 2023. Under the settlement, the Company agreed to pay $ 30.0 million in cash and $ 14.0 million in shares of its common stock to settle all outstanding claims. The Company's insurance carriers paid the $ 30.0 million cash component of the settlement. During the three months ended March 31, 2023, the Company issued 760,083 shares of common stock pursuant to the securities class action settlement.

Shareholder Derivative Litigation

In April 2020, a purported shareholder derivative complaint, Behesti v. Kim, et al., was filed in the United States District Court for the Eastern District of Pennsylvania, naming eight current and former directors of the Company as defendants. The lawsuit asserted state and federal claims and was based on the same alleged misstatements as the shareholder class action complaint described above. The lawsuit accused the Company's board of directors of failing to exercise reasonable and prudent supervision over the Company's management, policies, practices, and internal controls. The plaintiff sought unspecified monetary damages on behalf of the Company as well as governance reforms. Between June 2020 and August 2020, additional shareholder derivative complaints were filed and later consolidated by the court.

In March 2022, an additional shareholder derivative complaint was filed in the Delaware Court of Chancery, asserting substantially similar claims as those in the consolidated derivative action. In May 2022, the Delaware Court of Chancery entered a stay of the litigation.

In March 2023, the parties submitted a joint status report to the Court of Chancery reporting that the parties agreed to a settlement in principle, which also provided for the resolution of the consolidated derivative action and certain stockholder demands.

In April 2023, the plaintiffs in the consolidated derivative action filed a motion for preliminary approval of settlement with the United States District Court for the Eastern District of Pennsylvania. The proposed settlement provided for resolution of the consolidated derivative action, the derivative action pending in the Delaware Court of Chancery, and certain stockholder demands.

In June 2023, the court entered an order preliminarily approving the proposed settlement of the derivative claims, in accordance with a Stipulation of Settlement. The Stipulation of Settlement contemplated that, following the settlement hearing and the final approval of the settlement by the court, the Company would implement certain corporate governance reforms described in the Stipulation of Settlement. The preliminary order also approved the form and manner of the notice of the Settlement. As part of the Settlement, in July 2023 the Company paid $ 1.2 million to plaintiffs' counsel for their fees and expenses. In October 2023, the court entered an order and final judgment approving the Settlement, which became effective in November 2023. The Company has implemented the corporate governance reforms in response to the provisions of the Stipulation of Settlement.

VGXI Litigation

In June 2020, the Company filed a complaint in the Court of Common Pleas of Montgomery County, Pennsylvania against VGXI, Inc. and GeneOne Life Science, Inc., or GeneOne, and together with VGXI, Inc. collectively referred to as VGXI, alleging that VGXI had materially breached the Company's supply agreement with them. The complaint seeks declaratory judgments, specific performance of the agreement, injunctive relief, an accounting, damages, attorneys' fees, interest, costs and other relief from VGXI. In June 2020, the Company filed a petition for preliminary injunction, which was denied.

Following an appeal by the Company, in July 2020, VGXI filed counterclaims against the Company, alleging that the Company had breached the supply agreement, as well as misappropriation of trade secrets and unjust enrichment. The counterclaims seek injunctive relief, damages, attorneys' fees, interest, costs and other relief from the Company. VGXI also filed a third-party complaint against Ology Bioservices, Inc., a contract manufacturing organization that the Company had engaged to provide services similar to those that were being provided by VGXI. The Company filed an answer to VGXI's counterclaims, disputing the allegations and the claims raised in VGXI's filing. In October 2020, the Company filed a notice of discontinuance of appeal with the Pennsylvania Superior Court. A trial date for the litigation has not been set.

The Company intends to aggressively prosecute the claims set forth in its complaint against VGXI and to vigorously defend itself against VGXI's counterclaims.

GeneOne Litigation

In December 2020, GeneOne filed a complaint in the Court of Common Pleas of Montgomery County, Pennsylvania against the Company, alleging that the Company had breached the CELLECTRA Device License Agreement, or the Agreement, between the Company and GeneOne. The Company terminated the Agreement in October 2020. The complaint asserts claims for breach of contract, declaratory judgment, unfair competition, and unjust enrichment. The complaint seeks injunctive relief, an accounting, damages, disgorgement of profits, attorneys' fees, interest, and other relief from the Company. The Company filed preliminary objections to the complaint, which were overruled by the court. In September 2021, the Company filed an answer to the complaint, new matter, and counterclaims. The Company's counterclaims allege that GeneOne breached the Agreement and assert claims for breach of contract and declaratory judgment. The counterclaims seek damages, interest, expenses, attorney's fees, and costs. A trial date for this litigation has not been set.

The Company intends to aggressively prosecute the claims set forth in its counterclaims against GeneOne and to vigorously defend itself against the claims in GeneOne's complaint.

Other Matters

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of its business. Any of these claims could subject the Company to costly legal expenses and, while the Company generally believes that it has adequate insurance to cover many different types of liabilities, its insurance carriers may deny coverage or its policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the Company's consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. Except as described above, the Company is not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would be reasonably expected to have a material adverse effect on the Company's consolidated results of operations or financial position.

12. Income Taxes

In accordance with the guidance pursuant to accounting for income taxes, a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates which will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax asset will be realized.

The components of pretax loss from operations are as follows:

	Year Ended December 31,		
	2023	2022	2021
U.S. Domestic	$ (134,979,579)	$ (277,440,803)	$ (302,614,003)
Foreign	(137,772)	(211,249)	(610,320)
Pretax loss from operations	$ (135,117,351)	$ (277,652,052)	$ (303,224,323)

There was no provision for or benefit from income taxes for the years ended December 31, 2023, 2022 and 2021.

The reconciliation of income taxes attributable to continuing operations computed at the statutory tax rates to income tax benefit, using a 21% statutory tax rate for December 31, 2023, 2022 and 2021, is as follows:

	Year Ended December 31,		
	2023	2022	2021
Benefit from income taxes at statutory rates	$ (28,375,000)	$ (58,307,000)	$ (63,677,000)
State income tax, net of federal benefit	(3,922,000)	(3,601,000)	(3,447,000)
Change in valuation allowance	28,394,000	61,065,000	77,424,000
Research and development tax credits	(2,139,000)	(7,534,000)	(16,523,000)
Stock-based compensation	2,099,000	2,913,000	483,000
Uncertain tax positions	861,000	2,291,000	6,509,000
Goodwill Impairment	1,962,000	—	—
Expired NOLs and credits	1,352,000	1,459,000	616,000
Limited NOLs and credits	(997,000)	(1,337,000)	(542,000)
Change in tax rates	365,000	(187,000)	—
Foreign tax rate differential	(4,000)	(8,000)	(24,000)
Other	404,000	3,246,000	(819,000)
	$ —	$ —	$ —

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2023 and 2022 are shown below:

	As of December 31,	
	2023	2022
Deferred tax assets:		
Capitalized research expense	$ 50,143,000	$ 41,252,000
NOL carryforwards	235,624,000	212,768,000
Research and development and other tax credits	27,734,000	26,442,000
Deferred revenue	22,000	538,000
Stock-based compensation	3,683,000	3,945,000
Acquired intangibles	907,000	559,000
Investment in affiliated entity	1,406,000	1,569,000
Lease liability	2,822,000	3,247,000
Fixed assets	337,000	57,000
Other	6,808,000	11,062,000
	329,486,000	301,439,000
Valuation allowance	(327,493,000)	(299,124,000)
Total deferred tax assets	1,993,000	2,315,000
Deferred tax liabilities:		
Acquired intangibles	—	(199,000)
Right of use asset	(1,993,000)	(2,148,000)
Total deferred tax liabilities	(1,993,000)	(2,347,000)
Net deferred tax liabilities	$ —	$ (32,000)

As of December 31, 2023, the Company had federal, California and other state tax net operating loss (NOL) carryforwards of $ 1,013.3 million, $ 251.4 million and $ 102.6 million, respectively, net of the net operating losses that will expire due to IRC Section 382 limitations. The aggregate federal net operating losses generated in 2018 and after for the amount of $ 719.3 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year. The federal NOL carryforward began to expire in 2023, and the California and other state NOL carryforwards will begin and have begun to expire in 2028 and 2023, respectively, unless previously utilized.

The Company also had Korean NOL carryforwards of $ 1.1 million as of December 31, 2023. The Korean NOLs are available to offset up to 60% of future taxable income and will begin to expire in 2035, unless previously utilized.

In addition, as of December 31, 2023, the Company had federal and state research and development (R&D) tax credit carryforwards of $ 41.6 million and $ 6.1 million, respectively. The federal tax credit carryforwards will begin to expire in 2029. The California research tax credits do not expire.

Based upon statute, federal and state losses and credits are expected to expire as follows (in millions):

Expiration Date:	Federal NOLs	State NOLs	Foreign NOLs	Federal R&D	State R&D
2024	$ 18.9	$ 9.1	$ —	$ —	$ —
2025	13.7	5.2	—	—	—
2026	12.2	7.1	—	—	—
2027 and thereafter	249.2	332.0	1.1	41.6	—
Indefinite	719.3	0.6	—	—	6.1
	$ 1,013.3	$ 354.0	$ 1.1	$ 41.6	$ 6.1

Pursuant to Internal Revenue Code (IRC) Sections 382 and 383, annual use of the Company's NOL and R&D credit carryforwards may be limited in the event that a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has completed an IRC Section 382/383 analysis regarding the limitation of NOL and R&D credit carryforwards as of December 31, 2023. As a result of the analysis, the Company estimates that approximately $ 7.3 million of tax benefits related to NOL and R&D carryforwards will expire unused. Accordingly, the related NOL and R&D credit carryforwards have been removed from deferred tax assets accompanied by a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, limitations created by current and future ownership changes, if any, related to the Company's operations in the United States will not impact its effective tax rate. Any additional ownership changes, may further limit the ability to use the NOL and R&D carryforwards.

The Tax Cuts and Jobs Act of 2017 subjects a U.S. stockholder to tax on Global Intangible Low-Taxed Income (GILTI) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. For 2023, 2022 and 2021, the Company did not generate any GILTI due to losses earned by its foreign subsidiary.

The following table summarizes the activity related to the Company's unrecognized tax benefits:

	Year ended December 31,		
	2023	2022	2021
Balance at beginning of the year	$ 21,139,000	$ 18,819,000	$ 12,210,000
Increases related to current year tax positions	1,816,000	2,902,000	6,602,000
Increases (decreases) related to prior year tax positions	(841,000)	(582,000)	7,000
Balance at end of the year	$ 22,114,000	$ 21,139,000	$ 18,819,000

The amount of unrecognized tax benefits that, if recognized and realized, would affect the effective tax rate was $ 20.5 million, $ 19.7 million and $ 17.4 million as of December 31, 2023, 2022 and 2021, respectively, subject to valuation allowances. The Company has not recorded any interest and penalties on the unrecognized tax positions as the Company has continued to generate net operating losses after accounting for the unrecognized tax benefits. The Company does not anticipate that the total amount of unrecognized tax benefits will significantly increase or decrease within twelve months of the reporting date.

The Company and its subsidiaries are subject to U.S. federal income tax as well as income tax in multiple state and foreign jurisdictions. With few exceptions, the Company is no longer subject to United States federal income tax examinations for years before 2020 and state and local income tax examinations before 2019. However, to the extent allowed by law, the tax authorities may have the right to examine prior periods where net operating losses were generated and carried forward, and make adjustments up to the amount of the NOL carryforward amount. The Company is not to its knowledge currently under Internal Revenue Service (“IRS”), state, local or foreign tax examination.

13. 401(k) Plan

The Company has adopted a 401(k) Profit Sharing Plan covering substantially all of its employees. The defined contribution plan allows the employees to contribute a percentage of their compensation each year. The Company currently matches 50 % of its employees’ contributions, up to 6 % of their annual compensation. The Company’s contributions are recorded as expense in the accompanying consolidated statements of operations and totaled $ 1.4 million, $ 1.8 million and $ 1.5 million for the years ended December 31, 2023, 2022 and 2021, respectively.

14. Related Party Transactions

Plumbline Life Sciences, Inc.

The Company owned 597,808 shares of common stock in PLS as of December 31, 2023 and 2022, representing a 17.8 % and 18.7 % ownership interest, respectively. One of the Company's directors, Dr. David B. Weiner, acts as a consultant to PLS.

Revenue recognized from PLS consists of milestone, license and patent fees. For the years ended December 31, 2023, 2022 and 2021, the Company recognized revenue from PLS of $ 0 , $ 34,000 and $ 245,000 , respectively. At December 31, 2023 and 2022, the Company had an accounts receivable balance of $ 0 and $ 59,000 , respectively, related to PLS.

The Wistar Institute

The Company's director Dr. David B. Weiner is a director of the Vaccine Center of The Wistar Institute ("Wistar"). Dr. Weiner is also the Executive Vice President of Wistar.

In March 2016, the Company entered into collaborative research agreements with Wistar for preventive and therapeutic DNA-based immunotherapy applications and products developed by Dr. Weiner and Wistar for the treatment of cancers and infectious diseases. Under the terms of the agreement, the Company reimbursed Wistar for all direct and indirect costs incurred in the conduct of the collaborative research, not to exceed $ 3.1 million during the five-year term of the agreement. In March 2021, upon expiration of the March 2016 agreements, the Company entered into new collaborative research agreements with Wistar with the same terms. The Company has the exclusive right to in-license new intellectual property developed under this agreement.

In 2020, the Company received a $ 10.7 million sub-grant through Wistar, which was amended in 2021 to $ 13.6 million, for the preclinical development and translational studies of dMAbs as countermeasures for COVID-19, with funding extended through August 2024. The sub-grant also includes an option for an additional $ 1.6 million in funding through September 2025.

In December 2022, the Company received a $ 1.2 million sub-grant through Wistar with funding through November 2023, with an option for an additional $ 5.4 million in funding through November 2027. The Company will support the Wistar lead consortium in the research and development of synthetic DNA-launched nanoparticles (dLNPs) for vaccination against HIV infection.

Deferred grant funding recognized from Wistar and recorded as contra-research and development expense is related to work performed by the Company on the research sub-contract agreements. For the years ended December 31, 2023 and 2022, the Company recorded $ 1.0 million and $ 8.7 million, respectively, as contra-research and development expense from Wistar.

Research and development expenses recorded from Wistar relate primarily to the collaborative research agreements and sub-contract agreements related to Gates and CEPI (see Note 4). Research and development expenses recorded from Wistar for the years ended December 31, 2023, 2022 and 2021 were $ 1.8 million, $ 1.4 million and $ 2.9 million, respectively. At December 31, 2023 and 2022, the Company had an accounts receivable balance of $ 2.4 million and $ 9.9 million, respectively, and an accounts payable and accrued liability balance of $ 1.1 million and $ 1.2 million, respectively, related to Wistar. As of December 31, 2023 and 2022, the Company had a prepaid expense balance of $ 20,000 and $ 375,000 , respectively, and recorded $ 22,000 and $ 88,000 , respectively, as deferred grant funding on its consolidated balance sheet related to Wistar.

15. Geneos Therapeutics, Inc.

In 2016, the Company formed Geneos to develop and commercialize neoantigen-based personalized cancer therapies. Geneos was considered a variable interest entity (VIE) for which the Company was the primary beneficiary. The Company's Chief Scientific Officer Dr. Laurent Humeau is on the Board of Directors of Geneos. The Company's director Dr. David B. Weiner is the Chairman of the Scientific Advisory Board of Geneos.

Following a series of financing transactions through June 2020, the Company less than a majority of the outstanding equity of Geneos on an as-converted to common stock basis, which triggered a VIE reconsideration, as the Company no longer held a controlling financial interest. Based on the Company’s assessment, Geneos continued to be a VIE as it did not have sufficient equity at risk to finance its activities without additional subordinated financial support. However, the Company was not the primary beneficiary of Geneos, as it did not have the power to direct the activities that most significantly impact Geneos’ economic performance. Accordingly, the Company deconsolidated its investment in Geneos in 2020.

Following the deconsolidation, the Company accounts for its common stock investment in Geneos, in which the Company lacks control but does have the ability to exercise significant influence over operating and financial policies, using the equity method. Generally, the ability to exercise significant influence is presumed when the investor possesses more than 20% of the voting interests of the investee. This presumption may be overcome based on specific facts and circumstances that demonstrate that the ability to exercise significant influence is restricted. The Company's equity method investments are reviewed for indicators of impairment at each reporting period and are written down to fair value if there is evidence of a loss in value that is other-than-temporary. Any difference between the carrying amount of the Company’s investment and the amount of underlying equity in Geneos’ net assets is amortized into income or expense accordingly. There were no basis differences identified as of the deconsolidation date that would need to be amortized.

Upon deconsolidation, the Company recorded its investment at fair value. The Company determined that its investment in Geneos did not have a readily determinable fair value and therefore elected the measurement alternative in ASC 321 to subsequently record the investment at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. When fair value becomes determinable, from observable price changes in orderly transactions, the Company’s investment is marked to fair value. There have been no observable price changes or impairments identified since the deconsolidation date.

The Company’s share of net losses of Geneos for the three months ended March 31, 2021 was $ 1.5 million; however, only $ 434,000 was recorded, reducing the Company's total investment in Geneos to $ 0 . Of the total amount, $ 819,000 was allocated to the equity method investment, reducing the balance to $ 0 as of March 31, 2021. The remaining $ 4.2 million loss was allocated to the Company’s Series A and Series A-1 preferred stock investment in Geneos, on a ratable basis, reducing the balance to $ 0 as of March 31, 2021.

In February 2021, Geneos completed a second closing of its Series A-1 preferred stock financing, in which the Company did not participate. Following this transaction, the Company held approximately 35 % of the outstanding equity, on an as-converted to common stock basis.

In March 2022, Geneos completed the closing of a Series A-2 preferred stock financing. The Company invested $ 2.0 million in the Series A-2 preferred stock financing, which was led by outside investors. The closing date of this transaction was determined to be a VIE reconsideration event; based on the Company’s assessment, Geneos continued to be a VIE as it did not have sufficient equity at risk to finance its activities without additional subordinated financial support. The Company continued to not be the primary beneficiary of Geneos, as it did not have the power to direct the activities that most significantly impact Geneos’s economic performance and should not consolidate Geneos. Following this transaction, the Company held approximately 28 % of the outstanding equity, on an as-converted to common stock basis. Accordingly, the Company continued to account for its common stock investment in Geneos as an equity method investment under ASC 323 and its preferred stock investments as equity securities under ASC 321.

The fair value of Geneos’s Series A-2 preferred stock was based on the per share price paid by third-party investors. The Company concluded that its Series A-2 preferred stock investment was a similar financial instrument as its Series A-1 preferred stock, and therefore remeasured the carrying value of the Series A-1 preferred stock investment at the Series A-2 preferred stock price, resulting in a gain on remeasurement of $ 165,000 .

The Company recorded its current and accumulated share of net losses of Geneos of $ 2.2 million, which was allocated to the Series A-1 and Series A-2 preferred stock investment in Geneos, thereby reducing the balance to $ 0 as of March 31, 2022.

The Company has not made any further investment in Geneos subsequent to March 31, 2022. The Company will not reduce its investment below $ 0 and will not record its share of further net losses of Geneos as the Company has no obligation to fund Geneos.

In 2023, Geneos completed the closing of its Series A-3 preferred stock financing, in which the Company did not participate. Following this transaction, the Company held approximately 23 % of the outstanding equity of Geneos on an as-converted to common stock basis.

The Company continues to exclusively license its SynCon ® immunotherapy and CELLECTRA ® technology platform to Geneos to be used in the field of personalized, neoantigen-based therapy for cancer. The license agreement provides for potential royalty payments to the Company in the event that Geneos commercializes any products using the licensed technology. The Company is not obligated to use any of its assets to fund the future operations of Geneos.

16. Subsequent Events

On January 24, 2024, the Company implemented the 1-for-12 reverse stock split described in Note 2. All share information contained within this report, including the accompanying consolidated financial statements and footnotes, have been retroactively adjusted to reflect the effects of the reverse split.

From January 1, 2024 through the date of these financial statements, the Company sold 543,620 shares of common stock under the 2021 Sales Agreement for net proceeds of $ 5.2 million. The sales were made at a weighted average price of $ 9.76 per share.

On March 1, 2024, the Company's Convertible Senior Notes matured and the Company paid the $ 16.9 million obligation in full.

Exhibit 10.11

FIRST AMENDMENT
TO THE AMENDED AND RESTATED
LICENSE AND COLLABORATION AGREEMENT

This First Amendment to the Amended and Restated License and Collaboration Agreement (this "First Amendment"), dated as of June 14, 2023 (the "First Amendment Date"), is entered into by and between Beijing Apollo Saturn Biological Technology Limited, a People's Republic of China corporation having a principal place of business at B2358 Second Floor, Building 3, No8 Hangfeng Road, Fengtai, Beijing, China ("Apollo"), and Inovio Pharmaceuticals, Inc., a Delaware corporation having a principal place of business at 660 West Germantown Pike, Suite 110, Plymouth Meeting, PA 19462, U.S.A. ("Inovio"). Apollo and Inovio may be referred to herein, collectively, as the "Parties" or, individually, as a "Party."

WHEREAS, the Parties entered into the Amended and Restated License and Collaboration Agreement dated December 29, 2017 (the "Agreement"); and

WHEREAS, the Parties now desire to maintain the Agreement and modify certain rights and obligations under the Agreement by way of this First Amendment.

NOW, THEREFORE, in consideration of the mutual covenants, agreements and stipulations set forth herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise defined in this First Amendment, initially capitalized terms used herein shall have the respective meanings given in the Agreement.

ARTICLE II
AMENDMENT TO THE AGREEMENT

2.1 Section 1.4. Effective as of the First Amendment Date, Section 1.4 of the Agreement is hereby deleted in its entirety and replaced with the following new Section 1.4:

"1.4 "CFDA" shall mean the National Medical Products Administration (f/k/a China Food and Drug Administration), including without limitation the Center for Drug Evaluation, or any successor entity(ies) thereto performing similar functions."

2.2 Section 1.17. Effective as of the First Amendment Date, Section 1.17 of the Agreement is hereby deleted in its entirety and replaced with the following new Section 1.17:

"1.17 "Field" shall mean the diagnosis, treatment and/or prevention of any disease or health condition in humans or animals, including without limitation: (1) pre-dysplastic HPV infections including persistent HPV infections and (2) HPV-driven dysplasias of the genital tract including low grade squamous intraepithelial (LSIL) and high grade squamous intraepithelial (HSIL) of the cervix (previously known as CIN1, CIN2 or CIN3) or vulva, vagina and anus or head and neck; provided that (a) such disease or health condition does not involve any HPV driven cancers and (b) excludes any and all combinations of VGX-3100 with other immunostimulants.

2.4 Section 6.2(a)(2)(b). Effective as of the First Amendment Date, the Section 6.2(a)(2)(b) is hereby added to the Agreement in its entirety as follows:

"(b) first Marketing Approval, by Apollo, its Affiliates or Sublicensees, of the Product in the indication of cervical dysplasia or other indication within the Field by the CFDA

For the sake of clarity, the Parties agree that cervical dysplasia encompasses cervical high grade squamous intraepithelial neoplasia (HSIL) and cervical intraepithelial neoplasia (CIN) grade 1, 2 or 3; but does not include vulvar or anal intraepithelial neoplasias or persistent infection. For clarity, the maximum total amount payable under Section 6.2(a)(1) is $15,000,000."

2.5 Section 6.3(f). Effective as of the First Amendment Date, the Section 6.3(f) is hereby added to the Agreement in its entirety as follows:

"**6.3(f)** For purposes of clarity, Apollo shall pay separate Royalties to Inovio, as set forth in this Section 6.3, on the Net Sales of Product in connection with each indication included within the Field."

ARTICLE III
GENERAL

3.1 No Other Modifications. Except as specifically set forth in this First Amendment, the terms and conditions of the Agreement shall remain in full force and effect.

3.2 Governing Law. This First Amendment and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the laws of the State of New York, without reference to conflicts of laws principles.

3.3 Waiver. This First Amendment does not waive or release any rights or interests of either Party under the Agreement. The failure of a Party to assert a right hereunder or under the Agreement or to insist upon compliance with any term or condition of this First Amendment or the Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by a Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term.

3.4 Miscellaneous. This First Amendment may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. This First Amendment may be executed by the exchange of signature pages in electronic format (including PDF) or digital signatures.

[Intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the Parties have caused this First Amendment to be executed as of the First Amendment Date by their duly authorized representatives.

BEIJING APOLLO SATURN BIOLOGICAL TECHNOLOGY LIMITED

By: /s/ Li Shu, Ph.D.

Name: Li Shu, Ph.D.

Title: CEO

Date: 19 June 2023

INOVIO PHARMACEUTICALS, INC.

By: /s/ Jacqueline Shea

Name: Jacqueline Shea, Ph.D.

Title: President & CEO

Date: 15 June 2023

Exhibit 10.17

INOVIO PHARMACEUTICALS, INC.
SEVERANCE PLAN
AND
SUMMARY PLAN DESCRIPTION

APPROVED BY THE BOARD OF DIRECTORS:

1. Introduction. The purpose of this Inovio Pharmaceuticals, Inc. Severance Plan (the "Plan") is to provide specified severance benefits to eligible executives of the Company (as defined below) whose employment is terminated by the Company or a successor under certain circumstances. This Plan is an "employee welfare benefit plan," as defined in Section 3(1) of ERISA (as defined below). With the exception of certain definitions set forth below, and subject to Section 6, this Plan shall supersede any individual agreement between the Company and any Covered Employee (as defined below) and any other plan, policy or practice, whether written or unwritten, maintained by the Company with respect to a Covered Employee, in each case to the extent that such agreement, plan, policy or practice provides for equity acceleration or severance benefits upon the Covered Employee's separation from the Company. This document constitutes both the written instrument under which the Plan is maintained and the required summary plan description for the Plan.

2. Definitions. For purposes of the Plan, the terms below are defined as follows:

2.1 "Administrator" means the Board or Compensation Committee prior to a Change in Control (as defined below); or, after a Change in Control, one or more members of the successor Board or Compensation Committee or other persons designated by the Company's Board or Compensation Committee prior to such Change in Control.

2.2 "Board" means the Board of Directors of the Company.

2.3 "Cause" means with respect to such Covered Employees that the Company has determined in its sole discretion that the Covered Employee has engaged in any one or more of the following: (i) the Covered Employee's commission of a felony; (ii) any act or omission of the Covered Employee constituting dishonesty, fraud, immoral, or disreputable conduct that causes or could reasonably cause material harm to the Company; (iii) the Covered Employee's violation of Company policy that causes or could reasonably cause material harm to the Company; (iv) the Covered Employee's material breach of any written agreement between the Covered Employee and the Company which, if curable, remains uncured for thirty (30) days after notice; or (v) the Covered Employee's breach of fiduciary duty or other statutory or common law duty owed to the Company.

2.4 "Change in Control" has the meaning ascribed to such term in the Stock Plan.

2.5 "Change in Control Period" means the time period beginning on the date on which a Change in Control becomes effective and ending on the first anniversary of the effective date of such Change in Control (except as otherwise set forth in a Participation Agreement).

2.6 "COBRA" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

2.7 "Code" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

2.8 "Company" means Inovio Pharmaceuticals, Inc. and any successor.

2.9 "Compensation Committee" means the Compensation Committee of the Board.

2.10 "Covered Employee" means an employee of the Company who (i) is the Company's Chief Executive Officer or has been designated by the Administrator to participate in the Plan, (ii) has executed the Company's standard confidentially and inventions assignment agreement, and (iii) has timely and properly executed and delivered a Participation Agreement to the Company.

2.11 "Covered Termination" means a Covered Employee's termination of employment by the Company (or any parent or subsidiary of the Company) without Cause or as a result of a Covered Employee's resignation for Good Reason; provided, that, in either case, such termination is not due to the Covered Employee's death or disability.

2.12 "Disability" means a termination because a Covered Employee is unable due to a physical or mental condition to perform the essential functions of the Covered Employee's position with or without reasonable accommodation for six (6) months in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law.

2.13 "Disability Termination" means a Covered Employee's termination of employment by the Company (or any parent or subsidiary of the Company) due to such Covered Employee's Disability.

2.14 "Effective Date" means the date on which the Plan is approved by the Board.

2.15 "ERISA" means the Employee Retirement Income Security Act of 1974, as amended.

2.16 "Good Reason" means with respect to such Covered Employee, any of the following conditions or actions taken by the Company without Cause and without such Covered Employee's consent: (i) a material breach by the Company of an agreement between a Covered Employee and the Company; (ii) the Company significantly reducing the Covered Employee's base salary or the target percentage eligibility established for the Covered Employee's annual bonus, other than any Company-wide reduction in compensation of employees; (iii) the Company significantly reducing the Covered Employee's duties, authority or responsibilities relative to the Covered Employee's duties, authority or responsibilities in effect immediately prior to such reduction; or (iv) the relocation of the Covered Employee's principal place of employment by fifty (50) or more miles from the Covered Employee's then-current principal place of employment; provided, further, that in each case above, in order for the Covered Employee's resignation to be deemed to have been for Good Reason, the Covered Employee must first give the Company written notice of the action or omission giving rise to "Good Reason" within thirty (30) days after the first occurrence thereof; the Company must fail to reasonably cure such action or omission within thirty (30) days after receipt of such notice (the "Cure Period"); and the Covered Employee's resignation must be effective not later than thirty (30) days after the expiration of such Cure Period.

2.17 "Participation Agreement" means an agreement between a Covered Employee and the Company in substantially the form of **Appendix A** attached hereto, and which may include such other terms as the Administrator deems necessary or advisable in the administration of the Plan.

2.18 "Performance Award" means an equity award that vests only upon satisfaction of performance criteria.

2.19 "Severance Benefits" means the compensation and other benefits the Covered Employee will be provided pursuant to Section 4.

2.20 "Stock Plan" means the Company's 2023 Omnibus Incentive Plan, as amended or amended and restated from time to time, or any successor thereto.

2.21 "Termination Date" means the Covered Employee's last day of employment with the Company.

3. Eligibility for Severance Benefits. An individual is eligible for Severance Benefits under the Plan, in the amounts set forth in Section 4, only if such individual is a Covered Employee on the date

such individual experiences a Covered Termination, or, as applicable and as described more fully in Section 4, a Disability Termination or such Covered Employee's death during their employment.

4. Severance Benefits.

4.1 Covered Termination **Outside** the Change in Control Period. If, at any time outside of the Change in Control Period, a Covered Employee experiences a Covered Termination, then, subject to the Covered Employee's compliance with Section 5 and the conditions set forth in this Plan, the Covered Employee shall receive the following Severance Benefits from the Company (the "Standard Severance Benefits"):

4.1.1 Cash Severance Benefits. The Covered Employee shall receive cash severance in an amount equal to the Covered Employee's base salary (as in effect immediately prior to any reduction giving rise to Good Reason, if applicable) for the applicable number of months set forth in the Covered Employee's Participation Agreement (the "Standard Severance Period"). The cash amount shall be paid, less applicable tax withholdings, in equal installments on the Company's regular payroll schedule, provided, that no payment shall be made prior to the first payroll date following the effective date of the Release (the "Initial Payment Date"). On the Initial Payment Date, the Company shall pay the Covered Employee in a lump sum the cash amount that the Covered Employee would have received on or prior to the Initial Payment Date under the original schedule but for the delay while waiting for the Initial Payment Date in compliance with Section 409A (as defined below) and the effectiveness of the Release (as defined below), with the balance of the cash amount being paid as originally scheduled. Notwithstanding the foregoing, the Company may pay the cash amount in the form of a lump sum, which amount will be paid on the Initial Payment Date, but such lump sum payment shall be made only if the Company, in consultation with its advisors, determines that such payment will not result in adverse taxation under Section 409A.

4.1.2 COBRA Premiums. Provided the Covered Employee is eligible for and timely makes the necessary elections for continuation coverage pursuant to COBRA the Company shall pay the applicable premiums (inclusive of premiums for the Covered Employee's dependents) for such coverage following the date of the Covered Employee's Covered Termination for the Standard Severance Period (such period of months, the "Standard COBRA Payment Period") (but in no event after such time as the Covered Employee is eligible for coverage under a health, dental or vision insurance plan of a subsequent employer or as the Covered Employee and the Covered Employee's dependents are no longer eligible for COBRA coverage). The Covered Employee shall notify the Company immediately if the Covered Employee becomes covered by a health, dental, or vision insurance plan of a subsequent employer or if the Covered Employee's dependents are no longer eligible for COBRA coverage. Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of paying COBRA premiums on the Covered Employee's behalf, the Company will instead pay such Covered Employee on the last day of each remaining month of the Standard COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the "Special Severance Payment"), such Special Severance Payment to be made without regard to the Covered Employee's election of COBRA coverage or payment of COBRA premiums and without regard to such Covered Employee's continued eligibility for COBRA coverage during the Standard COBRA Payment Period. Such Special Severance Payment shall end upon expiration of the Standard COBRA Payment Period.

4.2 Covered Termination During the Change in Control Period. If, at any time during the Change in Control Period, a Covered Employee experiences a Covered Termination, then, subject to the Covered Employee's compliance with Section 5 and the conditions set forth in this Plan, the Covered Employee shall receive the following Severance Benefits from the Company (the "CIC Severance Benefits"):

4.2.1 Cash Severance Benefits. The Covered Employee shall receive cash severance in an amount equal to the Covered Employee's base salary (as in effect immediately prior to any reduction giving rise to Good Reason, if applicable) for the applicable number of months set forth in the Covered Employee's Participation Agreement (the "CIC Severance Period"). The cash amount shall be paid, less applicable tax withholdings, in equal installments on the Company's regular payroll schedule, provided, that no payment shall be made prior to the Initial Payment Date. On the Initial Payment Date, the Company shall pay the Covered Employee in a lump sum the cash amount that the Covered Employee would have received on or prior to the Initial Payment Date under the original schedule but for the delay while waiting for the Initial Payment Date in compliance with Section 409A (as defined below) and the effectiveness of the Release, with the balance of the cash amount being paid as originally scheduled. Notwithstanding the foregoing, the Company may pay the cash amount in the form of a lump sum, which amount will be paid on the Initial Payment Date, but such lump sum payment shall be made only if the Company, in consultation with its advisors, determines that such payment will not result in adverse taxation under Section 409A.

4.2.2 Target Annual Bonus Entitlement. The Covered Employee will additionally be eligible to receive a multiple of such Covered Employee's target annual bonus, as established by the Board for the year in which the Covered Termination occurs and set forth on the Covered Employee's Participation Agreement. Such payment shall be paid, less applicable tax withholdings, in equal installments on the Company's regular payroll schedule, provided, that no payment shall be made prior to the Initial Payment Date. On the Initial Payment Date, the Company shall pay the Covered Employee in a lump sum the cash amount that the Covered Employee would have received on or prior to the Initial Payment Date under the original schedule but for the delay while waiting for Initial Payment Date in compliance with Section 409A (as defined below) and the effectiveness of the Release, with the balance of the cash amount being paid as originally scheduled. Notwithstanding the foregoing, the Company may pay the cash amount in the form of a lump sum, which amount will be paid on the Initial Payment Date, but such lump sum payment shall be made only if the Company, in consultation with its advisors, determines that such payment will not result in adverse taxation under Section 409A.

4.2.3 COBRA Premiums. Provided the Covered Employee is eligible for and timely makes the necessary elections for continuation coverage pursuant to COBRA, the Company shall pay the applicable premiums (inclusive of premiums for the Covered Employee's dependents) for such coverage following the date of the Covered Employee's Covered Termination for up to the CIC Severance Period (such period of months, the "CIC COBRA Payment Period") (but in no event after such time as the Covered Employee is eligible for coverage under a health, dental or vision insurance plan of a subsequent employer or as the Covered Employee and the Covered Employee's dependents are no longer eligible for COBRA coverage). The Covered Employee shall notify the Company immediately if the Covered Employee becomes covered by a health, dental, or vision insurance plan of a subsequent employer or if the Covered Employee's dependents are no longer eligible for COBRA coverage. Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of paying COBRA premiums on the Covered Employee's behalf, the Company will instead pay such Covered Employee on the last day of each remaining month of the CIC COBRA Payment Period a Special Severance Payment to be made without regard to the Covered Employee's election of COBRA coverage or payment of COBRA premiums and without regard to such Covered Employee's continued eligibility for COBRA coverage during the CIC COBRA Payment Period. Such Special Severance Payment shall end upon expiration of the CIC COBRA Payment Period.

4.2.4 Equity Vesting. Each of the Covered Employee's then-outstanding equity awards subject to time-based vesting shall accelerate and become vested and exercisable as to the percentage of the unvested shares subject to the equity award set forth in the Covered Employee's Participation Agreement (the "Equity Acceleration Percentage"), except any award granted after the Effective Date that explicitly overrides this provision in writing.

Subject to Section 5, the accelerated vesting described in this section shall be effective as of the Termination Date. Notwithstanding anything herein to the contrary, nothing in the Plan shall limit the Company's ability to accelerate vesting and/or exercisability of outstanding equity awards pursuant to the terms of the applicable equity incentive plan of the Company. In order to give effect to the intent of the foregoing provision, notwithstanding anything to the contrary set forth in the applicable equity incentive plan of the Company or the applicable equity award agreements that provide that any then-unvested portion of the Covered Employee's award will immediately expire upon such Covered Employee's termination of service, such Covered Employee's equity awards shall remain outstanding following such Covered Employee's Covered Termination to give effect to such acceleration as necessary.

4.3 Disability Termination. If, at any time a Covered Employee experiences a Disability Termination, then, subject to the Covered Employee's compliance with Section 5 and the conditions set forth in this Plan, the Covered Employee shall receive the following Disability Severance Benefits from the Company (the "Disability Severance Benefits"):

4.3.1 Cash Severance Benefits. The Covered Employee shall receive cash severance in an amount equal to the Covered Employee's base salary (as in effect immediately prior to any reduction giving rise to Good Reason, if applicable) for the applicable number of months set forth in the Covered Employee's Participation Agreement (the "Disability Severance Period"). The cash amount shall be paid, less applicable tax withholdings, in equal installments on the Company's regular payroll schedule, provided, that no payment shall be made prior to the Initial Payment Date. On the Initial Payment Date, the Company shall pay the Covered Employee in a lump sum the cash amount that the Covered Employee would have received on or prior to the Initial Payment Date under the original schedule but for the delay while waiting for the Initial Payment Date in compliance with Section 409A (as defined below) and the effectiveness of the Release, with the balance of the cash amount being paid as originally scheduled. Notwithstanding the foregoing, the Company may pay the cash amount in the form of a lump sum, which amount will be paid on the Initial Payment Date, but such lump sum payment shall be made only if the Company, in consultation with its advisors, determines that such payment will not result in adverse taxation under Section 409A.

4.3.2 COBRA Premiums. Provided the Covered Employee is eligible for and timely makes the necessary elections for continuation coverage pursuant to COBRA, the Company shall pay the applicable premiums (inclusive of premiums for the Covered Employee's dependents) for such coverage following the date of the Covered Employee's Disability Termination for up to the Disability Severance Period (such period of months, the "Disability COBRA Payment Period") (but in no event after such time as the Covered Employee is eligible for coverage under a health, dental or vision insurance plan of a subsequent employer or as the Covered Employee and the Covered Employee's dependents are no longer eligible for COBRA coverage). The Covered Employee shall notify the Company immediately if the Covered Employee becomes covered by a health, dental, or vision insurance plan of a subsequent employer or if the Covered Employee's dependents are no longer eligible for COBRA coverage. Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of paying COBRA premiums on the Covered Employee's behalf, the Company will instead pay such Covered Employee on the last day of each remaining month of the Disability COBRA Payment Period a Special Severance Payment to be made without regard to the Covered Employee's election of COBRA coverage or payment of COBRA premiums and without regard to such Covered Employee's continued eligibility for COBRA coverage during the Disability COBRA Payment Period. Such Special Severance Payment shall end upon expiration of the CIC COBRA Payment Period.

4.3.3 Equity Vesting. Each of the Covered Employee's then-outstanding equity awards, other than Performance Awards, shall continue to vest on the original vesting dates notwithstanding such Disability Termination, except any award granted after the Effective Date that explicitly overrides this provision in writing. In addition, Performance Awards held by the Covered Employee shall remain outstanding and eligible to vest based on the Company's actual performance through the end of the applicable performance period.

4.4 Termination due to Death. If, at any time a Covered Employee experiences a termination due to such Covered Employee's death, then, the Covered Employee's estate shall receive the following Death Severance Benefits from the Company (the "Death Severance Benefits"):

4.4.1 Equity Vesting. Each of the Covered Employee's then-outstanding equity awards, other than Performance Awards, shall accelerate and become vested based on the Equity Acceleration Percentage, except any award granted after the Effective Date that explicitly overrides this provision in writing. In addition, Performance Awards held by the Covered Employee shall remain outstanding and eligible to vest based on the Company's actual performance through the end of the applicable performance period.

5. Conditions to Receipt of Severance.

5.1 Release Agreement. As a condition to receiving any Severance Benefits described in Section 4 herein, a Covered Employee (or the representative for such Covered Employee's estate, as applicable) must sign a separation agreement containing among other provisions, a release of all claims in favor of the Company and its subsidiaries and affiliates (the "Release") in such form as may be provided by the Company.

The Release must become effective in accordance with its terms, which must occur in no event more than sixty (60) days following the date of the applicable Covered Termination, Disability Termination or termination due to such Covered Employee's death. In no event shall payment of any benefits under the Plan be made prior to a Covered Employee's Termination Date or prior to the effective date of the Release. If the Company determines that any payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, and the Covered Employee's Termination Date occurs at a time during the calendar year when the Release could become effective in the calendar year following the calendar year in which the Covered Employee's "separation from service" within the meaning of Section 409A of the Code and the final regulations and any guidance promulgated thereunder ("Section 409A") occurs, then regardless of when the Release is returned to the Company and becomes effective, the Release will not be deemed effective any earlier than the latest permitted effective date; provided, that except to the extent that payments may be delayed in accordance with Section , on the first regular payroll date following the effective date of a Covered Employee's Release, the Company shall (i) pay the Covered Employee a lump sum amount equal to the sum of the appliable Severance Benefits that the Covered Employee would otherwise have received through such payroll date but for the delay in payment related to the effectiveness of the Release and (ii) commence paying the balance, if any, of the Severance Benefits in accordance with the applicable payment schedule.

5.2 Other Requirements. A Covered Employee's receipt of Severance Benefits pursuant to Section 4 will be subject to such Covered Employee's continued material compliance with the terms of the Release, the Participation Agreement, the non-disparagement provisions of a separation agreement provided by the Company, and any confidential information agreement, proprietary information and inventions agreement and any other agreement between the Covered Employee and the Company. Severance Benefits under this Plan shall terminate immediately for a Covered Employee if such Covered Employee is in material violation, at any time, of any legal or contractual obligation owed to the Company.

5.3 Section 280G. Any provision of the Plan to the contrary notwithstanding, if any payment or benefit a Covered Employee would receive from the Company and its subsidiaries or an acquiror pursuant to the Plan or otherwise (a "Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment will be equal to the Higher Amount. The "Higher Amount" will be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Covered Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" within the meaning of Section 280G of the Code is necessary so that the Payment equals the Higher Amount, reduction will occur in the manner that results in the greatest economic benefit for a Covered Employee and, to the extent applicable, complies with Section 409A. In no event will the Company, any subsidiary or any stockholder be liable to any Covered Employee for any amounts not paid as a result of the operation of this Section 5.3. The Company will use commercially reasonable efforts to cause the accounting or law firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to a Covered Employee and the Company within fifteen (15) calendar days after the date on which such Covered Employee's right to a Payment is triggered (if requested at that time by such Covered Employee or the Company) or such other time as requested by such Covered Employee or the Company.

6. Non-Duplication of Benefits. The Severance Benefits provided to a Covered Employee are intended to be and are exclusive and in lieu of any other change in control severance benefits or payments to which such Covered Employee may otherwise be eligible, either at law, tort, or contract, in equity, or under the Plan, in the event of any termination of such Covered Employee's employment. The Covered Employee will be eligible to no change in control severance benefits or payments upon a termination of employment that constitutes a Covered Termination other than those benefits expressly set forth herein and those benefits required to be provided by applicable law or as negotiated in accordance with applicable law (including any severance benefits that may be included in a severance agreement, employment agreement or similar contract between the Company or a subsidiary of the Company and the Covered Employee). Notwithstanding the foregoing, if a Covered Employee is eligible to any benefits other than the benefits under the Plan by operation of applicable law or as negotiated in accordance with applicable law, such Covered Employee's benefits under the Plan shall be provided only to the extent

more favorable than such other arrangement. The Administrator, in its sole discretion, shall have the authority to reduce or otherwise adjust a Covered Employee's benefits under the Plan, in whole or in part, by any other severance benefits, pay and benefits in lieu of notice, or other similar benefits payable to such Covered Employee under the Plan that become payable in connection with the Covered Employee's termination of employment pursuant to (i) any applicable legal requirement, including the Worker Adjustment and Retraining Notification Act (the "WARN Act"), or any other similar state law, or (ii) any policy or practice of the Company providing for the Covered Employee to remain on payroll for a limited period of time after being given notice of termination. The benefits provided under the Plan are intended to satisfy, in whole or in part, any and all statutory obligations of the Company that may arise out of a Covered Employee's termination of employment, and the Administrator shall so construe and implement the terms of the Plan. Notwithstanding anything in this Section 6 to the contrary, to the extent a Covered Employee is a party to a written agreement with the Company, including but not limited to any outstanding equity awards, and such written agreement explicitly provides severance benefits specific to equity acceleration in the event the Company undergoes a Change in Control and/or the Covered Employee is terminated in a Covered Termination, a Disability Termination or due to death, then the terms of such written agreement shall control with respect to such equity acceleration terms that are more favorable to the Covered Employee than those of this Plan (as determined by the Company in its sole discretion).

7. Clawback; Recovery. All payments and Severance Benefits provided under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Administrator may impose such other clawback, recovery or recoupment provisions as the Administrator determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of common stock of the Company or other cash or property upon the occurrence of a termination of employment for Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for Good Reason, constructive termination, or any similar term under any plan of or agreement with the Company.

8. Section 409A. Notwithstanding anything to the contrary in the Plan, no severance payments or benefits will become payable until the Covered Employee has a "separation from service" within the meaning of Section 409A. Further, if some or all of the Covered Employee's Severance Benefits are subject to Section 409A and such Covered Employee is a "specified employee" within the meaning of Section 409A at the time of such Covered Employee's separation from service (other than due to death), then such Severance Benefits otherwise due to such Covered Employee on or within the six-month period following such Covered Employee's separation from service will accrue during such six-month period and will become payable in a lump sum payment (less applicable withholding taxes) on the date six months and one day following the date of the Covered Employee's separation from service if necessary to avoid adverse taxation under Section 409A. All subsequent payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if the Covered Employee dies following such Covered Employee's separation from service but prior to the six-month anniversary of such Covered Employee's date of separation, then any payments delayed in accordance with this paragraph will be payable in a lump sum (less applicable withholding taxes) to the Covered Employee's estate as soon as administratively practicable after the date of such Covered Employee's death and all other benefits will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under the Plan is intended to constitute a separate payment for purposes of Section 409A. It is the intent of this Plan to comply with or be exempt from the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under the Plan comply with Section 409A, and in no event shall the Company or any of its representatives be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Covered Employee on account of non-compliance with Section 409A.

9. Withholding. The Company will withhold from any Severance Benefits all federal, state, local and other taxes required to be withheld therefrom and any other required payroll deductions.

10. Administration. The Plan will be administered and interpreted by the Administrator (in the Administrator's sole discretion). The Administrator is the "named fiduciary" of the Plan for purposes of ERISA and will be subject to the fiduciary standards of ERISA when acting in such capacity. Any decision made or other action taken by the Administrator with respect to the Plan, and any interpretation by the Administrator of any term or condition of the Plan, or any related document, will be conclusive and binding on all persons and be given the maximum possible deference allowed by law. Any decision made or other action taken by the Administrator with respect to the Plan, and any interpretation by the Administrator of any term or condition of the Plan, or any related document that (i) does not affect the benefits payable under the Plan shall not be subject to review unless found to be arbitrary and capricious or (ii) does affect the benefits payable under the Plan shall not be subject to review unless found to be unreasonable or not to have been made in good faith.

11. Amendment or Termination. The Company, by action of the Administrator, reserves the right to amend or terminate the Plan at any time, without advance notice to any Covered Employee and without regard to the effect of the amendment or termination on any Covered Employee or on any other individual. Any amendment or termination of the Plan will be in writing. Notwithstanding the foregoing, a Covered Employee's rights to receive payments and benefits pursuant to this Plan under an effective Participation Agreement may not be adversely affected, without the Covered Employee's written consent, by an amendment or termination of this Plan.

12. Claims Procedure. Claims for benefits under the Plan shall be administered in accordance with Section 503 of ERISA and the Department of Labor Regulations thereunder. Any employee or other person who believes they are entitled to any payment under the Plan (a "claimant") may submit a claim in writing to the Administrator within ninety (90) days of the earlier of (i) the date the claimant learned the amount of such claimant's Severance Benefits under the Plan or (ii) the date the claimant learned that they will not be eligible to any benefits under the Plan. In determining claims for benefits, the Administrator or its delegate has the authority to interpret the Plan, to resolve ambiguities, to make factual determinations, and to resolve questions relating to eligibility for and amount of benefits. If the claim is denied (in full or in part), the claimant will be provided a written notice explaining the specific reasons for the denial and referring to the provisions of the Plan on which the denial is based. The notice will also describe any additional information or material that the Administrator needs to complete the review and an explanation of why such information or material is necessary and the Plan's procedures for appealing the denial (including a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA following a denial on review of the claim, as described below). The denial notice will be provided within ninety (90) days after the claim is received. If special circumstances require an extension of time (up to 90 days), written notice of the extension will be given to the claimant (or representative) within the initial 90-day period. This notice of extension will indicate the special circumstances requiring the extension of time and the date by which the Administrator expects to render its decision on the claim. If the extension is provided due to a claimant's failure to provide sufficient information, the time frame for rendering the decision will be tolled from the date the notification is sent to the claimant about the failure to the date on which the claimant responds to the request for additional information. The Administrator has delegated the claims review responsibility to the Company's Chief Financial Officer or such other individual designated by the Administrator, except in the case of a claim filed by or on behalf of the Company's Chief Financial Officer or such other individual designated by the Administrator, in which case, the claim will be reviewed by the Company's Chief Executive Officer.

13. Appeal Procedure. If the claimant's claim is denied, the claimant (or such claimant's authorized representative) may apply in writing to an appeals official appointed by the Administrator (which may be a person, committee or other entity) for a review of the decision denying the claim. Review must be requested within sixty (60) days following the date the claimant received the written notice of a claim denial or else the claimant will lose the right to such review. A request for review must set forth all the grounds on which such request is based, all facts in support of the request, and any other matters that the claimant feels are pertinent. In connection with the request for review, the claimant (or representative) has the right to review and obtain copies of all documents and other information relevant to the claim, upon request and at no charge, and to submit written comments, documents, records and

other information relating to such claimant's claim. The review shall take into account all comments, documents, records and other information submitted by the claimant (or representative) relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination. The appeals official will provide written notice of its decision on review within 60 days after it receives a review request. If special circumstances require an extension of time (up to 60 days), written notice of the extension will be given to the claimant (or representative) within the initial 60-day period. This notice of extension will indicate the special circumstances requiring the extension of time and the date by which the appeals official expects to render its decision. If the extension is provided due to a claimant's failure to provide sufficient information, the time frame for rendering the decision on review is tolled from the date the notification is sent to the claimant about the failure to the date on which the claimant responds to the request for additional information. If the claim is denied (in full or in part) upon review, the claimant will be provided a written notice explaining the specific reasons for the denial and referring to the provisions of the Plan on which the denial is based. The notice shall also include a statement that the claimant will be provided, upon request and free of charge, reasonable access to, and copies of, all documents and other information relevant to the claim and a statement regarding the claimant's right to bring an action under Section 502(a) of ERISA. The Administrator has delegated the appeals review responsibility to the Company's Chief Financial Officer, except in the case of an appeal filed by or on behalf of the Company's Chief Financial Officer, in which case, the appeal will be reviewed by the Company's Chief Executive Officer.

14. Arbitration. No arbitration proceeding shall be brought to recover benefits under the Plan until the claims procedures described in Sections 12 and 13 have been exhausted and the Plan benefits requested have been denied in whole or in part. Notwithstanding any other provision of the Plan, to ensure the timely and economical resolution of disputes, all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance or interpretation of this Plan will be resolved to the fullest extent permitted by law by final, binding and confidential arbitration, by a single arbitrator, in Philadelphia, Pennsylvania conducted by JAMS, Inc. ("JAMS") under the then-applicable JAMS rules (currently available at the following web address: https://www.jamsadr.com/rules-employment). By agreeing to this arbitration procedure, each Covered Employee and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. Covered Employees will have the right to be represented by legal counsel at any arbitration proceeding. In addition, all claims, disputes, or causes of action under this Section, whether by a Covered Employee or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law or any claims alleging sexual harassment or a nonconsensual sexual action or sexual contact, to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "Excluded Claims"). The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. The arbitrator shall be authorized to award any or all remedies that a Covered Employee or the Company would be eligible to seek in a court of law. The Company shall pay all JAMS' arbitration fees in excess of the amount of court fees that would be required of a Covered Employee if the dispute were decided in a court of law. Nothing in this paragraph is intended to prevent either a Covered Employee or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction. Any arbitration must be commenced within one year after the Covered Employee's receipt of notification that their appeal was denied. The foregoing provisions shall apply to the extent consistent with and permitted by ERISA.

15. Source of Payments. All Severance Benefits will be paid in cash from the general funds of the Company; no separate fund will be established under the Plan; and the Plan will have no assets. No

right of any person to receive any payment under the Plan will be any greater than the right of any other general unsecured creditor of the Company.

16. Inalienability. In no event may any current or former employee of the Company or any of its subsidiaries or affiliates sell, transfer, anticipate, assign or otherwise dispose of any right or interest under the Plan. At no time will any such right or interest be subject to the claims of creditors nor liable to attachment, execution or other legal process.

17. No Enlargement of Employment Rights. Neither the establishment nor maintenance of the Plan, any amendment of the Plan, nor the making of any benefit payment hereunder, will be construed to confer upon any individual any right to be continued as an employee of the Company. The Company expressly reserves the right to discharge any of its employees at any time, with or without Cause. However, as described in the Plan, a Covered Employee may be eligible to benefits under the Plan depending upon the circumstances of such Covered Employee's termination of employment.

18. Successors. Any successor to the Company of all or substantially all of the Company's business or assets (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) will assume the obligations under the Plan and agree expressly to perform the obligations under the Plan in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under the Plan, the term "Company" will include any successor to the Company's business or assets which become bound by the terms of the Plan by operation of law, or otherwise.

19. Applicable Law. The provisions of the Plan will be construed, administered and enforced in accordance with ERISA and, to the extent applicable, the internal substantive laws of the State of Connecticut (except its conflict of laws provisions).

20. Severability. If any provision of the Plan is held invalid or unenforceable, its invalidity or unenforceability will not affect any other provision of the Plan, and the Plan will be construed and enforced as if such provision had not been included.

21. Headings. Headings in this Plan document are for purposes of reference only and will not limit or otherwise affect the meaning hereof.

22. Additional Information.

Plan Name:	Inovio Pharmaceuticals, Inc. Severance Plan
Plan Sponsor:	Inovio Pharmaceuticals, Inc.
Plan Year:	Fiscal year ending December 31
Plan Administrator:	Inovio Pharmaceuticals, Inc. Attention: Administrator of the Inovio Pharmaceuticals, Inc. Severance Plan
Agent for Service of Legal Process:	Inovio Pharmaceuticals, Inc. Attention: Administrator of the Inovio Pharmaceuticals, Inc. Severance Plan Service of process may also be made upon the Administrator.
Type of Plan:	Severance Plan/Employee Welfare Benefit Plan
Plan Costs:	The cost of the Plan is paid by the Company.

23. Statement of ERISA Rights.

As a Covered Employee under the Plan, you have certain rights and protections under ERISA:

(a) You may examine (without charge) all Plan documents, including any amendments and copies of all documents filed with the U.S. Department of Labor. These documents are available for your review in the office of the Company's Chief Financial Officer.

(b) You may obtain copies of all Plan documents and other Plan information upon written request to the Administrator. A reasonable charge may be made for such copies.

In addition to creating rights for Covered Employees, ERISA imposes duties upon the people who are responsible for the operation of the Plan. The people who operate the Plan (called "fiduciaries") have a duty to do so prudently and in the interests of you and the other Covered Employees. No one, including the Company or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a benefit under the Plan or exercising your rights under ERISA. If your claim for a severance benefit is denied, in whole or in part, you have a right to know why it was denied, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules. The claim review procedure is explained in Sections 12 and 13, above.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of Plan documents and do not receive them within thirty (30) days, you may file suit in a federal court. In such a case, the court may require the Administrator to provide the materials and to pay you up to $110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Administrator. If you have a claim which is denied or ignored, in whole or in part, you may file suit in a federal court. If it should happen that you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a federal court. The court will decide who should pay court costs and legal fees. If you are successful, the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example, if it finds your claim is frivolous.

If you have any questions regarding the Plan, please contact the Administrator. If you have any questions about this statement or about your rights under ERISA, you may contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor (listed in your telephone directory) or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration at 1-866-444-3272.

Appendix A

INOVIO PHARMACEUTICALS, INC.
SEVERANCE PLAN

Participation Agreement

Inovio Pharmaceuticals, Inc. (the "Company") is pleased to inform you, [], that you have been selected to participate in the Company's Severance Plan (the "Plan") as a Covered Employee. A copy of the Plan was delivered to you with this Participation Agreement. Your participation in the Plan is subject to all of the terms and conditions of the Plan. The capitalized terms used but not defined herein will have the meanings ascribed to them in the Plan.

In order to become a Covered Employee under the Plan, you must complete and sign this Participation Agreement and return it to [] no later than [].

The Plan describes in detail certain circumstances under which you may become eligible for Severance Benefits and the amount of those benefits. As described more fully in the Plan, you may become eligible for certain Severance Benefits if you experience a Covered Termination.

If you become eligible for Standard Severance Benefits under Section 4.1 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	[ ] months
[Equity Acceleration Percentage	100%]
COBRA Premiums	[ ] months

If you become eligible for CIC Severance Benefits under Section 4.2 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	[ ] months
Target Annual Bonus Entitlement	[ ]x
Equity Acceleration Percentage	100%
COBRA Premiums	[ ] months

If you become eligible for Disability Severance Benefits under Section 4.3 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	[ ] months
Continued Equity Vesting	
COBRA Premiums	[ ] months

In order to receive any Severance Benefits for which you otherwise become eligible under the Plan, you must sign and deliver to the Company the Release, which must have become effective and irrevocable, and otherwise comply with the requirements under Section 5 of the Plan.

In accordance with Section 6 of the Plan, the benefits, if any, provided under the Plan are intended to be the exclusive benefits for you related to your termination of employment in connection with a change in control of the Company and will supersede and replace, except as provided for in Section 6 of the Plan, any change in control severance benefits to which you otherwise would be eligible to participate in any other Company change in control severance policy, plan, agreement or other arrangement (whether or not subject to ERISA).

By your signature below, you and the Company agree that your participation in the Plan is governed by this Participation Agreement and the provisions of the Plan. Your signature below confirms that: (i) you have received a copy of the Plan; (ii) you have carefully read this Participation Agreement and the Plan and you acknowledge and agree to its terms, including, but not limited to, Section 6 of the Plan; (iii) you agree that this Participation Agreement and the provisions of the Plan supersede any individual agreement between you and the Company and any other plan, policy or practice, whether written or unwritten, maintained by the Company with respect to equity acceleration or severance benefits upon your separation from the Company; and (iv) decisions and determinations by the Administrator under the Plan will be final and binding on you and your successors.

INOVIO PHARMACEUTICALS, INC.	**COVERED EMPLOYEE**
__ Signature	__ Signature
Name:__	Name:__
Title:__	Title:__
Date:__	Date:__

Attachment: Inovio Pharmaceuticals, Inc. Severance Plan

Exhibit 10.18

Appendix A

INOVIO PHARMACEUTICALS, INC.
SEVERANCE PLAN

Participation Agreement

Inovio Pharmaceuticals, Inc. (the "Company") is pleased to inform you, Jacqueline E. Shea, that you have been selected to participate in the Company's Severance Plan (the "Plan") as a Covered Employee. A copy of the Plan was delivered to you with this Participation Agreement. Your participation in the Plan is subject to all of the terms and conditions of the Plan and will be effective upon approval of the Plan by the Compensation Committee of the Company's Board of Directors (the "Compensation Committee"). The capitalized terms used but not defined herein will have the meanings ascribed to them in the Plan.

In order to become a Covered Employee under the Plan, you must complete and sign this Participation Agreement and return it to Robert Crotty, General Counsel and Chief Compliance Officer, within fourteen (14) days of receipt.

The Plan describes in detail certain circumstances under which you may become eligible for Severance Benefits and the amount of those benefits. As described more fully in the Plan, you may become eligible for certain Severance Benefits if you experience a Covered Termination.

If you become eligible for Standard Severance Benefits under Section 4.1 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	18 months
COBRA Premiums	18 months

If you become eligible for CIC Severance Benefits under Section 4.2 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	24 months
Target Annual Bonus Entitlement	2x
Equity Acceleration Percentage	100%
COBRA Premiums	24 months

If you become eligible for Disability Severance Benefits under Section 4.3 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	18 months
Continued Equity Vesting	
COBRA Premiums	18 months

In order to receive any Severance Benefits for which you otherwise become eligible under the Plan, you must sign and deliver to the Company the Release, which must have become effective and irrevocable, and otherwise comply with the requirements under Section 5 of the Plan.

In accordance with Section 6 of the Plan, the benefits, if any, provided under the Plan are intended to be the exclusive benefits for you related to your termination of employment in connection with a change in control of the Company and will supersede and replace, except as provided for in Section 6 of the Plan, any change in control severance benefits to which you otherwise would be eligible to participate in any other Company change in control severance policy, plan, agreement or other arrangement (whether or not subject to ERISA).

By your signature below, you and the Company agree that your participation in the Plan is governed by this Participation Agreement and the provisions of the Plan. Your signature below confirms that: (i) you have received a copy of the Plan; (ii) you have carefully read this Participation Agreement and the Plan and you acknowledge and agree to its terms, including, but not limited to, Section 6 of the Plan; (iii) you agree that this Participation Agreement and the provisions of the Plan supersede any individual agreement between you and the Company and any other plan, policy or practice, whether written or unwritten, maintained by the Company with respect to equity acceleration or severance benefits upon your separation from the Company; and (iv) decisions and determinations by the Administrator under the Plan will be final and binding on you and your successors.

INOVIO PHARMACEUTICALS, INC.	**COVERED EMPLOYEE**
/s/ Robert Crotty Signature	/s/ Jacqueline E. Shea Signature
Name: Robert Crotty	Name: Jacqueline E. Shea, Ph.D.
Title: General Counsel and Chief Compliance Officer	Title: President & Chief Executive Officer
Date: March 5, 2024	Date: March 5, 2024

Attachment: Inovio Pharmaceuticals, Inc. Severance Plan

Exhibit 10.19

Appendix A

INOVIO PHARMACEUTICALS, INC.
SEVERANCE PLAN

Participation Agreement

Inovio Pharmaceuticals, Inc. (the "Company") is pleased to inform you, Laurent M. Humeau, that you have been selected to participate in the Company's Severance Plan (the "Plan") as a Covered Employee. A copy of the Plan was delivered to you with this Participation Agreement. Your participation in the Plan is subject to all of the terms and conditions of the Plan and will be effective upon approval of the Plan by the Compensation Committee of the Company's Board of Directors (the "Compensation Committee"). The capitalized terms used but not defined herein will have the meanings ascribed to them in the Plan.

In order to become a Covered Employee under the Plan, you must complete and sign this Participation Agreement and return it to Robert Crotty, General Counsel and Chief Compliance Officer, within fourteen (14) days of receipt.

The Plan describes in detail certain circumstances under which you may become eligible for Severance Benefits and the amount of those benefits. As described more fully in the Plan, you may become eligible for certain Severance Benefits if you experience a Covered Termination.

If you become eligible for Standard Severance Benefits under Section 4.1 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	12 months
COBRA Premiums	12 months

If you become eligible for CIC Severance Benefits under Section 4.2 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	18 months
Target Annual Bonus Entitlement	1.5x
Equity Acceleration Percentage	100%
COBRA Premiums	18 months

If you become eligible for Disability Severance Benefits under Section 4.3 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	12 months
Continued Equity Vesting	
COBRA Premiums	12 months

In order to receive any Severance Benefits for which you otherwise become eligible under the Plan, you must sign and deliver to the Company the Release, which must have become effective and irrevocable, and otherwise comply with the requirements under Section 5 of the Plan.

In accordance with Section 6 of the Plan, the benefits, if any, provided under the Plan are intended to be the exclusive benefits for you related to your termination of employment in connection with a change in control of the Company and will supersede and replace, except as provided for in Section 6 of the Plan, any change in control severance benefits to which you otherwise would be eligible to participate in any other Company change in control severance policy, plan, agreement or other arrangement (whether or not subject to ERISA).

By your signature below, you and the Company agree that your participation in the Plan is governed by this Participation Agreement and the provisions of the Plan. Your signature below confirms that: (i) you have received a copy of the Plan; (ii) you have carefully read this Participation Agreement and the Plan and you acknowledge and agree to its terms, including, but not limited to, Section 6 of the Plan; (iii) you agree that this Participation Agreement and the provisions of the Plan supersede any individual agreement between you and the Company and any other plan, policy or practice, whether written or unwritten, maintained by the Company with respect to equity acceleration or severance benefits upon your separation from the Company; and (iv) decisions and determinations by the Administrator under the Plan will be final and binding on you and your successors.

INOVIO PHARMACEUTICALS, INC.	**COVERED EMPLOYEE**
/s/ Robert Crotty Signature	/s/ Laurent M. Humeau Signature
Name: Robert Crotty	Name: Laurent M. Humeau, Ph.D.
Title: General Counsel and Chief Compliance Officer	Title: Chief Scientific Officer
Date: March 5, 2024	Date: March 5, 2024

Attachment: Inovio Pharmaceuticals, Inc. Severance Plan

Exhibit 10.20

Appendix A

INOVIO PHARMACEUTICALS, INC.
SEVERANCE PLAN

Participation Agreement

Inovio Pharmaceuticals, Inc. (the "Company") is pleased to inform you, Michael Sumner, that you have been selected to participate in the Company's Severance Plan (the "Plan") as a Covered Employee. A copy of the Plan was delivered to you with this Participation Agreement. Your participation in the Plan is subject to all of the terms and conditions of the Plan and will be effective upon approval of the Plan by the Compensation Committee of the Company's Board of Directors (the "Compensation Committee"). The capitalized terms used but not defined herein will have the meanings ascribed to them in the Plan.

In order to become a Covered Employee under the Plan, you must complete and sign this Participation Agreement and return it to Robert Crotty, General Counsel and Chief Compliance Officer, within fourteen (14) days of receipt.

The Plan describes in detail certain circumstances under which you may become eligible for Severance Benefits and the amount of those benefits. As described more fully in the Plan, you may become eligible for certain Severance Benefits if you experience a Covered Termination.

If you become eligible for Standard Severance Benefits under Section 4.1 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	12 months
COBRA Premiums	12 months

If you become eligible for CIC Severance Benefits under Section 4.2 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	18 months
Target Annual Bonus Entitlement	1.5x
Equity Acceleration Percentage	100%
COBRA Premiums	18 months

If you become eligible for Disability Severance Benefits under Section 4.3 of the Plan, then subject to the terms and conditions of the Plan, you will receive:

Cash Severance Benefits	12 months
Continued Equity Vesting	
COBRA Premiums	12 months

In order to receive any Severance Benefits for which you otherwise become eligible under the Plan, you must sign and deliver to the Company the Release, which must have become effective and irrevocable, and otherwise comply with the requirements under Section 5 of the Plan.

In accordance with Section 6 of the Plan, the benefits, if any, provided under the Plan are intended to be the exclusive benefits for you related to your termination of employment in connection with a change in control of the Company and will supersede and replace, except as provided for in Section 6 of the Plan, any change in control severance benefits to which you otherwise would be eligible to participate in any other Company change in control severance policy, plan, agreement or other arrangement (whether or not subject to ERISA).

By your signature below, you and the Company agree that your participation in the Plan is governed by this Participation Agreement and the provisions of the Plan. Your signature below confirms that: (i) you have received a copy of the Plan; (ii) you have carefully read this Participation Agreement and the Plan and you acknowledge and agree to its terms, including, but not limited to, Section 6 of the Plan; (iii) you agree that this Participation Agreement and the provisions of the Plan supersede any individual agreement between you and the Company and any other plan, policy or practice, whether written or unwritten, maintained by the Company with respect to equity acceleration or severance benefits upon your separation from the Company; and (iv) decisions and determinations by the Administrator under the Plan will be final and binding on you and your successors.

INOVIO PHARMACEUTICALS, INC.	**COVERED EMPLOYEE**
/s/ Robert Crotty Signature	/s/ Michael Sumner Signature
Name: Robert Crotty	Name: Michael Sumner, M.D
Title: General Counsel and Chief Compliance Officer	Title: Chief Medical Officer
Date: March 5, 2024	Date: March 5, 2024

Attachment: Inovio Pharmaceuticals, Inc. Severance Plan

Exhibit 21.1

INOVIO PHARMACEUTICALS, INC.
Subsidiaries

Subsidiary Name(1)	Jurisdiction of Organization
Inovio Asia, LLC	South Korea

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-3 No. 333-275445) of Inovio Pharmaceuticals, Inc.,
2. Registration Statement (Form S-8 Nos. 333-142938, 333-150769, 333-161559, 333-166906, 333-174353, 333-181532, 333-192318, 333-196325, 333-209155, and 333-216061) pertaining to the 2007 Omnibus Incentive Plan, as amended, of Inovio Pharmaceuticals, Inc.,
3. Registration Statement (Form S-8 Nos. 333-216059, 333-223776, 333-230337, 333-231872, 333-236201, 333-253736, 333-263167 and 333-272047) pertaining to the 2016 Omnibus Incentive Plan, as amended, of Inovio Pharmaceuticals, Inc.,
4. Registration Statement (Form S-8 No. 333-265944) pertaining to the Inovio Pharmaceuticals, Inc. 2022 Inducement Plan, and
5. Registration Statement (Form S-8 No. 333-272045) pertaining to the Inovio Pharmaceuticals, Inc. 2023 Omnibus Incentive Plan.

of our report dated March 6, 2024, with respect to the consolidated financial statements of Inovio Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Inovio Pharmaceuticals, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

San Diego, California
March 6, 2024

Exhibit 31.1

Certification of CEO Pursuant to
Securities Exchange Act Rules 13a-15(e) and 15d-15(e)
as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Jacqueline E. Shea, certify that:

1. I have reviewed this annual report on Form 10-K of Inovio Pharmaceuticals, Inc.

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

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

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

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

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

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

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

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

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

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

Date: March 6, 2024

/s/ JACQUELINE E. SHEA

Jacqueline E. Shea
President, Chief Executive Officer and Director

Exhibit 31.2

Certification of CFO Pursuant to
Securities Exchange Act Rules 13a-15(e) and 15d-15(e)
as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Peter Kies, certify that:

1. I have reviewed this annual report on Form 10-K of Inovio Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control

Date: March 6, 2024

/s/ PETER KIES

Peter Kies
Chief Financial Officer

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Inovio Pharmaceuticals, Inc. (the “Company”) on Form 10-K for the year ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned, in the capacities and on the date indicated below, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Date: March 6, 2024

/s/ JACQUELINE E. SHEA

Jacqueline E. Shea
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 6, 2024

/s/ PETER KIES

Peter Kies
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 97.1

INOVIO PHARMACEUTICALS, INC.
Incentive Compensation Recoupment Policy

1. Introduction

The Board of Directors (the "***Board***") of Inovio Pharmaceuticals, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. Effective Date

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. Definitions

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the

Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. Recoupment

(1) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(2) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(3) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(a) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(b) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(4) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(5) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(6) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(7) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this

Policy. In carrying-out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("**SOX 304**") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

Approved: November 14, 2023

Inovio Pharmaceuticals, Inc.
Incentive Compensation Recoupment Policy

Form of Executive Acknowledgment

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Inovio Pharmaceuticals, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Inovio Pharmaceuticals, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

__

Name: __

Title: __

Date: __