TO OUR STAKEHOLDERS

As we reflect on 2024 and look ahead to 2025, I am very pleased to share some highlights of the considerable progress INOVIO has made and our plans for the potentially transformational year that lies ahead. We are on the cusp of bringing our first product candidate to market, which would also be the first DNA medicine available in the US. Our aim is to enable a potentially life-changing solution for patients suffering from recurrent respiratory papillomatosis (RRP), a devastating, chronic, and rare disease of the respiratory tract. To achieve this goal, we remain focused on our strategic priorities and are energized by our commitment to patients, who are at the heart of everything we do.

In 2025, we have three key goals:

1 Submit our Biologics License Application (BLA) for INO-3107

Our primary focus is to complete the submission of our BLA in the second half of 2025, with a goal of receiving FDA acceptance of the file by the end of the year. To achieve this, we anticipate completing the device verification testing in the first half of 2025 and requesting rolling submission from the FDA. If granted, we plan to begin the rolling submission process in mid-2025 and request priority review. We have completed the drafting of all non-device related modules for the BLA and are focused on completing the device-related modules as quickly as possible.

2 Advance Commercial Preparations

The potential approval of INO-3107 is not only a major proof point for our technology platform, it also offers the opportunity to generate meaningful revenues to enable the further development of other promising DNA medicines in our pipeline. To maximize this opportunity, we aim to continue advancing our commercial plans in 2025 to be prepared for a fast and efficient launch if we receive approval. Our efforts are guided by our market research indicating that INO-3107 has the potential to become the preferred treatment option for RRP based on the efficacy and tolerability results we have observed to date, as well as INO-3107's simple, patient-centric treatment regimen that recognizes that every surgery matters to patients.

3 Progress our Diversified Pipeline

While energized by the significant progress for our lead candidate, we are continuing to leverage the strengths of our platform and driving progress across our pipeline through collaborations and other potential strategic opportunities. For INO-3112, we are advancing plans for a Phase 3 study in combination with LOQTORZI® (toripalimab-tpzi) in patients with locoregionally advanced, high-risk, HPV16/18-positive oropharyngeal squamous cell carcinoma. For INO-5401 for GBM, following promising data in our Phase 1/2 trial, we are developing a design for a controlled Phase 2 trial in combination with a PD-1 inhibitor. We are also advancing the next generation of DNA medicine by building on the promising proof-of-concept Phase 1 data we recently announced for our DNA-encoded Monoclonal Antibody (DMAb™) technology.

We are excited about the work ahead and the tremendous opportunity to deliver on the power and potential of DNA medicine for patients and shareholders alike.

Thank you for your continued support and commitment to INOVIO's mission.

Jacqueline Shea

Dr. Jacqueline Shea, *President and CEO*

2024 IN REVIEW

Significant Progress for Lead Candidate INO-3107 for RRP

2020

- Authorization to begin Ph 1/2 clinical trial (US; RRP-001)
- Orphan Drug Designation (US)

2022

- Positive results from 1st cohort of Ph 1/2 trial announced (RRP-001)

2023

- Positive results from 2nd cohort of Ph 1/2 trial announced (RRP-001)
- Orphan Drug Designation (EU)
- Breakthrough Therapy Designation (US)
- INOVIO informed can submit BLA under FDA Accelerated Approval Pathway

2024

- Innovation Passport Designation (UK)
- ATMP Certification (EU)
- Pre-BLA Meeting (US)
- Testing as part of BLA req's found low-level breakage of plastic molded part of disposable single-use array
- Immunology data from RRP-001 presented
- Durability data from retrospective study (RRP-002) announced

2025 GOALS

- **Complete device verification (DV) process for array and device**
- **Submit IND to initiate confirmatory trial**
- **Submit BLA (will request rolling submission and priority review)**
- **Prepare for commercial launch**

Advanced Other Key Candidates

INO-3112: Signed clinical collaboration and supply agreement with Coherus BioSciences, Inc. Gained alignment with the FDA on the planned Phase 3 trial design and received initial feedback from European regulatory authorities on proposed trial design.

DMABs: Announced top-line interim results from an ongoing Phase 1 trial in March 2025 providing the first clinical proof-of-concept that DMAbs can be durably expressed in humans. This next-gen DNA medicine has the potential to overcome challenges with traditional monoclonal antibodies and transform treatments for a broad range of diseases.

INO-4201: Advanced development plans for a Phase 2 trial for INO-4201 as a potential booster to ERVEBO® (rVSV-ZEBOV).

INO-5401: Continued efforts to move INO-5401 into its next stage of development for glioblastoma, which we believe will be a controlled Phase 2 trial. Additionally, our partners at the University of Pennsylvania continued to advance a Phase 1 trial of INO-5401 exploring the potential to prevent cancer in people with BRCA1 or BRCA2 mutations.

Welcomed Steven Egge, Chief Commercial Officer

Steve joined INOVIO in July 2024, bringing extensive commercial launch and broad therapeutic area experience.

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, 2024

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 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 Capital 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 ☒

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 ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant 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 ☒

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, 2024 was approximately $208.0 million based on $8.08 per share, the closing price on that date of the Registrant's Common Stock on the Nasdaq Capital Market.

The number of shares outstanding of the Registrant's Common Stock, $0.001 par value, was 36,667,221 as of March 12, 2025.

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 2025 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, 2024.

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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.
- If we are unable to obtain FDA approval of our proprietary devices and DNA medicine candidates, we will not be able to commercialize them in the United States. In particular, because our product candidates are drug-device 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 developing and manufacturing a drug-device combination product. In addition, if the FDA and similar regulatory authorities do not provide marketing authorization for our CELLECTRA delivery devices, then we will not be able to bring to market our DNA medicines that rely on delivery by such a device.
- DNA medicines are a novel approach to treating and preventing disease, and our CELLECTRA delivery devices are a novel approach to administering medicines. 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 could have a negative impact on our ability to develop some of the product candidates in our pipeline and/or require us to seek alternative funding sources to advance those candidates.
- 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 may 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.
- 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.

Company Overview

We are a clinical-stage biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from HPV-associated diseases, 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® devices are designed to deliver the plasmids into the body's cells for optimal effect, without the use of chemical adjuvants, lipid nanoparticles or viral vectors.

Our lead candidate is INO-3107 for the treatment of recurrent respiratory papillomatosis (RRP) a chronic, rare and debilitating disease caused by HPV-6 and HPV-11. RRP is characterized by the recurring growth of small wart-like growths called papillomas in the respiratory tract. Although mostly benign, these papillomas can cause severe, sometimes life-threatening airway obstruction and respiratory complications. The standard of care for RRP is repeated invasive surgery and patients have expressed that even one less surgery would be life-changing. 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.

RRP patients are unable to mount an effective immune response to HPV-6 and HPV-11, leading to chronic disease. INO-3107 has the potential to induce a targeted immune response, enabling the body to generate new T-cells that travel to HPV-infected airway tissue to seek out and kill HPV-6 and HPV-11 infected cells. In a Phase 1/2 trial (RRP-001) of 32 participants, INO-3107 reduced the number of surgeries patients faced by helping prevent or slow papilloma growth. Of the 32 participants in the trial, 26 of them (81.3%) 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. Of these 32 patients, nine did not require surgical intervention during or after the dosing window. Patients in the trial had a median of 4 surgeries (range of 2-8) in the year prior to dosing. There was a statistically significant median decrease of three surgical interventions when comparing the year following treatment to the year prior to treatment. 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. A retrospective analysis (RRP-002) of 28 participants from the

RRP-001 trial showed extended durability of response and further reduction in surgical burden when patients were evaluated up to three years after initial dosing, including 50% (14/28) of patients meeting the criteria for Complete Response during Year 2 vs. 28% (9/32) during Year 1. 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. In the fourth quarter of 2023, we received feedback from the U.S. Food and Drug Administration, or FDA, that the data from the completed Phase 1/2 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. We previously expected to be able to submit our BLA by the end of 2024; however, during our device testing process we identified a manufacturing issue involving the single-use disposable administration component of the CELLECTRA 5PSP device that we will use in the confirmatory trial and will be submitted for approval for commercial use. We resolved the manufacturing issue in the first quarter of 2025 and are currently on track to begin a rolling submission of the BLA in mid-2025 and to request priority review, with a goal of receiving file acceptance by the FDA by the end of 2025.

We are developing INO-3112, a DNA medicine candidate targeting HPV 16 /18 combined with a DNA plasmid encoding for human IL-12 as an immune activator, for the treatment of high-risk, HPV-16 or 18 positive oropharyngeal squamous cell carcinoma, or OPSCC, a type of head and neck cancer commonly known as throat cancer. The incidence of HPV-related throat cancer has increased rapidly in recent years in the United States, with an estimated 20,000 new cases each year. In 2024 HPV-related throat cancer surpassed cervical cancer as the most common HPV-related cancer. In the United States, men are four to five times more likely to be diagnosed with HPV-associated oropharyngeal cancers than women.

We have entered into a clinical collaboration and supply agreement with Coherus BioSciences, Inc., or Coherus, to evaluate the combination of INO-3112 and LOQTORZI (toripalimab-tpzi) in a clinical trial for patients with locoregionally advanced, high-risk, HPV16/18 positive OPSCC. Under the terms of the supply agreement, Coherus will provide LOQTORZI for a planned Phase 3 clinical trial. We have also gained alignment with the FDA on the design of the planned Phase 3 trial in the United States and received initial feedback from European regulatory authorities on the proposed design of the trial in Europe.

We are developing INO-5401, an immunotherapy consisting of three DNA plasmids encoding for three tumor associated antigens, for the treatment of glioblastoma multiforme, or GBM, an aggressive type of brain cancer that accounts for more than 50% of all primary malignant brain tumors. GBM is one of the most complex, deadly, and treatment-resistant cancers. In the United States, nearly 15,000 people were expected to receive a GBM diagnosis in 2023, and it is estimated that more than 10,000 individuals will succumb to the disease each year.

In addition to our development efforts with the product candidates described above, we, or with partners, are actively developing or planning to develop DNA medicines for other indications, including HPV-related anal dysplasia; cancers in people with certain gene mutations; 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 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, monoclonal antibodies to fight a specific pathogen, or therapeutic proteins to replace defective or missing proteins in the body. 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. Some of the key 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. **Safety and Tolerability:** DNA medicines have been well tolerated by clinical trial participants when evaluated against multiple disease targets. Our DNA medicines have been administered over 19,000 times across nearly 6,000 participants to date.

c. **Ability to Re-dose:** DNA medicines have been used in clinical trials to boost or sustain immune response via 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 delivery devices use electroporation to 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.

DNA Plasmid Design Technology

Our precisely designed DNA plasmids are circular double-stranded DNA constructs 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 viral antigens that elicit antigen-specific T cell responses to fight HPV. We start by identifying one or more viral antigens that we believe are the best targets for directing the immune system toward HPV and then apply our 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 our DNA medicines against various tumor-associated antigens, as well as against different strains of certain infectious diseases in human clinical trials. Because the engineered genetic sequences are substantially similar to the original sequences, without matching them exactly, we believe they are patentable.

Once a sequence is designed and optimized with our proprietary gene optimization algorithm, which we refer to as GOAL, the sequence is synthesized and 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, the DNA plasmids have been optimized to enable high expression in human cells. 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

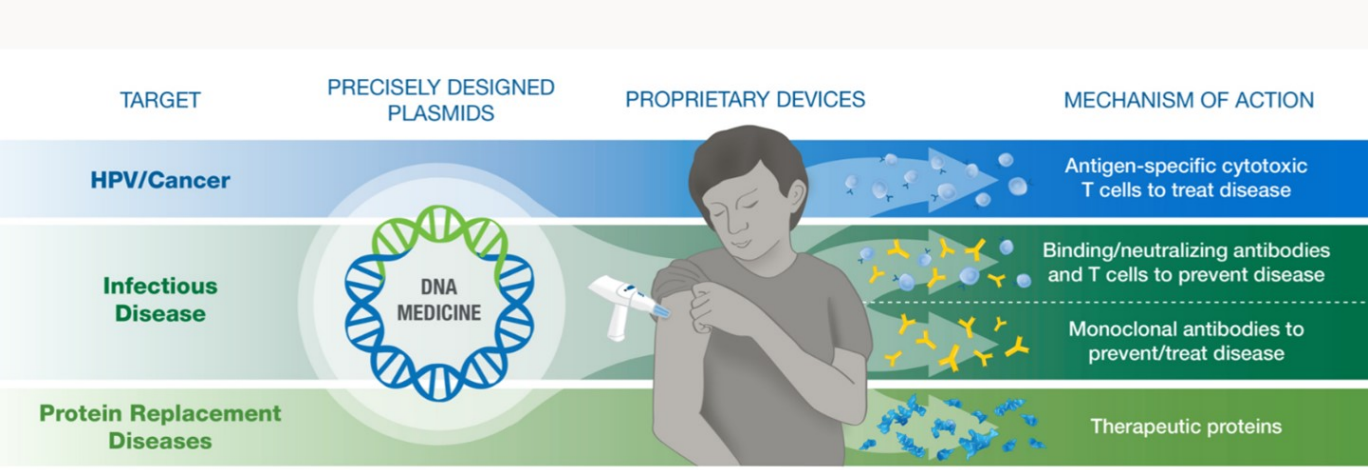
DNA medicines need a pathway into the cell to work effectively. To help DNA plasmids, which are relatively large molecules, pass through the cell membrane, we use our proprietary CELLECTRA delivery technology. After injecting the DNA medicine either intramuscularly (IM) or intradermally (ID), CELLECTRA 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 and delivers both the DNA medicine and the EP to the patient. 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 medicine 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 DNA medicine 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. We have CE-marked the CELLECTRA 5PSP model in the EU, which allows us to commercialize the device in the EU and other geographies that recognize CE-marking.

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



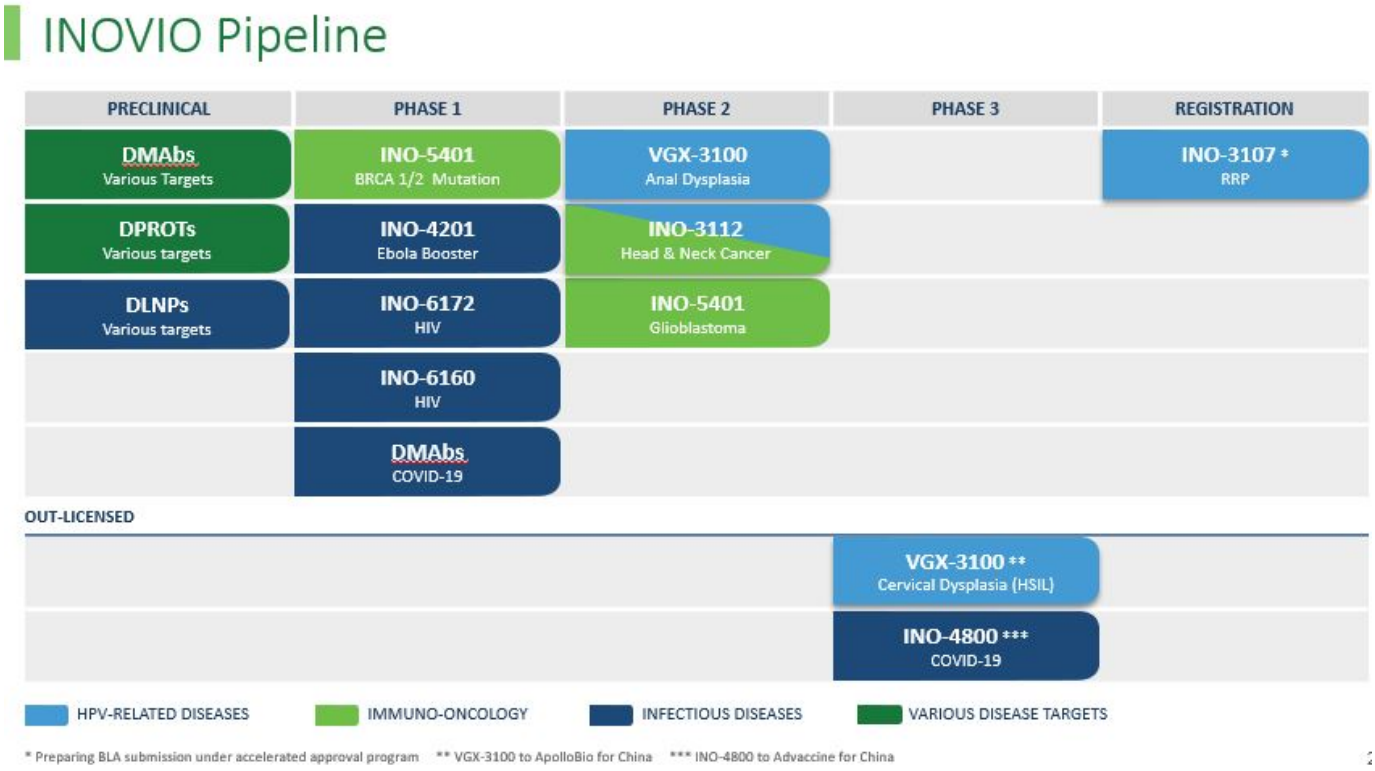
DNA Medicines and HPV-related Diseases

There are more than 200 known types of HPV. It is believed that nearly all humans will become infected with at least some type of HPV during their lifetime, but most people are able to eliminate the virus before it causes disease. Certain types of HPV are known for being more difficult to clear and have a greater likelihood of leading to disease. For example, HPV-6 and HPV-11 may lead to benign growths (either warts or papillomas) that can develop into conditions such as RRP, while HPV-16 and HPV-18 may lead to cell changes and lesions, also known as 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.

Our DNA Medicines in Development

The chart below provides an overview of our DNA medicines pipeline. We have focused 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.



(DMAb = DNA-encoded monoclonal antibody; DPROT = DNA-encoded protein technology; dLNP = DNA-launched nanoparticle)

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, also known as bronchiectasis, and, ultimately, progressive pulmonary failure. In approximately 2% of cases, 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 repeated 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 an immunotherapy composed of plasmids encoding for HPV-6 and HPV-11 antigens, as well as human interleukin-12 (IL-12). In May 2023, preliminary results from an open-label, multicenter Phase 1/2 trial (RRP-001; NCT:04398433) evaluating the efficacy, safety, tolerability and immunogenicity of 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.

An interim analysis was published in a scientific peer-reviewed journal, The Laryngoscope, in 2023. The full safety and efficacy results from the RRP-001 trial were presented in October 2024 at the International Society of Vaccines Congress and published in the scientific journal Nature Communications in February 2025.

The RRP-001 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 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 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 cellular 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.

In 2024, immunology data from the RRP-001 trial were presented at the American Association for Cancer Research (AACR) Special Conference: Tumor Immunology and the Immunotherapy and the International Papillomavirus Conference. These data support the mechanism of action of INO-3107 and demonstrated the ability of INO-3107 to induce antigen-specific T cell responses against HPV-6 and HPV-11 and drive recruitment of those T cells into airway tissues and papilloma of RRP patients, resulting in the slowing or elimination of papilloma regrowth. The immunology data showed that INO-3107 induced significant clonal T cell expansion in the blood, including antigen-specific killer T cells and T cell infiltration into airway tissue, which was positively associated with clinical response. The immunology data was consistent with the clinical effect observed in the RRP-001 trial, which showed an elimination or reduction in the incidence of papilloma in the airway of RRP patients. In the immunological assessment, the T cell infiltration observed in airway tissues of clinical responders was predominantly comprised of a T cell population detectable only after administration of INO-3107.

Further data reported in 2024 showed that patients exhibited extended durability of clinical response and further reduction in surgical burden when evaluated two and three years after initial dosing. In a retrospective trial (RRP-002) of 28 participants from the Phase 1/2 RRP-001 trial, half of the patients treated with INO-3107 achieved a complete response (CR) and required no surgery when evaluated at the end of year two and into year three post initial treatment, increasing from the initial CR rate of 28% at the end of the first year. The retrospective analysis showed that of those patients who had an initial CR, 88% maintained their CR by end of the second year and 63% into the third year. Of the patients included in the retrospective analysis, 95% maintained or enhanced their original Overall Response Rate ("ORR," defined as those patients who achieved either a CR or a partial response) after two years, while 86% of patients maintained or enhanced their ORR into year three.

The FDA granted INO-3107 Orphan Drug Designation (ODD) in July 2020 and Breakthrough Therapy Designation in 2023. The European Commission has also granted INO-3107 Orphan Drug Designation. In 2024, INO-3107, was designated an innovative medicine as part of the U.K.'s Innovative Licensing and Access Pathway (ILAP). In 2024, the European Medicines Agency's Committee for Advanced Therapies (CAT) certified the quality and non-clinical data for INO-3107, confirming that the chemistry, manufacturing and controls (CMC) data and nonclinical results available to date comply with the scientific and technical standards that would be used for evaluating a European Marketing Authorization application.

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

INO-3112 is a DNA immunotherapy consisting of two plasmids 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 ORR of 27.6% with 4 complete responses and 4 partial responses in the overall group of 29 evaluable patients and increased presence of 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 and almost three times the historical overall survival period for monotherapy durvalumab in a similar patient population. Objective responses, including complete responses, 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. to evaluate the combination of INO-3112 and LOQTORZI™ as a potential treatment for patients with locoregionally advanced, high-risk, HPV-16/-18 positive OPSCC. Under the terms of the supply agreement, Coherus will provide LOQTORZI for a planned Phase 3 clinical trial to be conducted by us. We have submitted our Phase 3 trial design to the FDA and European regulators and gained alignment with FDA on the proposed trial design. We have also received initial feedback from European regulatory authorities on the proposed design of the trial.

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

In 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 second Phase 3 trial of VGX-3100. 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.

An ad hoc integrated efficacy analysis of the results for the two completed Phase 3 trials of VGX-3100 showed statistical significance in the biomarker-selected and all-participants populations for lesion regression and viral clearance.

In addition, in both Phase 3 trials, administration of VGX-3100 by the CELLECTRA 5PSP device was well tolerated and there were no treatment-related serious adverse events, with most adverse events considered to be mild to moderate.

The combined data set from the two Phase 3 trials 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. See "Collaborations and Alliances" below.

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 2020, we announced Phase 2 results from this trial. One-half of the 22 participants treated with VGX-3100 showed resolution of HPV-16/18-associated anal HSIL at six months following the start of treatment. Administration of VGX-3100 by our CELLECTRA-5PSP device was also well tolerated in the trial.

A separate Phase 2 trial of VGX-3100 is currently being sponsored by the AIDS Malignancy Consortium. The trial 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 has enrolled 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.

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 to be 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 but 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 immunotherapy candidate INO-5401 consists 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 conducted a Phase 1/2 immuno-oncology trial of INO-5401 and INO-9012 (a DNA plasmid encoding for IL-12) in 52 participants with newly diagnosed GBM, in combination with cemiplimab (Libtayo®), a PD-1 immune checkpoint inhibitor developed by Regeneron Pharmaceuticals. The primary endpoint was safety and tolerability, and the trial also evaluated immunogenicity as well as efficacy based on OS rates.

We presented the OS data at the 2022 American Society of Clinical Oncology (ASCO). Median OS in patients with an unmethylated MGMT promoter (Cohort A) was 17.9 months, which compared favorably to historical durations between 14.6 and 16 months. Median OS in patients with an MGMT methylated promoter (Cohort B) was 32.5 months, which also compared favorably to historical durations between 23.2 and 25 months. Overall, co-administration of INO-5401 with INO-9012 and with Libtayo and RT/TMZ (radiation and temozolomide) was well tolerated. Treatment was also observed to be immunogenic, eliciting antigen-specific T cells that may infiltrate GBM tumors. As of the end of 2024, GBM patients in the trial remained on

drug treatment. We are considering various options for continuing clinical investigation of INO-5401 and INO-9012 in patients with GBM.

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

We are collaborating with researchers at the University of Pennsylvania to conduct a Phase 1b investigator-sponsored trial to evaluate the tolerability and immunogenicity of INO-5401 alone or in combination with INO-9012, in each case delivered with our CELLECTRA device, for 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 technology, we are able to create precisely designed DNA plasmids that encode for specific monoclonal antibodies (mAbs). They are delivered directly into cells of the body using our CELLECTRA delivery system, enabling the body to manufacture its own DNA encoded mAbs (DMAbs) in vivo, as opposed to conventional recombinant mAb production *in vitro*. 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 for new disease targets that may not be currently addressable with conventional recombinant mAbs and also targets of existing, commercially available mAb products.

In 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 potentially preventive treatment for COVID-19.

In 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 the mAb product candidates encoded on our DNA plasmid, administered intramuscularly followed immediately by electroporation using our CELLECTRA 2000 device in a 1- dose (Day 0), 2-dose (Days 0 and 3) and 4-dose regimen (Days 0, 3, 28 and 31) in healthy adults (NCT05293249).

In March of 2025 interim results from the trial were shared in preprint on Research Square. In the trial, 100% (24/24) of participants who have reached week 72 maintained biologically relevant levels of DMAbs, confirming the durability of in vivo antibody production. Notably, no participant developed anti-drug antibodies, a common challenge observed in other gene-based delivery platforms, such as adeno-associated virus (AAV))-mediated antibody expression. Additionally, the DMAbs were well tolerated in the trial, with the most common side effects being mild, temporary injection site reactions, such as pain and redness. The study is ongoing and we and our collaborators plan to present and publish the interim clinical data this year.

INO-4201 for Ebola Virus Disease

The Ebola virus (EBOV) 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. EBOV 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 2019, the European Medicines Agency (EMA) conditionally approved the preventative vaccine ERVEBO®, the World Health Organization pre-qualified that vaccine for use in high-risk countries and the

FDA approved the vaccine for use in the United States. However, ERVEBO has not been approved for repeat dosing and there are currently no approved booster vaccines available in the United States.

In 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 2023, we announced results from the Phase 1b trial. INO-4201 was well tolerated and boosted humoral responses in all 36 participants treated in the trial. In 2024 we announced new antibody response data from the Phase 1b trial. Utilizing the FANG assay, which allows us to more accurately benchmark our data against the primary vaccines on the market, we observed that INO-4201 elicited strong antibody responses, comparable to the ERVEBO primary series vaccination. We and our collaborators plan to publish the data from this Phase 1b trial in a peer-reviewed scientific journal.

In 2024, we also submitted a proposed Phase 2 trial design to the FDA. We have been advised that the FDA is in alignment with our proposal to use a non-human primate (NHP) challenge study to immunobridge to the Phase 2 clinical study. Results from these two studies would subsequently inform the design of a potential Phase 3 study.

INO-6160 for HIV

We are developing our DNA medicine candidate INO-6160 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 evaluating the safety and immunogenicity of INO-6160.

DNA-Launched Nanoparticles (DLNPs)

We 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, our 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 evaluating 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.

DNA Encoded Protein Technology (DPROT)

Our DNA-encoded protein technology, or DPROT platform is a new approach to therapeutic protein replacement that aims to address some of the shortcomings of conventional therapeutic protein replacement that uses either repeated recombinant protein injections, infusions or viral based gene therapy. Similar to our DMAb technology, DPROT targets long-term protein expression with the ability to re-dose due to the lack of anti-vector immunity. Research is currently in the preclinical stage for various targets.

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, Coherus Biosciences, Defense Advanced Research Projects Agency (DARPA), 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 BioLogics, the University of Pennsylvania, the Walter Reed Army Institute of Research, and The Wistar Institute.

In 2017, we entered into an Amended and Restated License and Collaboration Agreement (the "ApolloBio Agreement"), with ApolloBio Corporation ("ApolloBio"), which was amended in June 2023. Under the terms of the ApolloBio 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 the agreed upon territories.

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 ApolloBio Agreement. In the event that VGX-3100 is approved for marketing, 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.

ApolloBio dosed its first participant in a separate Phase 3 trial in China (HPV-303CHN) in 2021, and the trial remains ongoing as of the date of this report.

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 immunotherapy/vaccine research and development. These include AbbVie, AstraZeneca, BioNTech, Bristol-Myers Squibb, Gilead, 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 immunotherapy and vaccine technologies, including but not limited to Agenus, AIVITA, Barinthus Biotherapeutics (formerly Vaccitech), BL Corp, BlueSphere Bio, Dynavax, Entos Pharma, Flow Pharma, Frantz Viral Therapeutics, Immunocore, Immunome, Imunon, ImVax, Iovance, 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, Precigen is developing a product candidate, PRG-2012, based on a Gorilla adenovirus-based vector. Precigen reported that they submitted a BLA in December 2024 based on their Phase 1/2 trial of PRG-2012 for the treatment of RRP, have initiated a confirmatory trial and believe that no additional randomized, placebo-controlled trial will be required to support their BLA submission under FDA's accelerated approval pathway. 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 locoregionally 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 oropharyngeal 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. A potential limitation of the technology stems from problems with unwanted immune responses against components of the viral vector itself, making repeated administration to boost or maintain immune responses 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 and/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 as compared to those of our competitors, as well as 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.

Manufacturing

We rely on third parties for the manufacture of clinical supplies for all of our product candidates. We have service agreements in place for multiple manufacturers for drug substance and drug product depending on the product and clinical stage, including Richter BioLogics, Kaneka Eurogentec, Gedeon Richter and Alliance Medical Products.

Replacement of any third-party manufacturers would require us to qualify new manufacturers and negotiate and execute contractual agreements with them. If any of our supply or service agreements with third-party manufacturers are terminated, we would likely experience delays and additional expenses.

Production processes for biological products are complex, highly regulated, and vary widely from product to product. Shifting or adding manufacturing capacity can be a very lengthy process requiring significant capital expenditures, process modifications, and regulatory approvals. Accordingly, if we were to experience extended shutdowns at one of our own facilities, extended failure of a contract supplier or contract manufacturing organization, or extraordinary unplanned increases in demand, we could experience an interruption in supply of certain products or product shortages until production could be resumed or expanded.

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 planned clinical trials.

We manufacture materials for our CELLECTRA device at our device manufacturing facilities located in San Diego. Most of the principal materials we use in our manufacturing operations are available from more than one source. However, we have single source suppliers for molded plastic parts, machined metal parts and fully assembled printed circuit boards (PCBs). In the event one of these suppliers was unable to provide the materials or product, we would generally seek to maintain sufficient inventory to supply the market until an alternative source of supply can be implemented. However, in the event of an extended failure of a supplier, it is possible that we could experience an interruption in supply until we can establish new sources or, in some cases, implement alternative processes.

Commercialization

We currently have no approved products in the United States or any country. We cannot market or promote a new product in a country until a marketing application has been approved by the appropriate regulatory authority for that jurisdiction. Subject to receiving marketing authorization in a jurisdiction, we believe we will be able to commercialize in that market 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 2024, we continued to advance the development of our commercialization plans for INO-3107 in the United States based on the notification from the FDA that the data from our completed Phase 1/2 trial (RRP-001) could be used to submit a BLA under the FDA's accelerated approval program. We have not fully established a sales, marketing or distribution infrastructure. If we are unable to enter into a third-party commercial arrangement with respect to the United States, we believe that we could establish an appropriately sized organization to commercialize INO-3107 and any other approved products. Outside the United States, our strategy is to enter into arrangements with third-party commercial partners for any of our product candidates that obtain marketing approval.

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, 2024, our patent portfolio included approximately 60 issued U.S. patents and approximately 80 U.S. patent applications as well as approximately 590 issued foreign counterpart patents and approximately 770 counterpart foreign patent applications. These are comprised, in part, of:

- one issued U.S. patent, three U.S. patent applications and approximately 40 counterpart foreign patent applications directed to treatment of RRP;
- eight issued U.S. patents and five 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 50 issued U.S. patents and approximately 65 U.S. patent applications, as well as approximately 425 issued foreign counterpart patents and approximately 490 counterpart foreign patent applications, directed to our other earlier-stage product candidates; and
- three issued U.S. patents and four U.S. patent applications, as well as approximately 160 issued foreign counterpart patents and approximately 45 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 2025 and 2036 and our pending patent applications, if issued, would expire between about 2025 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. Under the accelerated approval pathway, FDA may require the conduct of confirmatory trials before full 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.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need for such diseases or condition. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the application. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

In addition, the FDA may designate a biologic as a "breakthrough therapy" upon a request made by the IND sponsor. A breakthrough therapy is a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, which are intended to expedite the development and review of an application for approval of a breakthrough therapy.

Finally, the FDA may designate an application for priority review if it is for a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over existing therapy. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on an original marketing application from ten months to six months from the date of filing.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Accelerated Approval Pathway

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will require that a sponsor of a product receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, 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 is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug or biologic, such as an effect on IMM.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a program or development candidate approved on this basis is typically subject to rigorous post-marketing compliance requirements,

including the completion of Phase 4 or post-approval clinical trials to establish the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, may allow the FDA to withdraw approval of the drug. The FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA's website.

All promotional materials for products approved under the accelerated approval program are subject to prior review by the FDA.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a biologic for this type of disease or condition will be recovered from sales in the United States for that biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use will be disclosed publicly by the FDA; the posting will also indicate whether the biologic is no longer designated as an orphan drug. More than one program or development candidate may receive an orphan drug designation for the same indication. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan product exclusivity. During the seven-year exclusivity period, the FDA may not approve any other applications to market a product containing the same active moiety for the same disease, except in very limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Thus, orphan drug exclusivity could block the approval of one of our potential products for seven years if a competitor obtains approval of the same product as defined by the FDA and we are not able to show the clinical superiority of our program or development candidate or if our program or development candidate's indication is determined to be contained within the competitor's product orphan indication. In addition, the FDA will not recognize orphan drug exclusivity if a sponsor fails to demonstrate upon approval that the product is clinically superior to a previously approved product containing the same active moiety for the same orphan condition, regardless of whether or not the previously approved product was designated an orphan drug or had orphan drug exclusivity. A product that has received orphan drug designation may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received the designation. Orphan exclusivity does not prevent the FDA from approving a different drug or biological product for the same disease or condition, or the same product for a different disease or condition.

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.

Biosimilars and Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic without such alteration or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product.

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 amendments to and judicial and Congressional challenges to certain aspects of the ACA. For example, 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 the American Rescue Plan Act of 2021 was signed 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, effective January 1, 2024.

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, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare drug price negotiation program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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 years ended December 31, 2024 and 2023, we derived 100% and 29%, respectively, of our revenue from ApolloBio.

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 $75.6 million in 2024 and $86.7 million in 2023.

Geographic Information

All of our revenue for the years ended December 31, 2024 and 2023 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, 2025, we employed 134 people on a full-time basis. Of the total, 99 were in product research, which includes research and development, quality assurance, clinical, engineering and manufacturing, and 35 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, 2024 our accumulated deficit was $1.7 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 as combination products 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 to commercialize any product that obtains regulatory approval;
- 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. In particular, biotech and small-cap companies tend to feel these difficulties acutely. 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 proprietary devices and DNA medicine candidates, we will not be able to commercialize them in the United States. In particular, because our product candidates are drug-device 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 developing and manufacturing a drug-device combination product. In addition, if the FDA and similar regulatory authorities do not provide marketing authorization for our CELLECTRA delivery devices, then we will not be able to bring to market our DNA medicines that rely on delivery by such a device.

We need FDA approval prior to marketing our proprietary device and DNA medicine candidates as combination products in the United States. If we fail to obtain FDA approval to market our proprietary device and DNA medicine candidates as combination products, 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 combination products as well as the evaluation of our device design, 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. In determining what is needed to demonstrate the safety and effectiveness of a combination product, the FDA takes into account the questions and considerations, reflected in the statutory and regulatory provisions associated with each constituent part in the FDA’s review of the combination product as a whole and its constituent parts. This includes how the constituent parts may interact and interrelate and is a complex process. 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 drug-device 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 developing and manufacturing a drug-device combination product. In addition, if the FDA and similar regulatory authorities do not provide marketing authorization for 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 marketing authorization for our devices would result in significant harm to our business.

Pursuing accelerated approval for INO-3107 or any of our other product candidates 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, particularly when the clinical testing involves drug and device combination products such as ours. 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 products for use in humans.

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 meets the standard of reasonable assurance of safety and effectiveness or that our 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 regulations or marketing authorization and approval policies of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for marketing authorization or 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 Institutional 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 therapies, including 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, particularly given the complexity concerning the manufacturing of combination products, 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. 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, even if our product candidates receive regulatory approval from the FDA and similar regulatory authorities, 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 that meet the relevant current good manufacturing practice (cGMP) requirements for combination products. 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, as part of the testing process required for BLA submission for INO-3107, we identified a manufacturing issue in the single use administration component of our CELLECTRA 5PSP device that we are working to resolve. However, the timeline on which we expect to be able to commence our confirmatory trial and submit our BLA for INO-3107 has been delayed as a result. There can be no assurance we will be able to rectify this manufacturing issue on the timeline we expect or at all or that we will not identify additional issues with our device that could further delay our planned regulatory submission or impair our ability to receive regulatory approval.

In addition, 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 pass preapproval inspection of our manufacturing facilities and 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, and any amendments thereto, 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 proprietary device and DNA medicine candidates.

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 proprietary device and DNA medicine candidates. 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 product candidates receive regulatory approval, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any of our product candidates.

Even if FDA 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 authorities 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 devices 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;
- initiate injunction actions;
- 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.

FDA and comparable foreign regulatory authorities' policies may also change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Certain policies of any administration may impact our business and industry. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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 could have a negative impact on our ability to develop some of the product candidates in our pipeline and/or require us to seek alternative funding sources to advance those candidates.

We have entered into agreements with government agencies, such as the National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIH NIAID), Defense Advanced Research Projects Agency (DARPA), Medical CBRN Defense Consortium (MCDC) and the Department of Defense (DoD) Joint Program Executive Office (JPEO) for Chemical, Biological, Radiological and Nuclear Defense (CBRN), 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. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products, less favorable coverage policies and reimbursement rates may be implemented in the future.

Risks Related to Employee and Operational Matters

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 in the United States and other high income countries 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 announced in late 2024 that it has submitted a BLA 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, “hacktivists,” 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.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of ours could be leaked, disclosed, or revealed as a result of or in connection with our personnel's or vendors' use of artificial intelligence (AI) technologies, including generative AI, and machine learning (ML) technologies (collectively, AI/ML technologies). Any sensitive information (including confidential, competitive, proprietary, or personal data) that we input into a third-party generative AI/ML platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI/ML model. Additionally, where an AI/ML model ingests personal data and makes connections using such data, those technologies may reveal other personal or sensitive information generated by the model.

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 amendments to and executive, judicial, and Congressional challenges to certain aspects of the ACA. For example., on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed 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, the American Rescue Plan Act of 2021 was signed 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, effective 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.

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, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare drug price negotiation program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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;
- the Health Insurance Portability and Accountability Act (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 Federal Food, Drug and Cosmetic Act (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 may 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. Certain Chinese biotechnology companies and contract development and manufacturing organizations may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could potentially impact our ability to secure the materials we need for our product candidates. For example, the recently proposed BIOSECURE Act that was passed by the U.S. House of Representatives in September 2024, as well as a substantially similar bill in the U.S. Senate, target U.S. government contracts, grants, and loans for entities that use equipment and services from certain named Chinese biotech companies, and authorize the U.S. government to name additional Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies

to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We may also be exposed to fluctuations in the value of the local currency in China. These disruptions, failures or uncertainties may have adverse impacts on the development of our product candidates, our ability to commercialize our DNA medicine candidates, if approved, our business operations, our ability to enforce the contracts we have entered into 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 due to reasons including, among other things, inflation, rising interest rates, energy costs, geopolitical issues, political changes and trends such as protectionism, economic nationalism resulting in government actions impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures, 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. Other jurisdictions have adopted and may adopt stringent data localization and cross-border data transfer laws.

In addition to data privacy and security laws, we may be contractually subject to certain 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 statements regarding data privacy and security. Regulators in the United States have scrutinized and are increasingly scrutinizing these statements and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Our personnel and certain third parties with whom we work may use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. Due to inaccuracies or flaws in the inputs, outputs, or logic of the AI/ML, AI models could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.

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 has in the past and may in the future 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 our cybersecurity threats and risks. The IT Department identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and our 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 Certified Information Systems Security Professional (CISSP).

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

We have 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 5,600 square feet and the initial term continues through June 2028.We have also entered into an office lease, or the First San Diego Lease, for other property in San Diego, California that we use for office, manufacturing and research and development purposes. The total space under the First San Diego Lease is approximately 51,000 square feet and the term continues through May 2027.

Rent payments under both leases 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 in connection with the First San Diego Lease.

Plymouth Meeting Lease

We have 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 approximately 57,400 square feet and extend the lease term through December 31, 2029.

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 two sublease terms through December 31, 2026, one through December 31, 2027 and one through December 31, 2029.

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

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, we 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, but VGXI later discontinued its third-party claims. 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. In October 2021, GeneOne filed its answer to our counterclaims and new matter. In 2024, we filed a motion for summary judgment, which was denied. 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 12, 2025, we had approximately 65 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 12, 2025 was $2.05, as reported on the Nasdaq Capital Market.

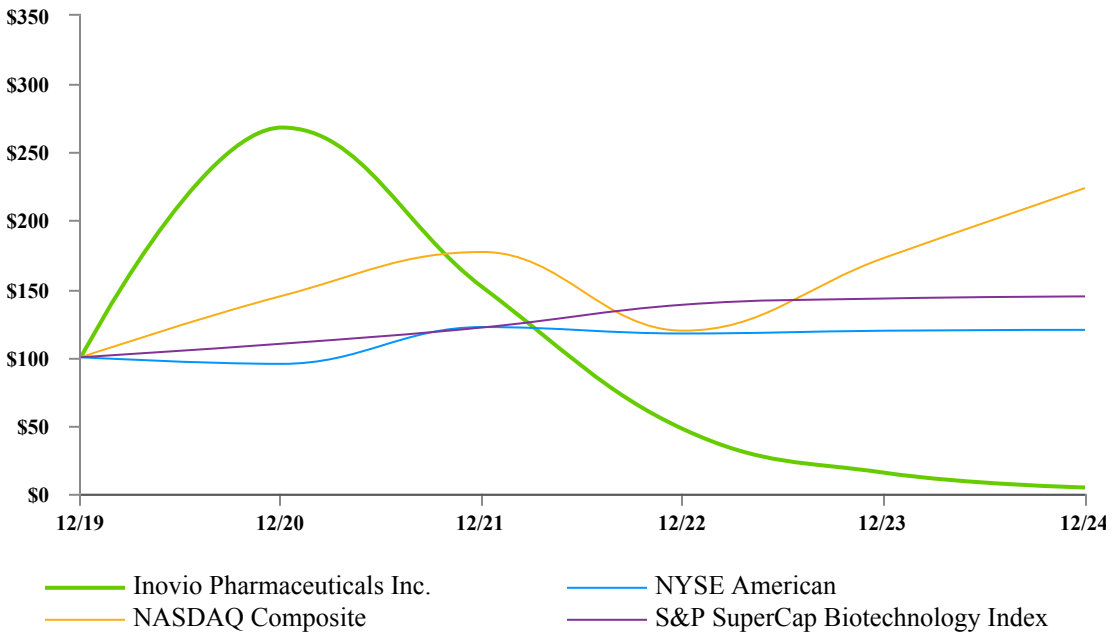
Dividends

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, 2024. The graph assumes a $100 investment on December 31, 2019 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 12/31/19 in stock or index, including reinvestment of dividends.
Fiscal year ended December 31.

	12/19	12/20	12/21	12/22	12/23	12/24
Inovio Pharmaceuticals, Inc.	100.00	268.18	151.21	47.27	15.45	4.62
NYSE American	100.00	95.14	122.10	117.38	119.42	120.04
Nasdaq Composite	100.00	144.92	177.06	119.45	172.77	223.87
S&P SuperCap Biotechnology Index	100.00	109.90	121.80	138.47	142.98	144.54

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.

INOVIO, CELLECTRA, the INOVIO logo, and our other trademarks or service marks appearing in this Annual Report are our property. Solely for convenience, the trademarks and trade names in this report are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. Products or service names of other companies mentioned in this Annual Report may be trademarks, trade names or service marks 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.

Overview

We are a clinical-stage biotechnology company focused on developing and commercializing DNA medicines to help treat and protect people from HPV-associated diseases, 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® devices are designed to deliver the plasmids into the body's cells for optimal effect, without the use of chemical adjuvants, lipid nanoparticles or viral vectors.

Our lead candidate is INO-3107 for the treatment of recurrent respiratory papillomatosis, or RRP, a chronic, rare and debilitating 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. The standard of care for RRP is repeated invasive surgery.

In 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. We previously expected to be able to submit our BLA by the end of 2024; however, during our device testing process we identified a manufacturing issue involving the single-use disposable administration component of the CELLECTRA 5PSP device that we plan to use in the confirmatory trial and that will be submitted for approval for commercial use. We resolved the manufacturing issue in the first quarter of 2025 and are currently on track to begin a rolling submission of the BLA in mid-2025 and to request priority review, with a goal of receiving file acceptance by the FDA by the end of 2025.

We are developing INO-3112, a DNA medicine candidate targeting HPV 16/18 combined with a DNA plasmid encoding for human IL-12 as an immune activator, for the treatment of oropharyngeal squamous cell carcinoma, or OPSCC, a type of head and neck cancer commonly known as throat cancer.

We have entered into a clinical collaboration and supply agreement with Coherus BioSciences, Inc. to evaluate the combination of INO-3112 and LOQTORZI (toripalimab-tpzi) in a clinical trial for patients with locoregionally advanced, high-risk, HPV16/18 positive OPSCC. Under the terms of the supply agreement, Coherus will provide LOQTORZI for a planned Phase 3 clinical trial. We have also gained alignment with FDA on the design of the planned Phase 3 trial in the United States and received initial feedback from European regulatory authorities on the proposed design of the trial in Europe.

We are also developing INO-5401, an immunotherapy consisting of three DNA plasmids encoding for three tumor associated antigens, for the treatment of glioblastoma multiforme, or GBM, an aggressive type of brain cancer that accounts for more than 50% of all primary malignant brain tumors. GBM is one of the most complex, deadly, and treatment-resistant cancers.

In addition to our development efforts with the product candidates described above, we are actively developing or planning to develop DNA medicines for other indications, including HPV-related anal dysplasia; cancers in people with certain gene mutations; 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 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, Coherus Biosciences, Defense Advanced Research Projects Agency (DARPA), 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 BioLogics, 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, 2024, we had an accumulated deficit of $1.7 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:

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, 2024 and 2023 is presented in the following table and the results of these periods are used in the discussion thereafter.

	Year Ended December 31,		Increase/(Decrease) 2024 vs. 2023	
	2024	2023	$	%
Revenue from collaborative arrangements and other contracts, including affiliated entity	$ 217,756	$ 832,010	$ (614,254)	(74)%
Operating expenses:				
Research and development	75,620,340	86,676,563	(11,056,223)	(13)
General and administrative	36,996,338	47,582,104	(10,585,766)	(22)
Impairment of goodwill	—	10,513,371	(10,513,371)	100
Total operating expenses	112,616,678	144,772,038	(32,155,360)	(22)
Loss from operations	(112,398,922)	(143,940,028)	31,541,106	22
Interest income	4,766,993	8,133,290	(3,366,297)	(41)
Interest expense	(177,833)	(1,222,789)	1,044,956	(85)
Change in fair value of common stock warrant liability	2,808,608	—	2,808,608	100
(Loss) gain on investment in affiliated entity	(1,166,443)	773,145	(1,939,588)	*
Net unrealized gain on available-for-sale equity securities	2,077,182	5,850,626	(3,773,444)	*
Other expense, net	(3,163,711)	(4,711,596)	1,547,885	*
Net loss	$ (107,254,126)	$ (135,117,352)	$ 27,863,226	21 %

*Not meaningful

Revenue

Revenue was primarily derived under collaborative arrangements and other contracts, including arrangements with affiliated entity, for the years ended December 31, 2024 and 2023. We derived 100% and 29%, respectively, of our revenue from a single collaborator, ApolloBio, in those years.

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, 2024 and 2023:

	Years Ended December 31,		Increase (Decrease)	
(dollars in thousands)	2024	2023	$	%
INO-3107	$ 29,930	$ 17,841	$ 12,089	68 %
INO-5401 and other Immuno-oncology	6,293	11,759	(5,466)	(46)
Other research and development programs (a)	(77)	18,702	(18,779)	(100)
Engineering and device-related	19,394	8,863	10,531	119
Stock-based compensation	2,821	4,606	(1,785)	(39)
Other unallocated expenses (b)	17,259	24,906	(7,647)	(31)
	$ 75,620	$ 86,677	$ (11,057)	(13)%

(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 2023.

The $11.1 million overall decrease in research and development expenses year over year was primarily the result of:

- $12.3 million in lower employee compensation, including stock-based compensation, due to lower headcount following our corporate restructuring undertaken in 2023;
- $8.1 million in lower drug manufacturing expenses for other programs;
- $7.5 million in lower drug manufacturing and clinical study expenses related to INO-4800 after we discontinued this program in 2022;
- $3.4 million in lower drug manufacturing and engineering services related to other COVID-19 studies that we ceased after we discontinued development of INO-4800;
- $2.0 million related to the impairment charge on intangible assets in 2023 which did not recur;
- $1.9 million in lower immunology and clinical study expenses related to INO-3107;
- $1.3 million in lower clinical study expenses related to VGX-3100 as we discontinued development of this product candidate in the third quarter of 2023; and
- $1.3 million in lower clinical study and subcontractor expenses related to our CEPI LASSA and MERS grants.

These decreases were offset by:

- $10.6 million in higher drug manufacturing related to INO-3107;
- $6.8 million in higher engineering professional and outside services related to our device development;
- $4.7 million of lower contra-research and development expense recorded from grant agreements; and
- $4.6 million of higher expensed inventory.

Contributions received from current grant agreements and recorded as contra-research and development expense were $2.1 million and $6.8 million for the years ended December 31, 2024 and 2023, respectively. The decrease was primarily due to decreases of $3.6 million and $553,000, respectively, in reimbursements from Advaccine and expenses earned under the sub-grants through Wistar.

General and Administrative Expenses

General and administrative expenses, which include business development expenses and patent expenses, were $37.0 million for the year ended December 31, 2024 as compared to $47.6 million in 2023. The $10.6 million overall decrease was primarily the result of:

- $5.4 million in lower employee compensation, including employee and consultant stock-based compensation, as a result of lower headcount and lower weighted average grant date fair value for the awards granted during 2024; and
- $4.7 million in lower legal expenses related to litigation matters settled in 2023 that did not recur in 2024.

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, 2024 and 2023 was $6.4 million and $10.4 million, of which $2.8 million and $4.5 million was included in research and development expenses and $3.6 million and $5.9 million was included in general and administrative expenses, respectively.

Interest Income

The $3.4 million decrease in interest income for the year ended December 31, 2024 as compared to 2023 was primarily due to a lower short-term investment balance.

Interest Expense

The $1.0 million decrease in interest expense for the year ended December 31, 2024 as compared to 2023 was primarily due to our senior convertible promissory notes that were repaid in full on March 1, 2024.

Change in Fair Value of Common Stock Warrant Liability

We recognized a gain of $2.8 million from a decrease in the fair value of our common stock warrant liability for the year ended December 31, 2024. This change was related to the revaluation of the liability associated with the Warrants, as defined below, we issued in December 2024 and was primarily the result of a decrease in our stock price during the period between the issuance date and December 31, 2024. We will continue to estimate the fair value of these Warrants at each balance sheet date and will record gain or loss on the statement of operations for changes between balance sheet dates.

(Loss) Gain on Investment in Affiliated Entity

The (loss) gain on investment in affiliated entity resulted from the change in the fair market value of our investment in PLS of $(1.2) million and $773,000 for the years ended December 31, 2024 and 2023, 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 on Available-for-Sale Equity Securities

The net unrealized gain on available-for-sale equity securities for the years ended December 31, 2024 and 2023 was $2.1 million and $5.9 million, respectively, which resulted from a change in the fair market value of the investments.

Other Expense, net

Other expense, net, of $3.2 million for the year ended December 31, 2024 was primarily due to a realized loss on our short-term investments sold during the year, as well as the financing costs we incurred in connection with the issuance of the Warrants, as defined below, in December 2024. Other expense, net, of $4.7 million for the year ended December 31, 2023 was primarily the result of realized losses on short-term investments sold during the year.

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, 2024, we had net operating loss carry forwards for U.S. federal, California and Pennsylvania income tax purposes of $1.1 billion, $259.9 million and $88.6 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 $46.1 million and $7.9 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 2025.

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 and debt securities, indebtedness and grants and government contracts.

Working Capital and Liquidity

As of December 31, 2024, we had cash and short-term investments of $94.1 million and working capital of $62.5 million, as compared to $145.3 million and $110.5 million as of December 31, 2023, respectively.

Cash Flows

Operating Activities

Net cash used in operating activities was $104.1 million and $124.4 million for the years ended December 31, 2024 and 2023, 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 $104.1 million and $87.4 million for the years ended December 31, 2024 and 2023, 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 $51.5 million and $5.0 million for the years ended December 31, 2024 and 2023, respectively. The variance was primarily due to the aggregate net proceeds of $60.8 million from the April 2024 Offering and December 2024 Offering (described below) and net proceeds of $6.1 million from the sale of common stock under at-the-market sales agreements, offset by the repayment of our convertible senior notes of $16.4 million in March 2024.

Offering of Common Stock and Warrants

On December 16, 2024, we closed an underwritten public offering, or the December 2024 Offering, relating to the issuance and sale of 10,000,000 shares of the common stock, and accompanying warrants to purchase 10,000,000 shares of common stock, or the Warrants, at an offering price of $3.00 per share and accompanying Warrant. The net proceeds from the December 2024 Offering were $27.6 million, after deducting the underwriting discounts and commissions and offering expenses paid by us.

Offering of Common Stock and Pre-Funded Warrants

On April 18, 2024, we closed an underwritten registered direct offering, or the April 2024 Offering, relating to the issuance and sale of 2,536,258 shares of common stock at a price of $7.693 per share and pre-funded warrants to purchase up to 2,135,477 shares of common stock, or the Pre-Funded Warrants, at a price of $7.692 per Pre-Funded Warrant, which represents the per share price for the shares less the $0.001 per share exercise price for each Pre-Funded Warrant. The net proceeds from the April 2024 Offering were $33.2 million, after deducting the underwriting discounts and commissions and offering expenses paid by us.

At-The-Market Sales Agreements

On August 13, 2024, we entered into an Equity Distribution Agreement, or the 2024 Sales Agreement, with an outside sales agent, or Sales Agent, for the offer and sale of our common stock for an aggregate offering price of up to $60.0 million. The 2024 Sales Agreement provides that the Sales Agent is 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 Agent under the 2024 Sales Agreement, and we have provided the Sales Agent with certain indemnification rights.

During the year ended December 31, 2024, we sold 133,900 shares of common stock under the 2024 Sales Agreement. The sales were made at a weighted average price of $7.02 per share, resulting in aggregate net proceeds of $925,000. As of December 31, 2024, there was $59.1 million of remaining capacity under the 2024 Sales Agreement.

On November 9, 2021, we entered into an ATM Equity Offering Sales Agreement, or the 2021 Sales Agreement, with outside sales agents, under which we were able to offer and sell shares of our common stock with aggregate gross proceeds of up to $300.0 million.

During the three months ended March 31, 2024, we sold 543,620 shares of our common stock under the 2021 Sales Agreement at a weighted average price of $9.76 per share, resulting in aggregate net proceeds of $5.2 million. During the year ended December 31, 2023, we sold 875,305 shares of our common stock under the 2021 Sales Agreement at a weighted

average price of $6.33 per share, resulting in aggregate net proceeds of $5.5 million. We terminated the 2021 Sales Agreement in August 2024 in connection with the entry into the 2024 Sales Agreement described above.

Other Issuances of Common Stock

During the year ended December 31, 2024, stock options to purchase 8,159 shares of common stock were exercised for aggregate net proceeds to us of $68,000, which proceeds were offset by tax payments made related to net share settlement of RSU awards of $421,000. During the year ended December 31, 2023, no stock options were exercised and tax payments of $467,000 were made related to the net share settlement of RSU awards.

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, 2024, we had an accumulated deficit of $1.7 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 will not be sufficient to complete the clinical development of our product candidates beyond INO-3107, 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 INO-3107 or any other product candidates that may 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 expect our cash runway to extend through the fourth quarter of 2025, without giving effect to any further capital raising activities that we may undertake.

Our ability to continue operations is dependent upon our ability to obtain additional capital in the future and achieve profitable operations. We expect to continue to rely on outside sources of financing to meet our capital needs and we may never achieve positive cash flow. In light of these factors, management believes that there is substantial doubt about our ability to continue as a going concern beyond the fourth quarter of 2025. The consolidated financial statements as of and for the year ended December 31, 2024 do not include any adjustments that might result from the outcome of this uncertainty.

Contractual Obligations

As of December 31, 2024, 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
Operating lease obligations (1)	$ 14,435,000	$ 3,483,000	$ 6,510,000	$ 4,442,000	$ —
Manufacturing commitments (2)	$ 269,000	$ 269,000	$ —	$ —	$ —

(1) We have entered into operating leases for our facilities, which expire from 2027 to 2029, and operating leases for office equipment, which expire in 2025. We have four active subleases for portions of our Plymouth Meeting corporate headquarters facility with two sublease periods through December 31, 2026, one through December 31, 2027 and one through December 31, 2029. As of December 31, 2024, we expect to receive aggregate future minimum lease payments totaling $2.4 million (non-discounted) over the duration of the sublease agreements, which expected payments are not included in the table above.

(2) 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. Over the past several years, there has been a pronounced overall increase in prevailing interest rates in the United States, which has contributed to the accumulated unrealized loss of $1.9 million in the market value of our investment portfolio as of December 31, 2024.

Foreign Currency Risk

We operate primarily in the United States and most transactions during the year ended December 31, 2024 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, 2024.

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, 2024 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, 2024, 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, 2024.

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, 2024, 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, 2024, 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.

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 2024 fiscal year, under the captions "Election of Directors," "Corporate Governance" 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 2024 fiscal year, under the captions "Executive Compensation" (excluding the information under the subheading "Pay Versus Performance Disclosure") 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 2024 fiscal year, under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans."

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 2024 fiscal year, under the captions "Executive Officers and Other Information - 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 2024 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	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).
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on April 17, 2024).
4.3	Form of Warrant issued in December 2024 (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on December 16, 2024).
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	Equity Distribution Agreement, dated August 13, 2024, by and between Inovio Pharmaceuticals, Inc. and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed on August 13, 2024).

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 (incorporated by reference to Exhibit 10.11 of the registrant's Form 10-K annual report for the year ended December 31, 2023 filed on March 6, 2024).
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 (incorporated by reference to Exhibit 10.17+ of the registrant's Form 10-K annual report for the year ended December 31, 2023 filed on March 6, 2024).
10.18+	Participation Agreement under Severance Plan for Jacqueline Shea (incorporated by reference to Exhibit 10.18+ of the registrant's Form 10-K annual report for the year ended December 31, 2023 filed on March 6, 2024).
10.19+	Participation Agreement under Severance Plan for Laurent Humeau (incorporated by reference to Exhibit 10.19+ of the registrant's Form 10-K annual report for the year ended December 31, 2023 filed on March 6, 2024).
10.20+	Participation Agreement under Severance Plan for Michael Sumner (incorporated by reference to Exhibit 10.20+ of the registrant's Form 10-K annual report for the year ended December 31, 2023 filed on March 6, 2024).

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).
19.1	Insider Trading Policy (filed herewith)
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 (incorporated by reference to Exhibit 97.1 of the registrant's Form 10-K annual report for the year ended December 31, 2023 filed on March 6, 2024).
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 with Embedded Linkbase Documents.
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 18, 2025.

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 18, 2025
/s/ SIMON X. BENITO **Simon X. Benito**	Chairman of the Board of Directors	March 18, 2025
/s/ PETER KIES **Peter Kies**	Chief Financial Officer (Principal Accounting Officer and Principal Financial Officer)	March 18, 2025
/s/ ROGER D. DANSEY **Roger D. Dansey**	Director	March 18, 2025
/s/ ANN C. MILLER **Ann C. Miller**	Director	March 18, 2025
/s/ JAY SHEPARD **Jay Shepard**	Director	March 18, 2025
/s/ DAVID B. WEINER **David B. Weiner**	Director	March 18, 2025
/s/ WENDY L. YARNO **Wendy L. Yarno**	Director	March 18, 2025
/s/ LOTA S. ZOTH **Lota S. Zoth**	Director	March 18, 2025

INOVIO PHARMACEUTICALS, INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Inovio Pharmaceuticals, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, has negative cash flows from operating activities, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the 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 account or disclosure to which it relates.

Accrual of clinical trial expenses

Description of the Matter	As of December 31, 2024, the Company accrued $2.0 million for clinical trial expenses. Clinical trial expenses primarily consists of external costs to be paid to clinical research organizations ("CROs") which are accrued and expensed based upon actual work completed in accordance with signed agreements. Auditing management's accounting for accrued clinical trial expenses is especially challenging because the evaluation is dependent upon data and inputs exchanged between 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 significant 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 18, 2025

Inovio Pharmaceuticals, Inc.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 65,813,297	$ 14,310,862
Short-term investments	28,300,232	130,982,913
Accounts receivable from affiliated entities	1,199,056	2,405,228
Prepaid expenses and other current assets, including with affiliated entity	2,517,465	5,414,097
Total current assets	97,830,050	153,113,100
Fixed assets, net	3,659,818	4,960,986
Investments in affiliated entity	1,613,844	2,780,287
Operating lease right-of-use assets	8,113,840	9,491,735
Other assets	1,979,654	605,315
Total assets	$ 113,197,206	$ 170,951,423
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 16,200,013	$ 19,847,744
Accounts payable and accrued expenses due to affiliated entities	1,351,163	1,070,519
Accrued clinical trial expenses	2,021,860	2,365,382
Common stock warrant liability	13,255,188	—
Operating lease liability	2,497,360	2,406,522
Grant funding liability, including from affiliated entity	—	109,407
Convertible senior notes	—	16,770,654
Total current liabilities	35,325,584	42,570,228
Operating lease liability, net of current portion	9,367,827	11,032,066
Total liabilities	44,693,411	53,602,294
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, 2024 and 2023	—	—
Common stock—par value $0.001; Authorized shares: 600,000,000 at December 31, 2024 and 2023, issued and outstanding: 36,099,991 at December 31, 2024 and 22,793,075 at December 31, 2023	36,099	22,792
Additional paid-in capital	1,799,362,625	1,740,954,074
Accumulated deficit	(1,730,219,262)	(1,622,965,136)
Accumulated other comprehensive loss	(675,667)	(662,601)
Total Inovio Pharmaceuticals, Inc. stockholders' equity	68,503,795	117,349,129
Total liabilities and stockholders' equity	$ 113,197,206	$ 170,951,423

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,	
	2024	**2023**
Revenue from collaborative arrangements and other contracts, including affiliated entity	$ 217,756	$ 832,010
Operating expenses:		
Research and development	75,620,340	86,676,563
General and administrative	36,996,338	47,582,104
Impairment of goodwill	—	10,513,371
Total operating expenses	112,616,678	144,772,038
Loss from operations	(112,398,922)	(143,940,028)
Other income (expense):		
Interest income	4,766,993	8,133,290
Interest expense	(177,833)	(1,222,789)
Change in fair value of common stock warrant liability	2,808,608	—
(Loss) gain on investment in affiliated entity	(1,166,443)	773,145
Net unrealized gain on available-for-sale equity securities	2,077,182	5,850,626
Other expense, net	(3,163,711)	(4,711,596)
Net loss	$ (107,254,126)	$ (135,117,352)
Net loss per share		
Basic and diluted	$ (3.95)	$ (6.09)
Weighted average number of common shares outstanding		
Basic and diluted	27,160,863	22,173,662

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,	
	2024	**2023**
Net loss	$ (107,254,126)	$ (135,117,352)
Other comprehensive loss:		
Foreign currency translation	32,403	(3,920)
Unrealized (loss) gain on short-term investments, net of tax	(45,469)	40,060
Comprehensive loss	$ (107,267,192)	$ (135,081,212)

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

Inovio Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity
	Number of shares	Amount	Number of shares	Amount				
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
Issuance of common stock for cash, net of financing costs	—	$ —	13,213,778	$ 13,214	$ 36,020,259	$ —	$ —	$ 36,033,473
Issuance of pre-funded warrants for cash, net of financing costs	—	—	—	—	16,146,397	—	—	16,146,397
Exercise of stock options for cash and vesting of RSUs, net of tax payments	—	—	93,138	93	(353,213)	—	—	(353,120)
Stock-based compensation	—	—	—	—	6,595,108	—	—	6,595,108
Net loss	—	—	—	—	—	(107,254,126)	—	(107,254,126)
Unrealized loss on short-term investments, net of tax	—	—	—	—	—	—	(45,469)	(45,469)
Foreign currency translation	—	—	—	—	—	—	32,403	32,403
Balance at December 31, 2024	9	$ —	36,099,991	$ 36,099	$ 1,799,362,625	$ (1,730,219,262)	$ (675,667)	$ 68,503,795

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,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (107,254,126)	$ (135,117,352)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,752,147	2,621,649
Amortization of intangible assets	—	145,417
Amortization of operating lease right-of-use assets	1,377,895	736,472
Change in fair value of common stock warrant liability	(2,808,608)	—
Impairment of goodwill	—	10,513,371
Impairment of intangible assets	—	1,984,444
Deferred taxes	—	(32,046)
Non-cash stock-based compensation	6,595,108	11,072,486
Non-cash interest on senior convertible notes	(355,654)	155,814
Amortization of discounts on investments	(1,690,527)	(4,686,144)
Realized loss on sales of short-term investments	1,905,369	4,805,804
Net (gain) loss on disposal of fixed assets	(22,466)	317,997
Loss (gain) on equity investment in affiliated entity	1,166,443	(773,145)
Net unrealized gain on available-for-sale equity securities	(2,077,182)	(5,850,626)
Changes in operating assets and liabilities:		
Accounts receivable, including from affiliated entities	1,206,172	9,332,988
Prepaid expenses and other current assets, including from affiliated entities	1,483,393	39,020,611
Other assets	38,900	78,729
Accounts payable and accrued expenses, including due to affiliated entities	(3,367,087)	(45,989,061)
Accrued clinical trial expenses	(343,522)	(8,228,691)
Operating lease right-of-use assets and liabilities, net	(1,573,401)	(2,020,971)
Grant funding liability, including from affiliated entity	(109,407)	(2,453,297)
Net cash used in operating activities	(104,076,553)	(124,365,551)
Cash flows from investing activities:		
Purchases of investments	(54,138,026)	(203,475,052)
Proceeds from sale or maturity of investments	158,637,578	284,932,562
Purchases of capital assets	(487,832)	(320,898)
Proceeds from sale of capital assets	59,319	6,219,263
Net cash provided by investing activities	104,071,039	87,355,875
Cash flows from financing activities:		
Repayment of convertible senior notes	(16,415,000)	—
Proceeds from issuance of pre-funded warrants, net of issuance costs	16,146,397	—
Proceeds from issuance of common stock, net of issuance costs	36,033,473	5,461,745
Proceeds from issuance of warrants	16,063,796	—
Proceeds from stock option exercises	67,675	—
Taxes paid related to net share settlement of equity awards	(420,795)	(466,646)
Net cash provided by financing activities	51,475,546	4,995,099
Effect of exchange rate changes on cash and cash equivalents	32,403	(3,920)
Increase (decrease) in cash and cash equivalents	51,502,435	(32,018,497)
Cash and cash equivalents, beginning of period	14,310,862	46,329,359
Cash and cash equivalents, end of period	$ 65,813,297	$ 14,310,862
Supplemental disclosure:		
Interest paid	$ 533,487	$ 1,066,975
Issuance of common stock as part of litigation settlement	$ —	$ 14,000,000

The accompanying notes are an integral part of these 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 HPV-associated diseases, 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 devices are designed to deliver the plasmids into the body's cells for optimal effect, without the use of chemical adjuvants, lipid nanoparticles or viral vectors.

INOVIO's lead candidate is INO-3107 for the treatment of recurrent respiratory papillomatosis (RRP), a chronic, 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 oropharyngeal squamous cell carcinoma (OPSCC) and anal dysplasia; 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 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, Coherus Biosciences, Defense Advanced Research Projects Agency (DARPA), 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 BioLogics, the University of Pennsylvania, the Walter Reed Army Institute of Research, and The Wistar Institute.

INOVIO was incorporated in Delaware in June 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 $107.3 million for the year ended December 31, 2024. The Company had working capital of $62.5 million and an accumulated deficit of $1.7 billion as of December 31, 2024. 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 $94.1 million as of December 31, 2024 are not sufficient to support the Company's operations for a period of at least 12 months from the date it is issuing these financial statements.

On December 16, 2024, the Company closed an underwritten public offering (the "December 2024 Offering"), relating to the issuance and sale of 10,000,000 shares of its common stock, par value $0.001 per share, and warrants to purchase 10,000,000 shares of common stock (the "Warrants"), at an offering price of $3.00 per share and accompanying Warrant. The exercise price of the Warrants is $3.76 per share. The net proceeds from the December 2024 Offering were $27.6 million, after deducting the underwriting discounts and commissions and offering expenses paid by the Company.

On April 18, 2024, the Company closed an underwritten registered direct offering (the "April 2024 Offering"), relating to the issuance and sale of 2,536,258 shares (the "Shares") of its common stock, par value $0.001 per share, at a price of $7.693 per share and pre-funded warrants to purchase up to 2,135,477 shares of common stock (the "Pre-Funded Warrants") at a price of $7.692 per Pre-Funded Warrant, which represents the per share price for the Shares less the $0.001 per share exercise price for each Pre-Funded Warrant. The net proceeds from the April 2024 Offering were $33.2 million, after deducting the underwriting discounts and commissions and offering expenses paid by the Company.

Going Concern

The Company's cash, cash equivalents and short-term investments of $94.1 million as of December 31, 2024 are expected to be sufficient to support the Company's planned operations through the fourth quarter of 2025. The Company's current

financial resources may not be sufficient to support its planned operations beyond this date without securing additional financing.

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 $60.8 million from equity offerings during the year ending December 31, 2024, and $6.1 million and $5.5 million from equity offerings under Sales Agreements during the years ending December 31, 2024 and 2023, respectively. 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’s ability to continue its operations is dependent upon its ability to obtain additional capital in the future and achieve profitable operations. The Company expects to continue to rely on outside sources of financing to meet its capital needs and may never achieve positive cash flow. In light of these factors, management believes that there is substantial doubt about the Company's ability to continue as a going concern beyond the fourth quarter of 2025. The Company's consolidated financial statements as of and for the year ended December 31, 2024 do not include any adjustments that might result from the outcome of this uncertainty. The Company has evaluated subsequent events after the balance sheet date through the date it issued these consolidated financial statements.

The Company is, and from time to time in the future may 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 its 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.

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 ("CODM"), the President and Chief Executive Officer, 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, as further described in Note 16.

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 common stock warrant liability. 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 estimated fair value of the common stock warrant liability is determined by using the Black-Scholes pricing model, as discussed in Note 5.

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, 2024 and 2023.

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, 2024 and 2023.

Short-term investments are recorded at fair value, based on current market valuations. Unrealized gains and losses on the Company's short-term debt securities 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 from Affiliated Entities

Accounts receivable from affiliated entities 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, 2024 or 2023.

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 years ended December 31, 2024 or 2023.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent

reporting period while the warrants are outstanding. The Pre-Funded Warrants issued in April 2024 met all the criteria for equity classification and were recorded as a component of additional paid-in capital on issuance. However, the Warrants issued in December 2024 did not meet all the criteria for equity classification and were recorded as a liability at fair value upon issuance. The Warrants met the definition of a derivative and did not meet any scope exceptions under ASC 815. As a result, the fair value of the liability associated with the Warrants will be remeasured at the end of each reporting period while the Warrants are outstanding, and any change in fair value between reporting periods will be recognized as gain or loss on the consolidated statement of operations for that reporting period.

Transaction costs associated with the issuance of the Warrants classified as a liability were expensed at the time of issuance and have been included as part of other expense, net, on the consolidated statement of operations for the year ended December 31, 2024.

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 carryforwards. 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 $349.2 million and $327.5 million at December 31, 2024 and 2023, 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.

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. The outstanding Pre-Funded Warrants (see Note 10) are included in the weighted-average common shares outstanding in the basic net loss per share calculation for the year ended December 31, 2024 given their nominal exercise price.

Diluted net loss per share is calculated in accordance with the treasury stock method for the outstanding Warrants, 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 Notes previously issued by the Company (discussed in Note 9) was 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, 2024 and 2023, basic and diluted net loss per share are the same, as the assumed exercise or settlement of common stock warrants, stock options, service-based RSUs, performance-and market-based RSUs and the potentially dilutive shares issuable upon conversion of the Notes prior to their repayment on March 1, 2024 would have been anti-dilutive.

Basic and diluted net loss per share for the year ended December 31, 2024 and 2023 are calculated as follows:

	Year Ended December 31,	
	2024	2023
Numerator:		
Net loss	$ (107,254,126)	$ (135,117,352)
Denominator:		
Shares used to compute net loss per share, basic and diluted		
Weighted-average common shares outstanding	25,655,527	22,173,662
Weighted-average shares underlying pre-funded warrants	1,505,336	—
Weighted-average common shares outstanding used to compute basic and diluted net loss per share	27,160,863	22,173,662
Net loss per share		
Basic and diluted	$ (3.95)	$ (6.09)

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,	
	2024	2023
Warrants to purchase common stock	10,000,000	—
Options to purchase common stock	1,337,228	1,128,864
Service-based restricted stock units	337,911	274,794
Performance-and market-based restricted stock units	128,800	—
Convertible preferred stock	275	275
Convertible notes	—	254,165
Total	11,804,214	1,658,098

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 service-based RSUs, performance-and market-based 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 Capital 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,	
	2024	2023
Risk-free interest rate	4.22%	4.05%
Expected volatility	105%	100%
Expected life in years	5.5	5.5
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,	
	2024	2023
Risk-free interest rate	4.21%	3.90%
Expected volatility	100%	89%
Expected life in years	6.5	10.0
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 has adopted ASU 2023-07 and included the segment disclosures in Note 16 below.

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 its consolidated financial statements.

ASU No. 2024-03. In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.* ASU

2024-03 requires public business entities to disaggregate operating expenses into specific categories such as employee compensation, depreciation, and intangible asset amortization, by relevant expense caption on the statement of operations. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, and may be applied either prospectively or retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance on the consolidated financial statements.

3. Revenue Recognition and Concentration of Credit Risk

During the years ended December 31, 2024 and 2023, 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	2024 Revenue	% of Total Revenue	2023 Revenue	% of Total Revenue
ApolloBio Corporation	$ 217,756	100 %	$ 245,056	29 %
All other, including affiliated entity	—	—	586,954	71
Total revenue	$ 217,756	100 %	$ 832,010	100 %

No revenue recognized during the years ended December 31, 2024 and 2023 was in deferred revenue as of December 31, 2023 and 2022, respectively.

As of December 31, 2024 and 2023, the Company had no accounts receivable balance.

4. Collaborative Agreements

Advaccine Biopharmaceuticals Suzhou Co., Ltd.

In 2020, the Company entered into a Collaboration and License Agreement with Advaccine Biopharmaceuticals Suzhou Co., Ltd. (“Advaccine”), which was amended and restated in 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 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. The Company has 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 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 accounts for the 2021 amendment under ASC Topic 808. Reimbursements from Advaccine are recognized as contra-research development expense on the consolidated statement of operations once earned and collectibility is assured. During the years ended December 31, 2024 and 2023, the Company received funding of $0 and $3.6 million respectively, from Advaccine that was recorded as contra-research and development expense.

ApolloBio Corporation

In 2017, the Company entered into an Amended and Restated License and Collaboration Agreement (the "ApolloBio Agreement"), with ApolloBio Corporation ("ApolloBio"), which was amended in June 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 years ended December 31, 2024 and 2023, the Company received $218,000 and $245,000, respectively, from the ApolloBio Agreement that was recorded as revenue.

Coalition for Epidemic Preparedness Innovations (CEPI)

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 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 year ended December 31, 2024, the Company received funding of $1.6 million in connection with the final close-out of these grants, which was recorded as contra-research and development expense. During the year ended December 31, 2023, the Company received funding of $1.8 million in connection with these grants.

Bill & Melinda Gates Foundation

In 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 2019, Gates funded an additional $1.1 million for the project. During the years ended December 31, 2024 and 2023, the Company recorded $39,000 and $70,000, respectively, as contra-research and development expense related to the Gates dMAb grant.

5. Short-term Investments and Fair Value Measurements

The following is a summary of available-for-sale securities as of December 31, 2024 and 2023:

		As of December 31, 2024			
	Contractual Maturity (in years)	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Mutual funds	---	$ 25,926,415	$ —	$ (1,445,706)	$ 24,480,709
Certificates of deposit	Less than 1	2,980,273	9,750	(281)	2,989,742
U.S. agency mortgage-backed securities	*	1,260,745	—	(430,964)	829,781
		$ 30,167,433	$ 9,750	$ (1,876,951)	$ 28,300,232

		As of December 31, 2023			
	Contractual Maturity (in years)	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

*No single maturity date.

During the years ended December 31, 2024 and 2023, the Company recorded gross realized gain on investments of $900 and $1,000, respectively, and gross realized loss on investments of $1.9 million and $4.8 million, respectively. During the years ended December 31, 2024 and 2023, the Company recorded net unrealized gain on available-for-sale equity securities of $2.1 million and $5.9 million, respectively. No material balances were reclassified out of accumulated other comprehensive loss for the years ended December 31, 2024 and 2023. 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, 2024, the Company had 19 available-for-sale securities with an aggregate total unrealized loss of $1.9 million. All of the securities had been in a loss position for longer than 12 months as of December 31, 2024.

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, 2024 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, 2024, 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 and liabilities that were measured at fair value on a recurring basis, determined using the following inputs as of December 31, 2024:

	Fair Value Measurements at December 31, 2024			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Unobservable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Short-term investments				
Mutual funds	$ 24,480,709	$ 24,480,709	$ —	$ —
Certificates of deposit	2,989,742	—	2,989,742	—
U.S. agency mortgage-backed securities	829,781	—	829,781	—
Total short-term investments	28,300,232	24,480,709	3,819,523	—
Investment in affiliated entity	1,613,844	1,613,844	—	—
Total assets measured at fair value	$ 29,914,076	$ 26,094,553	$ 3,819,523	$ —
Liabilities:				
Common stock warrant liability	$ 13,255,188	$ —	$ —	$ 13,255,188
Total liabilities	$ 13,255,188	$ —	$ —	$ 13,255,188

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	—
Investments in affiliated entity	2,780,287	2,780,287	—	—
Total assets measured at fair value	$ 133,763,200	$ 129,836,408	$ 3,926,792	$ —

Level 1 assets at December 31, 2024 consisted of mutual funds and the Company's investment in its affiliated entity, PLS. Level 1 assets at December 31, 2023 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, 2024 and 2023 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, 2024 or 2023.

Level 3 liabilities held as of December 31, 2024 consisted of liabilities associated with the Warrants to purchase common stock issued in the Company's underwritten public offering that closed in December 2024. See Note 10 for additional information about the liability-classified warrants.

The Company reassesses the fair value of the common stock warrant liability at each reporting date utilizing a Black-Scholes pricing model. The following assumptions were used to estimate the fair value of the warrant liability:

	On Issuance Date	December 31, 2024
Risk-free interest rate	4.3%	4.4%
Expected volatility	111%	111%
Expected life in years	5	5
Dividend yield	—	—

Changes in these assumptions as well as fluctuations in the Company's stock price between the valuation dates can have a significant impact on the fair value of the common stock warrant liability. Expected volatility was based on historical volatility. Historical volatility was computed using daily pricing observations for recent periods. The Company believes this method produced an estimate that was representative of the Company's expectations of future volatility over the expected term. Expected term is calculated based on the remaining contractual term of the Warrants. The risk-free rate was based on the U.S. Treasury rate that corresponds to the expected term of the Warrants. As a result of these calculations, the Company recorded a decrease in fair value of the liability of $2.8 million on the consolidated statement of operations for the year ended December 31, 2024.

The following table presents the changes in fair value of the Company's total Level 3 financial liabilities for the year ended December 31, 2024:

	Common Stock Warrant Liability
Balance at December 31, 2023	—
Issuance of common stock warrants in December 2024	16,063,796
Decrease in fair value of liability	(2,808,608)
Balance at December 31, 2024	$ 13,255,188

6. Certain Balance Sheet Items

Prepaid and other current assets at December 31, 2024 and 2023 consisted of the following:

	2024	2023
Prepaid clinical expenses (a)	627,962	3,410,442
Other prepaid expenses	1,889,503	2,003,655
	$ 2,517,465	$ 5,414,097

Accounts payable and accrued expenses at December 31, 2024 and 2023 consisted of the following:

	2024	2023
Trade accounts payable	$ 5,091,503	$ 3,577,826
Accrued compensation	10,007,180	9,837,104
Other accrued expenses (b)	1,101,330	6,432,814
	$ 16,200,013	$ 19,847,744

(a) As of December 31, 2024 and 2023, balance included $0 and $1.5 million, respectively, of prepaid manufacturing expenses.

(b) As of December 31, 2024 and 2023, balance included $0 and $4.3 million, respectively, of liability for unused grant funding.

7. Fixed Assets

Fixed assets at December 31, 2024 and 2023 consisted of the following:

	Cost	Accumulated Depreciation and Amortization	Net Book Value
As of December 31, 2024			
Leasehold improvements	$ 11,761,522	$ (8,390,612)	$ 3,370,910
Research and development equipment	2,835,298	(2,571,747)	263,551
Office furniture and fixtures	2,431,633	(2,416,232)	15,401
Computer equipment and other	3,093,812	(3,083,856)	9,956
	$ 20,122,265	$ (16,462,447)	$ 3,659,818
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

Depreciation expense for the years ended December 31, 2024 and 2023 was $1.8 million and $2.6 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, 2024, the Company sold fixed assets with no net book value for a gain of $59,000 and disposed of fixed assets with a net book value of $37,000. 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.

8. Goodwill and Intangible Assets

During 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 a quantitative impairment assessment of

its goodwill and long-lived assets. The goodwill was determined to be fully impaired as of September 30, 2023, and the Company recorded an impairment charge 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.

9. Convertible Debt

Convertible Senior Notes

In 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.

For the years ended December 31, 2024 and 2023, the Company recognized $178,000 and $1.2 million, respectively, of interest expense related to the Notes, of which $178,000 and $1.1 million, respectively, related to the contractual interest coupon.

10. Stockholders' Equity

Preferred Stock

			Shares Outstanding as of December 31,	
	Shares Authorized	Shares Issued	2024	2023
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, 2024, 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.

Offerings of Common Stock and Warrants

On December 16, 2024, the Company closed the December 2024 Offering (see "Basis of Presentation and Liquidity" in Note 2 above).

Each Warrant issued in the December 2024 Offering has an initial exercise price per share of $3.76, subject to certain adjustments. The Warrants may be exercised at any time, in whole or in part, until expiration on December 16, 2029. In the event there is no effective registration statement covering the shares of common stock underlying a Warrant exercise, the Warrants may be exercised via cashless exercise. A holder (together with its affiliates and other attribution parties) may not exercise any portion of a Warrant to the extent that immediately prior to or after giving effect to such exercise the holder would own more than 4.99% (or, for certain holders who so elected prior to the issuance of the Warrants, 9.99%) of the Company's outstanding Common Stock immediately after exercise, which percentage may be changed at the holder's election to a lower or higher percentage not in excess of 19.99% upon 61 days' notice to the Company subject to the terms of the Warrants.

As the Warrants are not indexed to the Company's common stock, the Company recorded a liability for the Warrants at fair value upon issuance on the Company's consolidated balance sheet. The common stock warrant liability is remeasured to fair value at the end of each reporting period.

As of December 31, 2024, no Warrants issued in the December 2024 Offering had been exercised.

On April 18, 2024, the Company closed the April 2024 Offering (see "Basis of Presentation and Liquidity" in Note 2 above).

Each Pre-Funded Warrant issued in the April 2024 Offering has an initial exercise price per share of $0.001, subject to certain adjustments. The Pre-Funded Warrants may be exercised at any time until exercised in full. A holder (together with its affiliates and other attribution parties) may not exercise any portion of a Pre-Funded Warrant to the extent that immediately prior to or after giving effect to such exercise the holder would own more than 9.99% of the Company's outstanding Common

Stock immediately after exercise, which percentage may be changed at the holder's election to a lower or higher percentage not in excess of 19.99% upon 61 days' notice to the Company subject to the terms of the Pre-Funded Warrants.

As the Pre-Funded Warrants issued in the April 2024 Offering are indexed to the Company's own shares of common stock (and otherwise meet the requirements to be classified in equity), the Company recorded the consideration received from the issuance of the Pre-Funded Warrants as additional paid-in capital on the Company's condensed consolidated balance sheet as of December 31, 2024.

As of December 31, 2024, no Pre-Funded Warrants had been exercised.

At-The-Market Sales Agreements

On August 13, 2024, the Company entered into an Equity Distribution Agreement (the "2024 Sales Agreement") with an outside sales agent (the "Sales Agent") for the offer and sale of its common stock for an aggregate offering price of up to $60.0 million. The 2024 Sales Agreement provides that the Sales Agent is 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 Agent under the 2024 Sales Agreement, and the Company has provided the Sales Agent with certain indemnification rights.

During the year ended December 31, 2024, the Company sold 133,900 shares of its common stock under the 2024 Sales Agreement. The sales were made at a weighted average price of $7.02 per share, resulting in aggregate net proceeds of $925,000. As of December 31, 2024, there was $59.1 million of remaining capacity under the 2024 Sales Agreement.

On November 9, 2021, the Company entered into an ATM Equity Offering Sales Agreement (the "2021 Sales Agreement") with outside 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 were entitled to compensation in an amount equal to up to 3.0% of the gross sales proceeds of any common stock sold under the 2021 Sales Agreement. During the three months ended March 31, 2024, the Company sold 543,620 shares of its common stock under the 2021 Sales Agreement at a weighted average price of $9.76 per share, resulting in aggregate net proceeds of $5.2 million. During the year ended December 31, 2023, the Company sold 875,305 shares of its common stock under the 2021 Sales Agreement at a weighted average price of $6.33 per share, resulting in aggregate net proceeds of $5.5 million. The 2021 Sales Agreement was terminated in August 2024 in connection with the entry into the 2024 Sales Agreement described above.

Other Issuances of Common Stock

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

Stock Options and Restricted Stock Units

The 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, 2024, the Company had 800,526 shares of common stock available for future grant under the 2023 Plan, 188,082 shares underlying outstanding but unvested RSUs and 282,579 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.

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. At December 31, 2024, the Company had 129,000 shares underlying outstanding but unvested RSU and options outstanding to purchase 904,669 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.

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, 2024 the Company had 84,328 shares of common stock available for future grant under the 2022 Inducement Plan, 20,829 shares underlying outstanding but unvested RSUs and options outstanding to purchase 53,684 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, 2024, the Company had options outstanding to purchase 96,296 shares of common stock under the 2007 Incentive Plan. The awards granted under the 2007 Incentive Plan generally vested 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, 2024 and 2023 was $6.4 million and $10.4 million, respectively, of which $2.8 million and $4.5 million was included in research and development expenses and $3.6 million and $5.9 million was included in general and administrative expenses, respectively.

At December 31, 2024 and 2023, there was $2.1 million and $4.3 million, respectively, of total unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of 1.5 years and 1.3 years, respectively.

At December 31, 2024 and 2023, there was $2.0 million and $3.5 million, respectively, of total unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of 1.6 years and 1.5 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, 2024 and 2023 was $226,000 and $669,000, respectively. As of December 31, 2024, options to purchase 66,056 shares of common stock granted to non-employees remained outstanding.

The following table summarizes total stock options outstanding at December 31, 2024:

	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
$1.78-$18.00	568,085	8.8	$ 10.95	205,698	$ 12.08
$18.01-$39.00	249,917	6.2	$ 35.52	191,644	$ 35.28
$39.01-$52.00	152,066	3.5	$ 44.95	151,949	$ 44.95
$52.01-$90.00	126,336	3.2	$ 76.92	123,316	$ 77.39
$90.01-$130.00	112,293	3.4	$ 98.68	112,293	$ 98.68
$130.01-$233.28	128,531	5.3	$ 137.48	128,531	$ 137.48
	1,337,228	6.4	$ 45.17	913,431	$ 59.52

At December 31, 2024, the aggregate intrinsic value of options outstanding was $1,000, the aggregate intrinsic value of options exercisable was $0, and the weighted average remaining contractual term of options exercisable was 5.5 years.

At December 31, 2024, the aggregate intrinsic value of unvested RSUs was $618,000 and the aggregate intrinsic value of RSUs which vested during the year ended December 31, 2024 was $1.3 million.

At December 31, 2024, options to purchase 1,337,228 shares of common stock and 337,911 RSUs were expected to vest.

Stock option activity under the Company’s equity incentive plans during the year ended December 31, 2024 was as follows:

	Number of Shares	Weighted-Average Exercise Price
Balance, December 31, 2023	1,128,864	$ 58.76
Granted	328,376	8.27
Exercised	(8,159)	8.29
Cancelled	(111,853)	76.67
Balance, December 31, 2024	1,337,228	$ 45.17

Restricted stock unit activity under the Company’s equity incentive plans during the year ended December 31, 2024 was as follows:

	Number of Shares
Balance, December 31, 2023	274,794
Granted	214,207
Vested	(126,133)
Cancelled	(24,957)
Balance, December 31, 2024	337,911

The weighted average exercise price per share was $139.02 for the 38,503 options which expired during the year ended December 31, 2024 and $38.86 for the 9,357 options which expired during the year ended December 31, 2023.

The weighted average grant date fair value per share was $6.69 and $11.19 for options granted during the years ended December 31, 2024 and 2023, respectively.

The weighted average grant date fair value was $8.30 and $10.34 per share for RSUs granted during the years ended December 31, 2024 and 2023, respectively.

The Company received $68,000 in proceeds from the exercise of stock options during the years ended December 31, 2024. No stock options were exercised during the year ended December 31, 2023. The aggregate intrinsic value of options exercised was $39,000 during the year ended December 31, 2024.

Performance- and Market-Based RSUs

In May 2024, the Company granted performance- and-market-based RSUs (such performance-based grants, the "PSU Awards") to key employees under the 2023 Plan. Each PSU was expressed as a target number of RSUs. With respect to the PSU Awards, the Company's Board of Directors established specified performance goals and corresponding performance periods over which the goals must be attained, the satisfaction of which are conditions to earning the PSU Awards and vesting of the underlying RSUs. As of December 31, 2024, 83,800 performance- and market-based RSUs were outstanding.

Of the target number of RSUs underlying each PSU Award, up to 70% (the "Milestone-based RSUs") will vest based on the achievement of specified milestones relating to the development, regulatory status and commercialization of the Company’s lead product candidate INO-3107 (each, a "Milestone," and collectively, the "Milestones"). Each Milestone has a specified deadline for achievement ranging between the end of 2025 and the end of 2027.

The remaining 30% of the target number of RSUs underlying each PSU Award (the "Market-based RSUs") will be eligible to vest based on the Company’s achievement of total stockholder return relative to a peer group consisting of companies in the Russell 2000 Biotechnology Subsector index (the “Relative TSR”) over the period beginning on June 1, 2024 and ending on December 31, 2027 (the “Performance Period”), expressed as a percentile ranking.

The number of Market-based RSUs, if any, actually earned based on the achievement of the Relative TSR goal may range from 50% of the target number of RSUs for performance at a specified threshold percentile, to 100% of the target number of RSUs for performance at the target percentile, and up to 150% of the target number of RSUs for performance at or above a specified maximum percentile. In the event that actual Relative TSR performance is between the threshold and target levels or between the target and maximum levels, the number of RSUs earned based on Relative TSR will be determined based on linear interpolation between the specified percentiles. If the Company’s actual Relative TSR performance is below the threshold percentile, then no RSUs would be earned based on Relative TSR. The number of RSUs earned based on Relative TSR may not exceed the target number of RSUs eligible to vest based on Relative TSR if the Company’s total stockholder return is negative for the Performance Period.

The Company valued the Milestone-based RSUs based on the grant date closing price per share. The Company recognizes stock-based compensation expense over the performance period, if it is probable that the performance condition will be achieved. Adjustments to stock-based compensation expense are made, as needed, each reporting period based on changes in the Company's estimate of the number of units that are probable of vesting.

The Company valued the Market-based RSUs on the grant date using the Monte Carlo simulation method, a generally accepted statistical technique used to simulate a range of possible future stock prices for the Company and the peer group. The determination of fair value was affected by the Company's stock price and a number of assumptions including the expected volatility and the risk-free interest rate. The Company will recognize stock-based compensation expense ratably over the performance period of the award. The market-based RSUs will cliff-vest at the end of the three-year period ranging from zero to 150% of the target number of awards granted.

The significant assumptions used in the Monte Carlo simulation method were as follows:

Risk-free interest rate	4.60%
Expected volatility	90%
Expected life in years	3.61
Dividend yield	—

The grant date fair value of the Milestone-based RSUs was $643,000 based on the grant date closing price per share of $10.96. As of December 31, 2024, the underlying performance milestones of the Milestone-based RSUs were determined to be not probable of achievement, and no stock-based compensation expense was recognized for the year then ended.

The grant date fair value of the Market-based RSUs was $269,000 based on the fair value of $10.69 per share as determined using the Monte Carlo simulation method. For the year ended December 31, 2024, the Company recognized $44,000 in stock-based compensation for the Market-based RSUs.

December 2024 Performance-Based Awards

In December 2024, the Company granted performance-based stock options and RSUs (such performance-based grants, the "December 2024 Awards") to key employees under the 2023 Plan. Each award was expressed as a target number of stock options and RSUs. With respect to the December 2024 Awards, the Company's Board of Directors established specified performance goals and a corresponding performance period over which the goals must be attained, the satisfaction of which are conditions to earning the December 2024 Awards and vesting of the underlying stock options and RSUs. As of December 31, 2024, December 2024 Awards were outstanding covering 25,686 shares of common stock underlying stock options and 19,314 shares of common stock underlying RSUs.

The grant date fair value of the performance-based RSUs was $34,000 based on the grant date closing price per share of $1.78. The grant date fair value of the performance-based stock options was $38,000 based on the Black-Scholes per share value of $1.46. As of December 31, 2024, the underlying performance milestones of the December 2024 Awards were determined to be not probable of achievement, and no stock-based compensation expense was recognized for the year then ended.

11. Commitments and Contingencies

Leases

The Company leases approximately 56,600 square feet of office, laboratory, and manufacturing space in San Diego, California and approximately 57,400 square feet of office space in Plymouth Meeting, Pennsylvania under various non-cancellable operating lease agreements with remaining lease terms as of December 31, 2024 of 2.4 to 5.0 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.

The base rent adjusts periodically throughout the term of the leases. Rent payments under the leases include base rent with annual increases of approximately two to three percent, and additional monthly fees to cover the Company's share of certain facility expenses, including utilities, property taxes, insurance and maintenance.

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, 2024, the maturities of the Company's operating lease liabilities were as follows:

Year ending December 31,	
2025	$ 3,483,000
2026	3,555,000
2027	2,955,000
2028	2,310,000
2029	2,132,000
Total remaining lease payments	14,435,000
Less: present value adjustment	(2,570,000)
Total operating lease liabilities	11,865,000
Less: current portion	(2,497,000)
Long-term operating lease liabilities	$ 9,368,000

Weighted-average remaining lease term	4.3 years
Weighted-average discount rate	9.0 %

Lease costs included in operating expenses in the consolidated statements of operations for the years ended December 31, 2024 and 2023 were $2.6 million and $3.5 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 2023, the Company entered into agreements to sublease a total of approximately 11,400 square feet in its Plymouth Meeting headquarters with sublease terms through December 31, 2026.

During 2024, the Company amended the sublease agreements for its Plymouth Meeting headquarters to extend one sublease term through December 31, 2027 and the other through December 31, 2029.

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 2020, a purported shareholder class action complaint was filed naming the Company and its former President and Chief Executive Officer as defendants and alleging that the Company made materially false and misleading statements in violation of certain federal securities laws. In 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 issued 760,083 shares of its common stock, with a value of $14.0 million at the time, to settle all outstanding claims. The Company's insurance carriers paid the $30.0 million cash component of the settlement.

Shareholder Derivative Litigation

In 2020, a purported shareholder derivative complaint was filed 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 2020 and 2022, additional shareholder derivative complaints were filed.

In June 2023, the court entered an order preliminarily approving a 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, but VGXI later discontinued its third-party claims. 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. In October 2021, GeneOne filed its answer to the Company's counterclaims and new matter. On February 29, 2024, the Company filed a motion for summary judgment. On April 1, 2024, GeneOne filed an opposition to the Company's motion for summary judgment. On June 28, 2024, the court denied the motion for summary judgment. 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,	
	2024	2023
U.S. Domestic	$ (107,254,126)	$ (134,979,579)
Foreign	—	(137,772)
Pretax loss from operations	$ (107,254,126)	$ (135,117,351)

There was no provision for or benefit from income taxes for the years ended December 31, 2024 and 2023.

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, 2024 and 2023, is as follows:

	Year Ended December 31,	
	2024	2023
Benefit from income taxes at statutory rates	$ (22,523,000)	$ (28,375,000)
State income tax, net of federal benefit	(1,543,000)	(3,922,000)
Change in valuation allowance	21,749,000	28,394,000
Research and development tax credits	(5,846,000)	(2,139,000)
Stock-based compensation	1,579,000	2,099,000
Uncertain tax positions	2,344,000	861,000
Goodwill impairment	—	1,962,000
Expired NOLs and credits	4,687,000	1,352,000
Limited NOLs and credits	(2,056,000)	(997,000)
Change in tax rates	403,000	365,000
Foreign tax rate differential	—	(4,000)
Other	1,206,000	404,000
	$ —	$ —

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2024 and 2023 are shown below:

	As of December 31,	
	2024	2023
Deferred tax assets:		
Capitalized research expense	$ 54,204,000	$ 50,143,000
NOL carryforwards	250,336,000	235,624,000
Research and development and other tax credits	31,250,000	27,734,000
Deferred revenue	—	22,000
Stock-based compensation	3,060,000	3,683,000
Acquired intangibles	774,000	907,000
Investment in affiliated entity	1,651,000	1,406,000
Lease liability	2,492,000	2,822,000
Fixed assets	441,000	337,000
Other	6,720,000	6,808,000
	350,928,000	329,486,000
Valuation allowance	(349,224,000)	(327,493,000)
Total deferred tax assets	1,704,000	1,993,000
Deferred tax liabilities:		
Right of use asset	(1,704,000)	(1,993,000)
Total deferred tax liabilities	(1,704,000)	(1,993,000)
Net deferred tax liabilities	$ —	$ —

As of December 31, 2024, the Company had federal, California and other state tax net operating loss (NOL) carryforwards of $1.1 billion, $259.9 million and $88.6 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 $801.9 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 2025, and the California and other state NOL carryforwards will begin and have begun to expire in 2028 and 2025, respectively, unless previously utilized.

The Company also had Korean NOL carryforward of $1.0 million as of December 31, 2024. 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, 2024, the Company had federal and state research and development (R&D) tax credit carryforwards of $46.1 million and $7.9 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
2025	$ 16.0	$ 5.2	$ —	$ —	$ —
2026	17.1	7.1	—	—	—
2027	6.1	1.9	—	—	—
2028 and thereafter	245.9	333.6	1.0	46.1	—
Indefinite	801.9	0.7	—	—	7.9
	$ 1,087.0	$ 348.5	$ 1.0	$ 46.1	$ 7.9

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, 2024. As a result of the analysis, the Company estimates that approximately $5.3 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, could 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 2024 and 2023, 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,	
	2024	2023
Balance at beginning of the year	$ 22,114,000	$ 21,139,000
Increases related to current year tax positions	2,297,000	1,816,000
Increases (decreases) related to prior year tax positions	197,000	(841,000)
Balance at end of the year	$ 24,608,000	$ 22,114,000

The amount of unrecognized tax benefits that, if recognized and realized, would affect the effective tax rate was $22.9 million and $20.5 million as of December 31, 2024 and 2023, 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 2021 and state and local income tax examinations before 2020. 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 $961,000 and $1.4 million for the years ended December 31, 2024 and 2023, respectively.

14. Related Party Transactions

Plumbline Life Sciences, Inc.

The Company owned 597,808 shares of common stock in PLS as of December 31, 2024 and 2023, representing a 17.3% and 17.8% ownership interest, respectively. The Company's investment in PLS is recorded as investment in affiliated entity on the consolidated balance sheet as of December 31, 2024 and 2023, and was valued at $1.6 million and $2.8 million, respectively, based on the closing price of the shares on the Korea New Exchange Market at the applicable balance sheet date. One of the Company's directors, Dr. David B. Weiner, acts as a consultant to PLS.

The Wistar Institute

Dr. Weiner is a director of the Vaccine Center of The Wistar Institute ("Wistar") and an Executive Vice President of Wistar.

In 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 2021,

upon expiration of the 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. In August 2024, the sub-grant was amended to a total of $12.5 million in funding through September 2025.

In 2022, the Company received a $1.2 million sub-grant through Wistar, which was amended in 2024 to $2.4 million with funding through November 2024, with an option for an additional $4.2 million in funding that extends the sub-grant 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, 2024 and 2023, the Company recorded $482,000 and $1.0 million, respectively, as contra-research and development expense from Wistar.

Research and development expenses recorded from Wistar relate primarily to the collaborative research agreements. Research and development expenses recorded from Wistar for the years ended December 31, 2024 and 2023 were $1.5 million and $1.8 million, respectively. At December 31, 2024 and 2023, the Company had an accounts receivable balance of $1.2 million and $2.4 million, respectively, and an accounts payable and accrued liability balance of $1.4 million and $1.1 million, respectively, related to Wistar. As of December 31, 2024 and 2023, the Company had a prepaid expense balance of $0 and $20,000, respectively, and recorded $0 and $22,000, respectively, as deferred grant funding on its consolidated balance sheet related to Wistar.

15. Geneos Therapeutics, Inc.

In 2016, the Company formed Geneos Therapeutics ("Geneos") to develop and commercialize neoantigen-based personalized cancer therapies. 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.

As of December 31, 2024, the Company held 23% of the outstanding equity of Geneos, on an as-converted to common stock basis. The Company accounts for its common stock investment in Geneos as an equity method investment under ASC 323. Due to continuing net losses of Geneos, the Company’s investment had been reduced to $0 as of each of December 31, 2024 and 2023. The Company has not made any further investment in Geneos. 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.

The Company continues to exclusively license its immunotherapy platform and CELLECTRA technology 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. Segment Information

The Company operates as one reportable segment in the United States, which includes all activities related to the development and commercialization of its DNA medicines to help treat and protect people from HPV-associated diseases, cancer and infectious diseases.

The Company's Chief Executive Officer (CEO) is its Chief Operating Decision Maker (CODM), responsible for allocating resources and assessing Company performance using aggregated financial information. Utilizing aggregated financial information enables the CODM to determine the most appropriate resource allocation across the organization, research and development projects or other initiatives consistent with the Company's corporate objectives. The CODM primarily uses total net loss as reported on the statements of operations and comprehensive loss to measure segment loss, supplemented by certain additional significant expense details reflected in the table below. The measure of segment assets is reported on the consolidated balance sheet as total assets.

Detailed information regarding the Company's single operating segment's revenues, expenses and operating loss are as follows:

	Year Ended December 31,	
	2024	2023
Revenue from collaborative arrangements and other contracts, including affiliated entity	$ 217,756	$ 832,010
Less:		
Research and development:		
INO-3107	29,930,344	17,840,728
INO-5401 and other Immuno-oncology	6,293,401	11,758,935
Other programs (a)	(77,955)	18,701,675
Engineering and device-related	19,393,929	8,863,170
Stock-based compensation	2,821,226	4,606,341
Other unallocated expenses (b)	17,259,395	24,905,714
General and administrative	36,996,338	47,582,104
Impairment of goodwill	—	10,513,371
Total operating expenses	112,616,678	144,772,038
Interest income	4,766,993	8,133,290
Interest expense	(177,833)	(1,222,789)
Change in fair value of common stock warrant liability	2,808,608	—
(Loss) gain on investment in affiliated entity	(1,166,443)	773,145
Net unrealized gain on available-for-sale equity securities	2,077,182	5,850,626
Other expense, net	(3,163,711)	(4,711,596)
Net loss	$ (107,254,126)	$ (135,117,352)

(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 2023.

17. Subsequent Events

From January 1, 2025 through the date of these financial statements, the Company sold 512,518 shares of common stock under the 2024 Sales Agreement at a weighted average price of $2.16 per share, for net proceeds of $1.1 million.