UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED MARCH 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**

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

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

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

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

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

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

The number of shares outstanding of the Registrant's Common Stock, $0.001 par value, was 25,910,701 as of May 10, 2024.

INOVIO PHARMACEUTICALS, INC.
FORM 10-Q

For the Quarterly Period Ended March 31, 2024

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SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

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 Item 1A. Risk Factors herein. These risk factors include, but are not limited to, the following:

- We have incurred significant losses in recent years, expect to incur significant net losses in the foreseeable future and may never become profitable.
- We have limited sources of revenue and our success is dependent on our ability to develop our DNA medicines and proprietary device technology.
- We will need substantial additional capital to develop our DNA medicines and proprietary device technology, which may prove difficult or costly to obtain.
- None of our DNA medicine candidates have been approved for sale, and we may never develop commercially successful DNA medicine products.
- DNA medicines are a novel approach to treating and preventing disease, and our CELLECTRA ® delivery devices are a novel approach to administering medicines, and negative perception of the efficacy, safety, or tolerability of any investigational medicines we develop or our devices could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals.
- If we and the contract manufacturers upon whom we rely fail to produce our proprietary devices and DNA medicine candidates in the volumes that we require on a timely basis, or at all, or if these contractors fail to comply with their obligations to us or with stringent regulations, we may face delays in the development and commercialization of our proprietary devices and DNA medicine candidates.
- If we lose or are unable to secure collaborators or partners, or if our collaborators or partners do not apply adequate resources to their relationships with us, our product development and potential for profitability will suffer.
- We have agreements with government agencies that are subject to termination and uncertain future funding. Termination or cessation of funding would have a negative impact on our ability to develop certain of our pipeline candidates and/or require us to seek alternative funding sources to advance product candidates.
- Our operating results may be harmed if our corporate restructuring plans and cost reduction efforts do not achieve the anticipated results or cause undesirable consequences.
- We are currently subject to litigation and may become subject to additional litigation, which could harm our business, financial condition and reputation.
- We face intense and increasing competition and steps taken by our competitors, such as the introduction of a new, disruptive technology may impede our ability to develop and commercialize our DNA medicines.
- We have entered into collaborations with Chinese companies and rely on clinical materials manufactured in China for our development efforts. Uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, a trade war, political unrest or unstable economic conditions in China could materially adversely affect our business, financial condition and results of operations.
- It is difficult and costly to generate and protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.
- If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.
- Failure or perceived failure to comply with laws, regulations, contracts, self-regulatory schemes, notices and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase our costs and otherwise negatively affect our operating results and business.

Part I. Financial Information

Item 1. Financial Statements

INOVIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,601,829	$ 14,310,862
Short-term investments	86,013,044	130,982,913
Accounts receivable from affiliated entities	2,551,082	2,405,228
Prepaid expenses and other current assets	3,517,081	5,393,665
Prepaid expenses and other current assets from affiliated entities	—	20,432
Total current assets	111,683,036	153,113,100
Fixed assets, net	5,015,067	4,960,986
Investment in affiliated entity	2,654,269	2,780,287
Operating lease right-of-use assets	9,156,478	9,491,735
Other assets	605,315	605,315
Total assets	$ 129,114,165	$ 170,951,423
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 16,675,922	$ 19,847,744
Accounts payable and accrued expenses due to affiliated entity	1,525,079	1,070,519
Accrued clinical trial expenses	3,022,486	2,365,382
Operating lease liability	2,155,540	2,406,522
Grant funding liability	—	87,489
Grant funding liability from affiliated entity	21,918	21,918
Convertible senior notes	—	16,770,654
Total current liabilities	23,400,945	42,570,228
Operating lease liability, net of current portion	11,271,257	11,032,066
Total liabilities	34,672,202	53,602,294
Stockholders' equity:		
Preferred stock	—	—
Common stock	23,370	22,792
Additional paid-in capital	1,748,529,814	1,740,954,074
Accumulated deficit	(1,653,435,007)	(1,622,965,136)
Accumulated other comprehensive loss	(676,214)	(662,601)
Total Inovio Pharmaceuticals, Inc. stockholders' equity	94,441,963	117,349,129
Total liabilities and stockholders' equity	$ 129,114,165	$ 170,951,423

See accompanying notes to unaudited condensed consolidated financial statements.

INOVIO PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Revenue from collaborative arrangements and other contracts	$ —	$ 114,943
Operating expenses:		
Research and development	20,913,790	30,176,511
General and administrative	10,571,179	13,890,610
Total operating expenses	31,484,969	44,067,121
Loss from operations	(31,484,969)	(43,952,178)
Other income (expense):		
Interest income	1,500,290	2,207,171
Interest expense	(177,833)	(313,488)
(Loss) gain on investment in affiliated entity	(126,018)	616,639
Net unrealized gain on available-for-sale equity securities	500,877	3,218,215
Other expense, net	(682,218)	(2,425,676)
Net loss	$ (30,469,871)	$ (40,649,317)
Net loss per share		
Basic and diluted [(1)]	$ (1.31)	$ (1.89)
Weighted average number of common shares outstanding		
Basic and diluted [(1)]	23,291,512	21,536,476

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

See accompanying notes to unaudited condensed consolidated financial statements.

INOVIO PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Net loss	$ (30,469,871)	$ (40,649,317)
Other comprehensive loss:		
Foreign currency translation	32,403	(1,918)
Unrealized (loss) gain on short-term investments, net of tax	(46,016)	117,862
Comprehensive loss	$ (30,483,484)	$ (40,533,373)

See accompanying notes to unaudited condensed consolidated financial statements.

INOVIO PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)

	Three Months Ended March 31, 2024							
	Preferred stock		Common stock [1]					
	Number of shares	Amount	Number of shares	Amount	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity
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	—	—	543,620	544	5,224,589	—	—	5,225,133
Vesting of RSUs, net of tax payments	—	—	34,558	34	(174,282)	—	—	(174,248)
Stock-based compensation	—	—	—	—	2,525,433	—	—	2,525,433
Net loss	—	—	—	—	—	(30,469,871)	—	(30,469,871)
Unrealized loss on short-term investments, net of tax	—	—	—	—	—	—	(46,016)	(46,016)
Foreign currency translation	—	—	—	—	—	—	32,403	32,403
Balance at March 31, 2024	9	$ —	23,371,253	$ 23,370	$ 1,748,529,814	$ (1,653,435,007)	$ (676,214)	$ 94,441,963

	Three Months Ended March 31, 2023							
	Preferred stock		Common stock [1]					
	Number of shares	Amount	Number of shares	Amount	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity
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
Vesting of RSUs, net of tax payments	—	—	43,901	44	(424,748)	—	—	(424,704)
Stock-based compensation	—	—	—	—	3,809,003	—	—	3,809,003
Net loss	—	—	—	—	—	(40,649,317)	—	(40,649,317)
Unrealized gain on short-term investments, net of tax	—	—	—	—	—	—	117,862	117,862
Foreign currency translation	—	—	—	—	—	—	(1,918)	(1,918)
Balance at March 31, 2023	9	$ —	21,894,922	$ 21,894	$ 1,728,271,686	$ (1,528,497,101)	$ (582,797)	$ 199,213,682

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

See accompanying notes to unaudited condensed consolidated financial statements.

INOVIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
ash flows from operating activities:		
et loss	$ (30,469,871)	$ (40,649,317)
djustments to reconcile net loss to net cash used in operating activities:		
Depreciation	424,473	707,378
Amortization of intangible assets	—	82,083
Amortization of operating lease right-of-use assets	335,257	362,664
Non-cash stock-based compensation	2,525,433	3,809,003
Non-cash interest on senior convertible notes	(355,654)	(219,999)
Amortization of discounts on investments	(684,651)	(1,159,083)
Loss on sales of short-term investments	691,168	2,425,676
Loss on disposal of fixed assets	—	334,297
Loss (gain) on equity investment in affiliated entity	126,018	(616,639)
Net unrealized gain on available-for-sale equity securities	(500,877)	(3,218,215)
hanges in operating assets and liabilities:		
Accounts receivable, including from affiliated entities	(145,854)	6,703,110
Prepaid expenses and other current assets, including from affiliated entities	1,897,016	39,324,542
Other assets	—	31,527
Accounts payable and accrued expenses, including due to affiliated entities	(3,160,238)	(40,737,879)
Accrued clinical trial expenses	657,104	(4,798,227)
Operating lease right-of-use assets and liabilities, net	(11,791)	(693,691)
Grant funding liability, including from affiliated entity	(87,489)	1,648,292
et cash used in operating activities	(28,759,956)	(36,664,478)
ash flows from investing activities:		
Purchases of investments	(9,751,047)	(80,431,174)
Proceeds from sale or maturity of investments	55,169,260	93,657,050
Purchases of capital assets	(35,578)	(296,983)
Proceeds from sale of capital assets	—	6,071,000
et cash provided by investing activities	45,382,635	18,999,893
ash flows from financing activities:		
Repayment of convertible senior notes	(16,415,000)	—
Proceeds from issuance of common stock, net of issuance costs	5,225,133	—
Taxes paid related to net share settlement of equity awards	(174,248)	(424,704)
et cash used in financing activities	(11,364,115)	(424,704)
Effect of exchange rate changes on cash and cash equivalents	32,403	(1,918)
ncrease (Decrease) in cash and cash equivalents	5,290,967	(18,091,207)
ash and cash equivalents, beginning of period	14,310,862	46,329,359
ash and cash equivalents, end of period	$ 19,601,829	$ 28,238,152
upplemental disclosures:		
mounts accrued for purchases of fixed assets	$ 442,976	$ —
nterest paid	$ 533,487	$ 533,187
suance of common stock as part of litigation settlement	$ —	$ 14,000,000

See accompanying notes to unaudited condensed consolidated financial statements.

INOVIO PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Organization and Operations

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

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

INOVIO's lead candidate is INO-3107 for the treatment of recurrent respiratory papillomatosis (RRP), a life-long, rare 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 August 2023 that it was ceasing development for this indication in the United States. However, its collaborator ApolloBio Corporation continues to conduct a Phase 3 clinical trial of this candidate in China and plans to seek regulatory approval for and potentially commercialize the candidate in that jurisdiction.

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

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

2. Basis of Presentation, Liquidity and Risks and Uncertainties

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Inovio have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) as contained in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The condensed consolidated balance sheet as of March 31, 2024, the condensed consolidated statements of operations, the condensed consolidated statements of comprehensive loss, the condensed consolidated statements of stockholders' equity and the condensed consolidated statements of cash flows for the three months ended March 31, 2024 and 2023 are unaudited, but include all adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of the financial position, results of operations, cash flows and changes in stockholders' equity for the periods presented.

The results of operations for the three months ended March 31, 2024 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2024, or for any other period. These unaudited financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2023, included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) on March 6, 2024. The balance sheet at December 31, 2023 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

These unaudited condensed consolidated financial statements include the accounts of Inovio Pharmaceuticals, Inc. and its subsidiary. As of March 31, 2024 and December 31, 2023, the Company consolidated its wholly-owned subsidiary Inovio Asia LLC. All intercompany accounts and transactions were eliminated upon consolidation.

Liquidity

The Company incurred a net loss attributable to common stockholders of $ 30.5 million for the three months ended March 31, 2024. The Company had working capital of $ 88.3 million and an accumulated deficit of $ 1.7 billion as of March 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.

On April 18, 2024, the Company closed an underwritten registered direct offering (the "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 Offering were approximately $ 33.2 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company. The Company's cash, cash equivalents and short-term investments of $ 105.6 million as of March 31, 2024, together with the net proceeds from the April 2024 Offering, are expected to be sufficient to support the Company's planned operations for a period of at least 12 months from the date of issuance of these financial statements.

In order to continue to fund future research and development activit ies, 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 At-the-Market Equity Offering Sales Agreements ("Sales Agreements"). The Company has a history of conducting debt and equity financings, including the receipt of net proceeds of $ 5.2 million and $ 5.5 million under a Sales Agreement during the three months ended March 31, 2024 and year ended December 31, 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 the Company may never achieve positive cash flow. These condensed consolidated financial statements do not include any adjustments to the specific amounts and classifications of assets and liabilities, which might be necessary should Inovio be unable to continue as a going concern. The Company's condensed consolidated financial statements as of and for the three months ended March 31, 2024 have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business for the foreseeable future. The Company has evaluated subsequent events after the balance sheet date through the date it issued these condensed consolidated financial statements.

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

Reverse Stock Split

On January 24, 2024, the Company filed with the Secretary of State of the State of Delaware a certificate of amendment to its certificate of incorporation, as previously amended, to effect a 1-for-12 reverse stock split of 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. All share amounts and per share amounts disclosed in this Quarterly Report on Form 10-Q have been restated to reflect the reverse stock split on a retroactive basis for all periods presented.

3. Critical Accounting Policies

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”).

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.

4. Short-term Investments and Fair Value Measurements

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

		As of March 31, 2024			
	Contractual Maturity (in years)	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Mutual funds	---	$ 45,541,438	$ —	$ (3,022,011)	$ 42,519,427
U.S. treasury securities	Less than 1	39,596,119	—	(8,719)	39,587,400
Certificates of deposit	Less than 1	2,979,254	11,222	(295)	2,990,181
U.S. agency mortgage-backed securities	*	1,331,885	—	(415,849)	916,036
		$ 89,448,696	$ 11,222	$ (3,446,874)	$ 86,013,044

		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 three months ended March 31, 2024 and 2023, the Company recorded gross realized gains on investments of $ 200 and $ 300 , respectively, and gross realized losses on investments of $ 691,000 and $ 2.4 million, respectively. During the three months ended March 31, 2024 and 2023, the Company recorded net unrealized gain on available-for-sale equity securities of $ 501,000 and $ 3.2 million, respectively. No material balances were reclassified out of accumulated other comprehensive loss for the three months ended March 31, 2024 and 2023. Interest and dividends on investments classified as available-for-sale are included in interest income in the condensed consolidated statements of operations. As of March 31, 2024, the Company had 25 available-for-sale securities with an aggregate total unrealized loss of $ 3.4 million. Of these securities, 19 had been in a loss position for longer than 12 months as of March 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 March 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 March 31, 2024, the Company has not recorded an allowance for credit losses related to its available-for-sale debt securities.

The following table presents the Company's assets that were measured at fair value on a recurring basis, determined using the following inputs as of March 31, 2024:

	Fair Value Measurements at March 31, 2024			
	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Unobservable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Short-term investments				
Mutual funds	$ 42,519,427	$ 42,519,427	$ —	$ —
U.S. treasury securities	39,587,400	39,587,400	—	—
Certificates of deposit	2,990,181	—	2,990,181	—
U.S. agency mortgage-backed securities	916,036	—	916,036	—
Total short-term investments	86,013,044	82,106,827	3,906,217	—
Investment in affiliated entity	2,654,269	2,654,269	—	—
Total assets measured at fair value	$ 88,667,313	$ 84,761,096	$ 3,906,217	$ —

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

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

Level 1 assets at March 31, 2024 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 March 31, 2024 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 March 31, 2024 or December 31, 2023.

5. Certain Balance Sheet Items

Prepaid and other current assets consisted of the following:

	March 31, 2024	December 31, 2023
Prepaid manufacturing expenses	228,378	1,486,638
Other prepaid expenses	3,288,703	3,907,027
	$ 3,517,081	$ 5,393,665

Accounts payable and accrued expenses consisted of the following:

	March 31, 2024	December 31, 2023
Trade accounts payable	$ 6,772,184	$ 3,577,826
Accrued compensation	5,685,560	9,837,104
Other accrued expenses (a)	4,218,178	6,432,814
	$ 16,675,922	$ 19,847,744

(a) As of March 31, 2024 and December 31, 2023, balance includes $ 2.3 million and $ 4.3 million, respectively, of liability for unused grant funding.

6. Convertible Debt

Convertible Senior Notes

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

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

For the three months ended March 31, 2024 and 2023, the Company recognized $ 178,000 and $ 313,000 , respectively, of interest expense related to the Notes, of which $ 178,000 and $ 267,000 , respectively, related to the contractual interes t coupon.

7. Stockholders’ Equity

The following is a summary of the Company's authorized and issued common and preferred stock as of March 31, 2024 and December 31, 2023:

			Outstanding as of	
	Authorized	Issued	March 31, 2024	December 31, 2023
Common Stock, par value $ 0.001 per share	600,000,000	23,371,253	23,371,253	22,793,075
Series C Preferred Stock, par value $ 0.001 per share	1,091	1,091	9	9

Issuances of Common Stock

On November 9, 2021, the Company entered into an ATM Equity Offering SM Sales Agreement (the “2021 Sales Agreement”) with outside sales agents (collectively, the “Sales Agents”) for the offer and sale of its common stock for an

aggregate offering price of up to $ 300.0 million. The 2021 Sales Agreement provides that the Sales Agents were entitled to compensation in an amount equal to up to 3.0 % of the gross sales proceeds of any common stock sold through the Sales Agents under the 2021 Sales Agreement. During the 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. As of March 31, 2024, the registration statement relating to the shares of common stock issuable under the 2021 Sales Agreement has expired, and therefore as of the date of these financial statements the Company may not sell any additional shares under the 2021 Sales Agreement.

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

Stock Options and Restricted Stock Units

The 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, restricted stock units ("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 March 31, 2024, the Company had 917,945 shares of common stock available for future grant under the 2023 Plan, 171,750 shares underlying outstanding RSUs and 260,109 shares underlying options outstanding to purchase common stock under the 2023 Plan. The awards granted and available for future grant under the 2023 Plan generally vest over three years and have a maximum contractual term of ten years . The 2023 Plan terminates by its terms on March 24, 2033.

At March 31, 2024, the Company had 207,594 shares underlying outstanding but unvested RSUs and options outstanding to purchase 950,763 shares of common stock under the 2016 Plan. The outstanding awards granted under the 2016 Plan generally vest over three years and have a maximum contractual term of ten years . Following adoption of the 2023 Plan, no further awards may be made under the 2016 Plan, but outstanding awards continue to be governed by their existing terms.

On June 24, 2022, the Company's board of directors adopted a stock-based incentive plan (the "2022 Inducement Plan"), which provides for the discretionary grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, RSU awards, performance awards, and other awards to individuals as a material inducement to entering into employment with the Company. The aggregate number of shares of the Company’s common stock that may be issued under the 2022 Inducement Plan will not exceed 166,666 shares. At March 31, 2024, the Company had 116,515 shares of common stock available for future grant under the 2022 Inducement Plan, 12,776 shares underlying outstanding but unvested RSUs and options outstanding to purchase 33,071 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 M arch 31, 2007 and terminated by its terms on March 31, 2017. At March 31, 2024, the Company had options outstanding to purchase 111,235 shares of common stock under the 2007 Incentive Plan. The outstanding awards granted under the 2007 Incentive Plan are fully vested and generally have a maximum contractual term of ten years .

8. Net Loss Per Share

Basic net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated in accordance with the treasury stock method for the outstanding stock options and RSUs and reflects the potential dilution that would occur if securities or other con tracts 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 6) 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 the 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 three months ended March 31, 2024 and 2023, basic and diluted net loss per share were the same, as the assumed exercise or settlement of stock options and RSUs and the potentially dilutive shares issuable upon conversion of the Notes would have been anti-dilutive.

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

	Three Months Ended March 31,	
	2024	2023
Options to purchase common stock	1,355,178	1,271,620
Service-based restricted stock units	392,120	179,149
Convertible preferred stock	275	275
Convertible notes	—	254,165
Total	1,747,573	1,705,209

9. Stock-Based Compensation

The Company incurs stock-based compensation expense related to RSUs and stock options. The fair value of restricted stock is determined by the closing price of the Company's common stock reported on the Nasdaq 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:

	Three Months Ended March 31,	
	2024	2023
Risk-free interest rate	4.21 %	4.09 %
Expected volatility	105 %	99 %
Expected life in years	5.5	5.5
Dividend yield	—	—

Total employee and director stock-based compensation expense recognized in the condensed consolidated statements of operations for the three months ended March 31, 2024 and 2023 was $ 2.4 million and $ 3.6 million, respectively, of which $ 1.0 million and $ 1.5 million, respectively, was included in research and development expenses, and $ 1.4 million and $ 2.1 million, respectively, was included in general and administrative expenses.

At March 31, 2024, there was $ 4.3 million of total unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of 1.7 years.

The weighted average grant date fair value per share, calculated using the Black-Scholes option pricing model, was $ 6.77 and $ 11.64 for employee and director stock options granted during the three months ended March 31, 2024 and 2023, respectively.

At March 31, 2024, there was $ 4.1 million of total unrecognized compensation expense related to unvested service-based RSUs, which is expected to be recognized over a weighted-average period of 1.9 years.

The weighted average grant date fair value per share was $ 8.39 and $ 14.40 for service-based RSUs granted during the three months ended March 31, 2024 and 2023, 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 three months ended March 31, 2024 and 2023 was $ 103,000 and $ 220,000 , respectively.

10. Related Party Transactions

Plumbline Life Sciences, Inc.

The Company owned 597,808 shares of common stock in PLS as of March 31, 2024, representing an ownership interest of 17.8 %, and 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 March 2016, the Company entered into collaborative research agreements with Wistar for preventive and therapeutic DNA-based immunotherapy applications and products developed by Dr. Weiner and Wistar for the treatment of cancers and infectious diseases. Under the terms of the agreement, the Company reimbursed Wistar for all direct and indirect costs incurred in the conduct of the collaborative research, not to exceed $ 3.1 million during the five-year term of the agreements. In March 2021, upon expiration of the March 2016 agreements, the Company entered into new collaborative research agreements with Wistar with the same terms. The Company has the exclusive right to in-license new intellectual property developed under this agreement.

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

In December 2022, the Company received a $ 1.2 million sub-grant through Wistar with funding through November 2023, with an option for an additional $ 5.4 million in funding 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 three months ended March 31, 2024 and 2023, the Company recorded $ 140,000 and $ 211,000 , 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 three months ended March 31, 2024 and 2023 were $ 475,000 and $ 422,000 , respectively. At March 31, 2024 and December 31, 2023, the Company had an accounts receivable balance of $ 2.5 million and $ 2.4 million, respectively, and an accounts payable and accrued liability balance of $ 1.5 million and $ 1.1 million, respectively, related to Wistar. At each of March 31, 2024 and December 31, 2023, the Company recorded $ 22,000 as deferred grant funding on its condensed consolidated balance sheet related to Wistar.

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 March 31, 2024 of 3.2 to 5.8 years, which represent the non-cancellable periods of the leases. The Company has excluded the extension options from its lease terms in the calculation of future lease payments as they are not reasonably certain to be exercised. The Company's lease payments consist primarily of fixed rental payments for the right to use the underlying leased assets over the lease terms as well as payments for common area maintenance and administrative services. The Company has received customary incentives from its landlords, such as reimbursements for tenant improvements and rent abatement periods, which effectively reduce the total lease payments owed for these leases.

In November 2023, the Company entered into a lease agreement for research and development laboratory space in San Diego, California. The total space under the lease is approximately 5,600 square feet. The term of the lease commenced on February 10, 2024 and the initial term is 4.3 years.

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

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 condensed 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 March 31, 2024, the maturities of the Company's operating lease liabilities were as follows:

Remainder of 2024	$	2,457,000
2025		3,467,000
2026		3,555,000
2027		2,955,000
2028		2,310,000
Thereafter		2,132,000
Total remaining lease payments		16,876,000
Less: present value adjustment		(3,449,000)
Total operating lease liabilities		13,427,000
Less: current portion		(2,156,000)
Long-term operating lease liabilities	$	11,271,000

Weighted-average remaining lease term	5.0 years
Weighted-average discount rate	9.0 %

Lease costs included in operating expenses in the condensed consolidated statements of operations for the three months ended March 31, 2024 and 2023 were $ 837,000 and $ 840,000 , respectively. Operating lease costs consisting of the fixed lease payments included in operating lease liabilities are recorded on a straight-line basis over the lease terms. Variable lease costs are recorded as incurred.

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

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

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

Legal Proceedings

Securities Litigation

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

Shareholder Derivative Litigation

In April 2020, a purported shareholder derivative complaint, Behesti v. Kim, et al., was filed in the United States District Court for the Eastern District of Pennsylvania, naming eight current and former directors of the Company as defendants. The lawsuit asserted state and federal claims and was based on the same alleged misstatements as the shareholder class action

complaint described above. The lawsuit accused the Company's board of directors of failing to exercise reasonable and prudent supervision over the Company's management, policies, practices, and internal controls. The plaintiff sought unspecified monetary damages on behalf of the Company as well as governance reforms. Between June 2020 and August 2020, additional shareholder derivative complaints were filed and later consolidated by the court.

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

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

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

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

VGXI Litigation

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

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

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

GeneOne Litigation

In December 2020, GeneOne filed a complaint in the Court of Common Pleas of Montgomery County, Pennsylvania against the Company, alleging that the Company had breached the CELLECTRA Device License Agreement, or the Agreement, between the Company and GeneOne. The Company terminated the Agreement in October 2020. The complaint asserts claims for breach of contract, declaratory judgment, unfair competition, and unjust enrichment. The complaint seeks injunctive relief, an accounting, damages, disgorgement of profits, attorneys' fees, interest, and other relief from the Company. The Company filed preliminary objections to the complaint, which were overruled by the court. In September 2021, the Company filed an answer to the complaint, new matter, and counterclaims. The Company's counterclaims allege that GeneOne breached the Agreement and assert claims for breach of contract and declaratory judgment. The counterclaims seek damages, interest, expenses, attorney's fees, and costs. 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. The Court has set the motion for summary judgment for a hearing on June 28, 2024. 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. Collaborative Agreements

Advaccine Biopharmaceuticals Suzhou Co., Ltd.

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

In connection with the June 2021 amendment, the Company determined that the global Phase 3 trial component of the agreement was a collaboration and not a contract with a customer and therefore accounted for the June 2021 amendment under ASC Topic 808. Reimbursements from Advaccine were recognized as contra-research development expense on the condensed consolidated statement of operations once earned and collectibility was assured. For the three months ended March 31, 2023, the Company received funding of $ 1.2 million from Advaccine that was recorded as contra-research and development expense. No funding was received during the three months ended March 31, 2024.

ApolloBio Corporation

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

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

There were no significant reimbursable program costs under the ApolloBio Agreement during the three months ended March 31, 2024 and 2023.

Coalition for Epidemic Preparedness Innovations

The Company previously entered into agreements with CEPI, pursuant to which the Company intended to develop vaccine candidates against Lassa fever and MERS. As part of the arrangement between the parties, CEPI agreed to fund up to an aggregate of $ 56 million of costs over a five-year period for preclinical studies, as well as planned Phase 1 and Phase 2 clinical trials, to be conducted by the Company and collaborators, with funding from CEPI based on the achievement of identified milestones. In November 2022, the Company announced that it and CEPI would discontinue the development of these product candidates targeting Lassa fever and MERS, following the initial analysis of data from the studies conducted by the Company and funded by CEPI. During the three months ended March 31, 2024 and 2023, the Company received funding of $ 0 and $ 1.6 million, respectively, related to these grants and recorded those payments as contra-research and development

expense. As of each of March 31, 2024 and December 31, 2023, the Company had $ 2.2 million recorded as an accrued liability on the condensed consolidated balance sheet related to these CEPI grants.

In January 2020, CEPI awarded the Company a grant of up to $ 9.0 million to support preclinical and clinical development of INO-4800 through Phase 1 human testing in the United States. In April 2020, CEPI awarded the Company a grant of $ 6.9 million to work with the International Vaccine Institute ("IVI") and the Korea National Institute of Health ("KNIH") to conduct clinical trials of INO-4800 in South Korea, a grant of $ 5.0 million to accelerate development of the Company's next-generation intradermal electroporation device, known as CELLECTRA 3PSP, for the intradermal delivery of INO-4800, and a grant of $ 1.3 million to support large-scale manufacturing of INO-4800. During the three months ended March 31, 2024 and 2023, the Company received funding of $ 0 and $ 53,000 , respectively, from CEPI related to these grants for INO-4800 and recorded such amounts as contra-research and development expense.

Bill & Melinda Gates Foundation

In October 2018, Gates awarded and funded the Company a grant of $ 2.2 million to advance the development of DMAbs to address issues in infectious disease prevention and therapy. This technology has high relevance for the control of influenza and HIV. This next-generation approach to the delivery of monoclonal antibodies would make the technology accessible to low and middle-income countries. In August 2019, Gates funded an additional $ 1.1 million for the project. During the three months ended March 31, 2024 and 2023, the Company recorded $ 39,000 and $ 59,000 , respectively, as contra-research and development expense related to the Gates DMAb grant. As of March 31, 2024, the Company had $ 49,000 recorded as an accrued liability on the condensed consolidated balance sheet related to the grant.

13. Income Taxes

The Company uses an estimated annual effective tax rate, which is based on expected annual income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates, to determine its quarterly provision for income taxes. Certain significant or unusual items are separately recognized in the quarter in which they occur and can be a source of variability in the effective tax rates from quarter to quarter. Due to the adoption of ASU 2019-12 which removes the exception under ASC 740-20-45-7 to consider all sources of income in order to determine the tax benefit resulting from a loss from continuing operations, ASC 740-20-45-7 no longer applies.

For the three months ended March 31, 2024 and 2023, the Company did not record any income tax provision/(benefit) due to the Company’s history of net operating losses generated and the maintenance of a full valuation allowance against its net deferred tax assets.

14. Geneos Therapeutics, Inc.

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

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

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

Upon deconsolidation, the Company recorded its investment at fair value. The Company determined that its investment in Geneos did not have a readily determinable fair value and therefore elected the measurement alternative in ASC 321 to subsequently record the investment at cost, less any impairments, plus or minus changes resulting from observable price

changes in orderly transactions for identical or similar investments of the same issuer. When fair value becomes determinable, from observable price changes in orderly transactions, the Company's investment is marked to fair value. There have been no observable price changes or impairments identified since the deconsolidation date.

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

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

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

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

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

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

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

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

15. Subsequent Events

On April 18, 2024, the Company closed an underwritten registered direct offering (the "Offering") relating to the issuance and sale by the Company of 2,536,258 shares (the "Shares") of the Company's common stock, par value $ 0.001 per share (the "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 (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 to the Company from the Offering were approximately $ 33.2 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company. All of the Shares and the Pre-Funded Warrants were sold by the Company.

Each Pre-Funded Warrant 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 % (if exceeding such percentage would result in a change of control under Nasdaq Listing Rule 5635(b) or any successor rule) upon 61 days' notice to the Company subject to the terms of the Pre-Funded Warrants.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly 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 Quarterly 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 condensed consolidated financial statements and the related notes and other financial information appearing elsewhere in this Quarterly Report and our audited consolidated financial statements and related notes for the year ended December 31, 2023 included in our Annual Report on Form 10-K, or 2023 Annual Report, filed with the U.S. Securities and Exchange Commission, or SEC, on March 6, 2024. Readers are also urged to carefully review and consider the various disclosures made by us that attempt to advise interested parties of the factors that affect our business, including without limitation the disclosures made in Item 1A of Part II of this Quarterly Report under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the disclosures made in our 2023 Annual Report under the caption "Risk Factors" and in our audited consolidated financial statements and related notes.

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 preclinical 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 smart device technology and DNA medicine candidates may fail to show the desired safety and efficacy traits in clinical trials; the availability of funding; the ability to manufacture our DNA medicine candidates; the availability or potential availability of alternative therapies or treatments for the conditions targeted by us or our collaborators, including alternatives that may be more efficacious or cost-effective than any therapy or treatment that we and our collaborators hope to develop; our ability to receive development, regulatory and commercialization event-based payments under our collaborative agreements; whether our proprietary rights are enforceable or defensible or infringe or allegedly infringe on rights of others or can withstand claims of invalidity; and the impact of government healthcare laws and proposals.

Overview

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

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

Our lead candidate is INO-3107 for the treatment of recurrent respiratory papillomatosis, or RRP, a 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. The standard of care for RRP is surgery. The most widely cited U.S. epidemiology data, published in 1995, estimated that there were 14,000 active cases for both adults and juveniles, and about 1.8 new cases per 100,000 adults each year.

In our completed Phase 1/2 clinical trial of INO-3107 for the treatment of HPV-6 and HPV-11-associated RRP, 81.3% of patients experienced a reduction in the number of surgical interventions in the year following administration of INO-3107, when compared with the year prior to treatment. In February 2023, we announced data from the second cohort of our Phase 1/2 clinical trial, which followed the announcement of the first cohort in October 2022. In the second cohort of 11 patients who were administered INO-3107 via an exploratory side port injection needle, 10 of the 11 patients (91%) saw a reduction in surgical interventions in the year following initial treatment, with the measurement beginning on Day 0, the start of trial therapy. Of these 10 patients, four did not require surgery. There was a statistically significant median decrease of three surgical interventions when comparing the year following treatment to the year prior to treatment. INO-3107 was well-tolerated and immunogenic among patients in the second cohort. The safety and efficacy results for the second cohort were consistent with results announced for the first cohort in October 2022.

In the fourth quarter of 2023, we received feedback from the U.S. Food and Drug Administration, or FDA, that the data from this completed trial could be used to support the submission of a Biologic License Application, or BLA, for review under the FDA's accelerated approval program. As part of submitting our BLA under the accelerated program, which we plan to do in the second half of 2024, we will need to satisfy all FDA filing requirements and initiate a confirmatory clinical trial prior to BLA submission.

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. The incidence of HPV-related throat cancer has increased rapidly in recent years in the United States, with an estimated approximately 20,000 new cases each year. HPV-related throat cancer has 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.

In January 2024, we announced a clinical collaboration and supply agreement with Coherus BioSciences, Inc. to evaluate the combination of INO-3112 and LOQTORZI (toripalimab-tpzi) 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 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 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 August 2023 that we were ceasing development for this indication in the United States. However, our collaborator ApolloBio Corporation continues to conduct a Phase 3 clinical trial of this candidate in China and plans to seek regulatory approval for and potentially commercialize the candidate in that jurisdiction.

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

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

As of March 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.

Recent Developments

On April 18, 2024, we closed an underwritten registered direct offering (the "Offering") relating to the issuance and sale of 2,536,258 shares (the "Shares") of our 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 Offering were approximately $33.2 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Critical Accounting Policies and Estimates

There have been no significant changes to our critical accounting estimates since December 31, 2023. For a description of our critical accounting estimates and significant judgments used in the preparation of our condensed consolidated financial statements, refer to Note 3 to our Condensed Consolidated Financial Statements included in this Quarterly Report, as well as Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2023 Annual Report and Note 2 to our audited Consolidated Financial Statements contained in our 2023 Annual Report.

Results of Operations

Revenue. Total revenue was $0 for the three months ended March 31, 2024 as compared to $115,000 for the three months ended March 31, 2023, all of which was derived under collaborative arrangements and other contracts.

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 table summarizes our research and development expense by product candidate for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,		Increase (Decrease)	
(dollars in thousands)	**2024**	**2023**	**$**	**%**
INO-4800 and other COVID-19 programs	$ 215	$ 8,922	$ (8,707)	(98) %
VGX-3100	380	2,138	(1,758)	(82) %
INO-3107	7,646	3,312	4,334	131 %
INO-5401 and other Immuno-oncology	2,021	2,152	(131)	(6) %
Other research and development programs (a)	28	3,729	(3,701)	(99) %
Engineering and device-related	3,751	2,438	1,313	54 %
Stock-based compensation	1,060	1,481	(421)	(28) %
Other unallocated expenses	5,813	6,005	(192)	(3) %
Research and development expense	$ 20,914	$ 30,177	$ (9,263)	(31) %

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

The $9.3 million decrease in research and development expenses for the three-month period year over year was primarily the result of:

- $7.8 million in lower drug manufacturing related to INO-4800 after we discontinued this program in the fourth quarter of 2022;
- $5.6 million in lower employee and consultant compensation, including stock-based compensation;

- $1.6 million in lower drug manufacturing related to other COVID-19 studies that we ceased after we discontinued development of INO-4800; and
- 1.0 million in lower clinical study expenses related to VGX-3100 as we discontinued development of this product candidate in the third quarter of 2023.

These decreases were partially offset by $2.9 million of lower contra-research and development expense recorded from grant agreements, $2.9 million of higher drug manufacturing expenses related to INO-3107, and $1.1 million of higher expensed inventory, among other variances.

Contributions received from current grant agreements and recorded as contra-research and development expense were $179,000 for the three months ended March 31, 2024 as compared to $3.1 million for the three months ended March 31, 2023. The decrease for the three-month period year over year was primarily due to a decrease of $1.6 million earned under the CEPI LASSA and MERS grants and $1.2 million in reimbursements from Advaccine.

General and administrative expenses. General and administrative expenses, which include business development expenses and patent expenses, were $10.6 million for the three months ended March 31, 2024, as compared to $13.9 million for the three months ended March 31, 2023. Decreases for the three-month period year over year included:

- $2.0 million in employee compensation, including employee and consultant stock-based compensation; and
- $1.1 million in legal expenses related to litigation matters settled in 2023 that did not recur in 2024.

Stock-based compensation. Stock-based compensation expense is measured at the grant date, based on the fair value of the award, and is recognized as expense over the requisite vesting period. Total employee and director stock-based compensation expense for the three months ended March 31, 2024 and 2023 was $2.4 million and $3.6 million, of which $1.0 million and $1.5 million was included in research and development expenses and $1.4 million and $2.1 million was included in general and administrative expenses, respectively. The decrease was due to a lower weighted average grant date fair value for the awards granted during 2024.

Interest income. Interest income for the three months ended March 31, 2024 and 2023 was $1.5 million and $2.2 million, respectively. The decrease for the three-month period year over year was primarily due to a lower short-term investment balance.

Interest expense. Interest expense for the three months ended March 31, 2024 and 2023 was $178,000 and $313,000, respectively. The decrease was primarily due to lower interest expense on our senior convertible promissory notes that were repaid in full on March 1, 2024.

(Loss) gain on investment in affiliated entities. The (loss) gain resulted from the change in the fair market value of our investment in PLS of $(126,000) and $617,000 for the three months ended March 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 condensed 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 three months ended March 31, 2024 and 2023 of $501,000 and $3.2 million, respectively, resulted from a change in the fair market value of the investments.

Other expense, net. Other expense, net, for the three months ended March 31, 2024 and 2023 of $(682,000) and $(2.4) million, respectively, related primarily to the realized loss on short-term investments sold during the periods.

Liquidity and Capital Resources

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

Working Capital and Liquidity

As of March 31, 2024, we had cash, cash equivalents and short-term investments of $105.6 million and working capital of $88.3 million, as compared to $145.3 million and $110.5 million, respectively, as of December 31, 2023.

Cash Flows

Operating Activities

Net cash used in operating activities was $28.8 million and $36.7 million for the three months ended March 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 $45.4 million and $19.0 million for the three months ended March 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 used in financing activities was $11.4 million and $425,000 for the three months ended March 31, 2024 and 2023, respectively. The variance was primarily due to the repayment of our convertible senior notes of $16.4 million, offset by net proceeds of $5.2 million from the sale of common stock under the Sales Agreement (defined below) during the three months ended March 31, 2024, compared to no proceeds received during the three months ended March 31, 2023.

Issuances of Common Stock

On November 9, 2021, we entered into an ATM Equity Offering℠ Sales Agreement, or the Sales Agreement, with outside sale s agents, or collectively, the 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, through the Sales Agents.

During the three months ended March 31, 2024 , we sold 543,620 shares of our common stock under the 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 Sales Agreement at a weighted average price of $6.33 per share, resulting in aggregate net proceeds of $5.5 million. As of March 31, 2024, the registration statement relating to the shares of common stock issuable under the Sales Agreement has expired, and therefore as of the date of this report we may not sell any additional shares under the Sales Agreement.

During the three months ended March 31, 2024, no stock options were exercised and tax payments of $174,000 were made related to the net sh are settlement of RSU awards. During the three months ended March 31, 2023 , no stock options were exercised and tax payments of $425,000 were made related to 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 condensed consolidated financial statements included in this report.

Funding Requirements

As of March 31, 2024, we had an accumulated deficit of $1.7 billion, and we expect to continue to operate at a loss for the near term. The amount of our accumulated deficit will continue to increase, as it will be expensive to continue research and development efforts. Our current cash resources, including the net proceeds of our April 2024 public offering of common stock, 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 believe that our current cash and short-term investments are sufficient to meet our planned working capital requirements for at least the next twelve months from the date of this report.

We expect our cash runway, including the net proceeds of the April 2024 offering, to extend into the third quarter of 2025, without giving effect to any further capital raising activities that we may undertake.

We have existing supply agreements with contract manufacturers to manufacture drug substance. At March 31, 2024, we had approximately $5.3 m illion in minimum purchase obligations in connection with these agreements. We expect to satisfy these obligations from existing cash over the next twelve months.

During the three months ended March 31, 2024, except for the repayment in full of our convertible senior notes as described above, there have been no other significant changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2023 Annual Report.

ITEM 3. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

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

2022, which has contributed to the unrealized loss of $3.4 million in the market value of our investment portfolio as of March 31, 2024.

Foreign Currency Risk

We operate primarily in the United States and most transactions during the three months ended March 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 three months ended March 31, 2024.

ITEM 4. 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 Quarterly 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 March 31, 2024 at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

Part II. Other Information

ITEM 1. 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, the Company filed a petition for preliminary injunction, which was denied.

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

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

GeneOne Litigation

In December 2020, GeneOne filed a complaint in the Court of Common Pleas of Montgomery County, Pennsylvania against us, alleging that we had breached the CELLECTRA Device License Agreement, or the Agreement, between us and GeneOne. We terminated the Agreement in October 2020. The complaint asserts claims for breach of contract, declaratory judgment, unfair competition, and unjust enrichment. The complaint seeks injunctive relief, an accounting, damages, disgorgement of profits, attorneys' fees, interest, and other relief from us. We filed preliminary objections to the complaint, which were overruled. In September 2021, we filed an answer to the complaint, new matter, and counterclaims. Our counterclaims allege that GeneOne breached the Agreement and assert claims for breach of contract and declaratory judgment. The counterclaims seek damages, interest, expenses, attorney's fees, and costs. On October 18, 2021, GeneOne filed its answer to our counterclaims and new matter. On February 29, 2024, we filed a motion for summary judgment. On April 1, 2024, GeneOne filed an opposition to our motion for summary judgment. The Court has set the motion for summary judgment for a hearing on June 28, 2024. 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 1A. RISK FACTORS

Our business is subject to numerous risks. You should carefully consider and evaluate each of the following factors as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes, the risk factors discussed in our 2023 Annual Report, which we filed with the SEC on March 6, 2024, in evaluating our business and prospects. 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 consider immaterial may also impair our business operations. If any of the following risks actually occur, our business and financial results could be harmed. In that case, the trading price of our common stock could decline. You should also consider the more detailed description of our business contained in our 2023 Annual Report.

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 March 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 smart device technology and thus may never have any significant future revenues or achieve and sustain profitability.

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

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

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

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

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

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

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

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

- the progress of our current and new product development programs;
- the progress, scope and results of our pre-clinical and clinical testing;
- the time and cost involved in obtaining regulatory approvals;
- the cost of manufacturing our DNA medicine candidates;
- the cost of prosecuting, enforcing and defending against patent infringement claims and other intellectual property rights;
- debt service obligations;
- competing technological and market developments; and
- our ability and the related costs to establish and maintain collaborative and other arrangements with third parties to assist in potentially bringing our products to market.

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

Our failure to successfully address ongoing liquidity requirements would have a substantially negative impact on our business. If we are unable to obtain additional capital on acceptable terms when needed, we may need to take actions that

adversely affect our business, our stock price and our ability to achieve cash flow in the future, including possibly surrendering our rights to some technologies or product opportunities, delaying our clinical trials or curtailing or ceasing operations.

Risks Related to Product Development, Manufacturing and Regulatory Approval

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

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

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

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

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

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

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

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

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our proprietary device or product candidate is safe and effective for any indication;
- the results of clinical trials may not meet the level of clinical or statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may not be successful in enrolling a sufficient number of participants in clinical trials;

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

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

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

- obtaining regulatory approval to commence a clinical trial;
- adverse results from third-party clinical trials involving gene-based therapies and the regulatory response thereto;
- reaching agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- future bans or stricter standards imposed on clinical trials of gene-based therapy;
- manufacturing sufficient quantities of our proprietary device and DNA medicine candidates for use in clinical trials;
- obtaining Internal Review Board, or IRB, approval to conduct a clinical trial at a prospective site;
- slower than expected recruitment and enrollment of patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for similar indications;
- conducting clinical trials with sites internationally due to regulatory approvals and meeting international standards;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up;
- collecting, reviewing and analyzing our clinical trial data; and
- global unrest, including geopolitical risks emanating from countries such as Russia and China, global pathogen outbreaks or pandemics, terrorist activities, the conflict between Israel and Hamas, bank failures and other economic and other external factors beyond our control.

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

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

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

If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our proprietary device and our DNA medicine candidates may be harmed and our ability to generate product revenues will be delayed or eliminated altogether. In addition, many of the factors that cause, or lead to, a delay in the commencement or

completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Further, delays in the commencement, conduct or completion of clinical trials may adversely affect the trading price of our common stock.

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

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

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

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

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

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

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

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

No DNA medicines have been granted EUA or have been approved to date by the FDA. Adverse events in clinical trials of our investigational medicines or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of DNA medicine, or other products that are perceived to be similar to DNA medicines, such as those related to other nucleic acid based vaccines such as mRNA vaccines, gene therapy or gene editing, could result in

a decrease in the perceived benefit of one or more of our programs, increased regulatory scrutiny, decreased confidence by patients and clinical trial collaborators in our investigational medicines, and less demand for any product that we may develop. Our pipeline of DNA medicine candidates could result in a greater quantity of reportable adverse events, including suspected unexpected serious adverse reactions, other reportable negative clinical outcomes, manufacturing reportable events or material clinical events that could lead to clinical delay or hold by the FDA or applicable regulatory authority or other clinical delays, any of which could negatively impact the perception of one or more of our programs, as well as our business as a whole. In addition, responses by U.S., state, or foreign governments to negative public perception may result in new legislation or regulations that could limit our ability to develop any investigational medicines or commercialize any approved products, obtain or maintain regulatory approval, or otherwise achieve profitability. More restrictive statutory regimes, government regulations, or negative public opinion would have an adverse effect on our business, financial condition, results of operations, and prospects and may delay or impair the development of our investigational medicines and commercialization of any approved products or demand for any products we may develop.

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

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

We manufacture some components of our proprietary devices and utilize the services of contract manufacturers to manufacture the remaining components of these devices. We also rely on third party contract manufacturers to produce our DNA medicine candidates for use in our clinical trials and potentially for commercial distribution, if any product candidate is approved by regulatory authorities. The manufacture of these devices and our DNA medicine candidates requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers often encounter difficulties in production, particularly in scaling up for commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the equipment and DNA medicine candidates and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations.

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

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

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

basis, pursuant to provided specifications and at commercially reasonable prices, we may be unable to meet demand for our products and would lose potential revenues.

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

We are dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, our 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 products receive regulatory approval, they may still face future development and regulatory difficulties.

Even if United States regulatory approval is obtained, regulators may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. This governmental oversight may be particularly strict with respect to gene-based therapies. Our products will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, record keeping and submission of safety and other post-market information. For example, the FDA strictly regulates the promotional claims that may be made about medical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's

approved labeling. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may in certain circumstances share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our DNA medicine candidates, or the manufacturing facilities for our DNA medicine candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

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

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

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

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

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

We have obtained Orphan Drug Designation from the FDA for INO-3107 for the treatment of RRP. We have sought and may continue to seek Orphan Drug Designation for one or more of our other DNA medicine candidates, although we may be unsuccessful in doing so. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as tax advantages and user fee waivers. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs for rare diseases, regardless of whether the drugs are designated for the orphan use. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances.

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

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

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

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

Risks Related to Reliance on Third Parties

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

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

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

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

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

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

We have entered into agreements with government agencies, such as the National Institutes of Health's National Institute of Allergy and Infectious Diseases (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.

Risks Related to Employee and Operational Matters

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

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

Furthermore, employees whose positions have been or will be eliminated in connection with these restructuring plans may seek future employment with our competitors. Although all our employees are required to sign a confidentiality agreement with us at the time of hire, we cannot be certain that the confidential nature of our proprietary information will be maintained in the course of such future employment. We cannot be certain that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our current or any future restructuring plans. In addition, if we continue to reduce our workforce, it may adversely impact our ability to respond rapidly to any new growth or

revenue opportunities. Any restructuring activities we undertake may take longer than expected and may require changes to our business that we are unable to implement. If we are unsuccessful in implementing our cost saving initiatives and restructuring plans or if we do not achieve our expected results, our results of operations and cash flows could be adversely affected.

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

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

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

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

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

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

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

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

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

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

however, research and development by others may render our technologies or product candidates obsolete or non-competitive, or result in treatments or cures superior to ours.

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

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

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

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

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

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

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

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

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

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

Changes in funding for the FDA and other government agencies could prevent new products from being developed or commercialized in a timely manner, which could negatively impact our business.

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

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

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

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

The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the compromise of information stored in our or our third-party providers' systems, portable media or storage devices. Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten our information and information technology systems and those of third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources such as traditional computer “hackers,” threat actors, “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.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, regulators, and other stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability.

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

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

We have obtained product liability insurance coverage for our clinical trials, but our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our business.

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

In both the United States and certain foreign jurisdictions there have been, and we anticipate there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell any of our products profitably. In the United States, the federal government enacted healthcare reform legislation, the Patient Protection and

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

There have been executive, judicial, and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties for not complying with the ACA's individual mandate to carry qualifying health insurance coverage for all or part of a year. In addition, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage was eliminated, along with the health insurer tax. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and our business. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011 included reductions to Medicare payments to providers of 2% per fiscal year, which, due to subsequent legislative amendments to the statute will remain in effect until 2032, unless Congressional action is taken. The American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has also been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, at the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and

marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, people from soliciting, receiving or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or ordering, or leasing of an item, good, facility or service, for which payment may be made by a federal healthcare program such as Medicare or Medicaid. The intent standard under the federal healthcare program Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, the ACA codified case law that a claim including items or services resulting from a violation of the federal healthcare program Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- federal civil and criminal false claims laws, including the civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- 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 rely on clinical materials manufactured in China for our development efforts. Uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, a trade war, political unrest or unstable economic conditions in China could materially adversely affect our business, financial condition and results of operations.

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

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

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions; provide accurate information to the FDA, the EMA, and other regulatory authorities; comply with healthcare fraud and abuse laws and regulations in the United States and abroad; or report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Sales, marketing, and business arrangements in the healthcare

industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, and prospects, including the imposition of significant fines or other sanctions.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to

seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Risks Related to an Investment in Our Common Stock

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

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

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

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

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

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

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

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

development of our product candidates. Pending their use, we may invest our cash, cash equivalents, and investments in a manner that does not produce income or that loses value.

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

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

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

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

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

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

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

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

General Risk Factors

Our quarterly operating results may fluctuate significantly.

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

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

- if any of our DNA medicine candidates receive regulatory approval, the levels of underlying demand for our products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). In the past few years, numerous U.S. states—

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

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

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

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

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are

perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

ITEM 5. OTHER INFORMATION

During the three months ended March 31, 2024, none of our directors and officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted or terminated any contracts, instructions or written plans for the purchase or sale of our securities.

ITEM 6. EXHIBITS

(a) Exhibits

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 to the registrant's registration statement Form S-3, 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 current report on Form 8-K filed on August 12, 2011).
31.1	Certification of Chief Executive Officer Pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer Pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1 *	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).*
101.INS	XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any filings.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Inovio Pharmaceuticals, Inc.

Date: May 13, 2024

By /s/ JACQUELINE E. SHEA

Jacqueline E. Shea

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

Date: May 13, 2024

By /s/ PETER KIES

Peter Kies

Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of CEO Pursuant to
Securities Exchange Act Rules 13a-15(e) and 15d-15(e)
as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Jacqueline E. Shea, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Inovio Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ JACQUELINE E. SHEA

Jacqueline E. Shea

President, Chief Executive Officer and Director (Principal Executive Officer)

Exhibit 31.2

Certification of CFO Pursuant to
Securities Exchange Act Rules 13a-15(e) and 15d-15(e)
as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Peter Kies, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Inovio Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ Peter Kies

Peter Kies
Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report of Inovio Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ending March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, in the capacities and on the date indicated below, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 13, 2024

/s/ JACQUELINE E. SHEA

Jacqueline E. Shea
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 13, 2024

/s/ PETER KIES

Peter Kies
Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not filed with the Securities and Exchange Commission as part of the Form 10-Q or as a separate disclosure document and is not incorporated by reference into any filing of Inovio Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.