

INOVIO PHARMACEUTICALS, INC.

Form 10-Q

November 07, 2012

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-Q**

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

For the quarterly period ended September 30, 2012

OR

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

For the transition period from            to

Commission File Number 001-14888

**INOVIO PHARMACEUTICALS, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**33-0969592**  
(I.R.S. Employer  
Identification No.)

**1787 SENTRY PARKWAY WEST**  
**BUILDING 18, SUITE 400**

**BLUE BELL, PENNSYLVANIA 19422**

(Address of principal executive offices) (Zip Code)

**(267) 440-4200**

(Registrant's telephone number, including area code)

**N/A**

(Former name, if changed since last report)

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

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

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

Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

Large accelerated filer  Accelerated filer  x  
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No  x

The number of shares outstanding of the registrant's Common Stock, par value \$0.001 per share, was 139,363,780 as of November 2, 2012.

---

**Table of Contents**

**INOVIO PHARMACEUTICALS, INC.**

**FORM 10-Q**

**For the Quarterly Period Ended September 30, 2012**

**INDEX**

<b><u>Part I. Financial Information</u></b>	3
<u>Item 1. Financial Statements</u>	3
a) <u>Condensed Consolidated Balance Sheets as of September 30, 2012 (Unaudited) and December 31, 2011</u>	3
b) <u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2011 (Unaudited)</u>	4
c) <u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2012 and 2011 (Unaudited)</u>	5
d) <u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2012 and 2011 (Unaudited)</u>	6
e) <u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	23
<u>Item 4. Controls and Procedures</u>	24
<b><u>Part II. Other Information</u></b>	25
<u>Item 1. Legal Proceedings</u>	25
<u>Item 1A. Risk Factors</u>	25
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
<u>Item 3. Default Upon Senior Securities</u>	37
<u>Item 4. Mine Safety Disclosures</u>	37
<u>Item 5. Other Information</u>	37
<u>Item 6. Exhibits</u>	37
<b><u>Signatures</u></b>	39

**Table of Contents****Part I. Financial Information****Item 1. Financial Statements****INOVIO PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

	September 30, 2012 (Unaudited)	December 31, 2011
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 4,588,658	\$ 17,350,116
Short-term investments	10,554,966	12,863,420
Accounts receivable	481,447	467,909
Accounts receivable from affiliated entity	134,320	38,406
Prepaid expenses and other current assets	487,721	746,049
Prepaid expenses and other current assets from affiliated entity	686,626	441,186
<b>Total current assets</b>	<b>16,933,738</b>	<b>31,907,086</b>
Restricted cash	100,323	100,059
Fixed assets, net	391,527	295,785
Intangible assets, net	7,939,741	9,310,485
Goodwill	10,113,371	10,113,371
Investment in affiliated entity	8,253,717	9,071,513
Investment in common stock warrants	520,600	100,000
Other assets	223,056	208,262
<b>Total assets</b>	<b>\$ 44,476,073</b>	<b>\$ 61,106,561</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 3,133,620	\$ 4,318,942
Accounts payable and accrued expenses due to affiliated entity	110,101	20,344
Accrued clinical trial expenses	1,384,462	1,059,372
Common stock warrants	6,162,948	5,176,319
Deferred revenue	84,146	79,502
Deferred revenue from affiliated entity	401,042	388,542
<b>Total current liabilities</b>	<b>11,276,319</b>	<b>11,043,021</b>
Deferred revenue, net of current portion	90,271	80,450
Deferred revenue from affiliated entity, net of current portion	1,680,444	1,961,694
Deferred rent	70,023	80,875
Deferred tax liabilities	78,859	78,859
<b>Total liabilities</b>	<b>13,195,916</b>	<b>13,244,899</b>
<b>Stockholders equity:</b>		
<b>Inovio Pharmaceuticals, Inc. stockholders equity:</b>		
Common stock	137,055	134,968
Additional paid-in capital	259,636,082	257,235,707
Accumulated deficit	(229,101,378)	(210,091,174)

Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

Accumulated other comprehensive income	93,102	35,393
<b>Total Inovio Pharmaceuticals, Inc. stockholders equity</b>	<b>30,764,861</b>	<b>47,314,894</b>
Non-controlling interest	515,296	546,768
Total stockholders equity	31,280,157	47,861,662
<b>Total liabilities and stockholders equity</b>	<b>\$ 44,476,073</b>	<b>\$ 61,106,561</b>

See accompanying notes.

Table of Contents

## INOVIO PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
<b>Revenues:</b>				
License fee and milestone revenue	\$ 22,495	\$ 76,888	\$ 68,240	\$ 129,712
License fee and milestone revenue from affiliated entity	106,250	106,250	318,750	305,208
Revenue under collaborative research and development arrangements with affiliated entity	116,234		116,234	
Grant and miscellaneous revenue	609,717	2,454,423	2,480,675	7,727,669
<b>Total revenues</b>	<b>854,696</b>	<b>2,637,561</b>	<b>2,983,899</b>	<b>8,162,589</b>
<b>Operating expenses:</b>				
Research and development	4,972,319	6,987,824	13,541,984	15,873,601
General and administrative	2,674,362	2,323,188	7,859,359	8,734,806
Gain on sale of assets	(500,000)	(337,000)	(1,151,000)	(587,000)
<b>Total operating expenses</b>	<b>7,146,681</b>	<b>8,974,012</b>	<b>20,250,343</b>	<b>24,021,407</b>
<b>Loss from operations</b>	<b>(6,291,985)</b>	<b>(6,336,451)</b>	<b>(17,266,444)</b>	<b>(15,858,818)</b>
<b>Other income (expense):</b>				
Interest and other income, net	37,013	5,738	109,593	15,392
Changes in fair value of common stock warrants	(1,113,638)	346,956	(1,067,029)	7,577,582
Gain (Loss) from investment in affiliated entity	736,121	1,427,176	(817,796)	(1,550,062)
<b>Net loss</b>	<b>(6,632,489)</b>	<b>(4,556,581)</b>	<b>(19,041,676)</b>	<b>(9,815,906)</b>
Net loss attributable to non-controlling interest	10,413	14,649	31,472	39,202
<b>Net loss attributable to Inovio Pharmaceuticals, Inc.</b>	<b>\$ (6,622,076)</b>	<b>\$ (4,541,932)</b>	<b>\$ (19,010,204)</b>	<b>\$ (9,776,704)</b>
<b>Loss per common share basic and diluted</b>				
<b>Net loss per share attributable to Inovio Pharmaceuticals, Inc. stockholders</b>	<b>\$ (0.05)</b>	<b>\$ (0.04)</b>	<b>\$ (0.14)</b>	<b>\$ (0.08)</b>
<b>Weighted average number of common shares outstanding basic and diluted</b>				
	135,389,308	127,256,907	135,108,699	125,184,087
	See accompanying notes.			

Table of Contents

## INOVIO PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net loss	\$ (6,632,489)	\$ (4,556,581)	\$ (19,041,676)	\$ (9,815,906)
<b>Other comprehensive income (loss):</b>				
Foreign currency translation adjustments	684	(4,084)	697	(3,591)
Unrealized gain (loss) on short-term investments	27,904	1,819	57,012	(4,465)
<b>Comprehensive loss</b>	<b>\$ (6,603,901)</b>	<b>\$ (4,558,846)</b>	<b>\$ (18,983,967)</b>	<b>\$ (9,823,962)</b>

See accompanying notes.



**Table of Contents****INOVIO PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

	<b>Nine Months Ended September 30, 2012</b>	<b>Nine Months Ended September 30, 2011</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (19,041,676)	\$ (9,815,906)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	124,123	101,905
Amortization of intangible assets	1,370,744	1,406,826
Change in value of common stock warrants	1,067,029	(7,577,582)
Stock-based compensation	1,176,874	1,431,976
Interest income accrued on short term investments	(1,148)	6,271
Deferred rent	(10,852)	1,168
Loss from investment in affiliated entity	817,796	1,550,062
Gain on sale of intangible assets	(1,151,000)	(587,000)
Changes in operating assets and liabilities:		
Accounts receivable	(13,538)	(394,061)
Accounts receivable from affiliated entity	(95,914)	43,903
Prepaid expenses and other current assets	258,328	(592,052)
Prepaid expenses and other current assets from affiliated entity	(245,440)	307,174
Restricted cash	(264)	
Other assets	(14,794)	50,866
Accounts payable and accrued expenses	(860,232)	513,939
Accounts payable and accrued expenses due to affiliated entity	89,757	(1,074,192)
Deferred revenue	14,465	(339,613)
Deferred revenue from affiliated entity	(268,750)	(255,208)
<b>Net cash used in operating activities</b>	<b>(16,784,492)</b>	<b>(15,221,524)</b>
<b>Cash flows from investing activities:</b>		
Purchases of short term investments	(7,642,157)	(5,768,000)
Maturities of short term investments	10,008,771	1,840,000
Purchases of capital assets	(219,865)	(113,964)
Proceeds from sale of intangible assets	650,000	350,000
Additional investment in affiliated entity		(101,123)
<b>Net cash provided by (used in) investing activities</b>	<b>2,796,749</b>	<b>(3,793,087)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock and warrants, net of issuance costs	1,225,588	24,309,472
Proceeds from stock option and warrant exercises		12,930
<b>Net cash provided by financing activities</b>	<b>1,225,588</b>	<b>24,322,402</b>
Effect of exchange rate changes on cash and cash equivalents	697	(3,591)
<b>(Decrease) Increase in cash and cash equivalents</b>	<b>(12,761,458)</b>	<b>5,304,200</b>
Cash and cash equivalents, beginning of period	17,350,116	19,998,489

Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

<b>Cash and cash equivalents, end of period</b>	\$ 4,588,658	\$ 25,302,689
---	--------------	---------------

See accompanying notes.

---

**Table of Contents**

**INOVIO PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Description of Business**

Inovio Pharmaceuticals, Inc. (the Company or Inovio) is engaged in the discovery, development, and delivery of a new generation of vaccines, called DNA vaccines, focused on cancers and infectious diseases. The Company's SynCo® technology enables the design of universal DNA-based vaccines capable of providing cross-protection against new, unmatched strains of pathogens such as influenza. The Company's electroporation DNA delivery technology uses brief, controlled electrical pulses to increase cellular DNA vaccine uptake. Initial human data has shown this method can safely and significantly increase gene expression and immune responses. The Company's clinical programs include human papillomavirus (HPV)/cervical cancer (therapeutic), avian influenza (preventive), prostate cancer (therapeutic), leukemia (therapeutic), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) vaccines. The Company is advancing preclinical research for a universal seasonal/pandemic influenza vaccine and other product candidates. The Company's partners and collaborators include University of Pennsylvania, Drexel University, National Microbiology Laboratory of the Public Health Agency of Canada, Program for Appropriate Technology in Health/Malaria Vaccine Initiative (PATH or MVI), National Institute of Allergy and Infectious Diseases (NIAID), Merck, ChronTech, University of Southampton, United States Military HIV Research Program (USMHRP), U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), HIV Vaccines Trial Network (HVTN) and Department of Homeland Security (DHS).

**2. 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) 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 September 30, 2012, condensed consolidated statements of operations for the three and nine months ended September 30, 2012 and 2011, condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2012 and 2011 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2012 and 2011, 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 and cash flows for the periods presented. The results of operations for the three and nine months ended September 30, 2012 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2012, or for any other period. These financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2011, included in the Company's Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 15, 2012. The balance sheet at December 31, 2011 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. The Company has evaluated subsequent events after the balance sheet date of September 30, 2012 through the date it filed these unaudited condensed consolidated financial statements with the SEC.

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

The Company incurred a net loss from operations of \$6.6 million and \$19.0 million, respectively, for the three and nine months ended September 30, 2012. The Company had working capital of \$5.7 million and an accumulated deficit of \$229.1 million as of September 30, 2012. 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 unaudited interim condensed consolidated financial statements do not include any adjustments to the specific amounts and classifications of assets and liabilities, which might be necessary should the Company be unable to continue in business. The Company's unaudited interim condensed consolidated financial statements as of and for the period ended September 30, 2012 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.

**3. Impact of Recently Issued Accounting Standards**

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

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

**Accounting Standards Update (ASU), No. 2011-04** In May 2011, the Financial Accounting Standards Board (FASB) issued an ASU, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards, or IFRS. This update amends Accounting

**Table of Contents**

Standards Codification Topic 820, Fair Value Measurement and Disclosure. ASU 2011-04 clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. The Company has adopted ASU 2011-04 as of January 1, 2012 and it has not had a significant impact on its financial position, results of operations or cash flows but on presentation and disclosure only ..

**ASU No. 2011-05** In June 2011, the FASB issued an ASU, Presentation of Comprehensive Income. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders' equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company has adopted ASU 2011-05 as of January 1, 2012 and there has been no impact on its financial position, results of operations or cash flows but on presentation and disclosure only.

**ASU No. 2011-08** In September 2011, the FASB issued an ASU, Goodwill Impairment Testing. For entities testing goodwill for impairment, ASU 2011-08 allows the option of performing a qualitative assessment before calculating the fair value of a reporting unit in step 1 of the impairment test. The two-step impairment test would be required only if the fair value of a reporting unit is qualitatively determined to be more likely than not less than the carrying amount. The Company has adopted the amendment provisions of ASU 2011-08 as of January 1, 2012 and it has not had an impact on its financial condition, results of operations or cash flows.

**4. Principles of Consolidation**

These unaudited condensed consolidated financial statements include the accounts of Inovio Pharmaceuticals, Inc. and its domestic and foreign subsidiaries. In conjunction with the acquisition in June 2009 of VGX Pharmaceuticals (the Merger), the Company acquired an 88% interest in VGX Animal Health and certain shares in VGX International, Inc. (VGX Int 1) (a publicly-traded company in South Korea). The Company consolidates Genetronics, Inc., VGX Pharmaceuticals and its subsidiary VGX Animal Health and records a non-controlling interest for the 9% of VGX Animal Health it does not own as of September 30, 2012 and December 31, 2011. The Company's investment in VGX Int 1, which is recorded as investment in affiliated entity within the condensed consolidated balance sheets is accounted for at fair value on a recurring basis, with changes in fair value recorded on the condensed consolidated statements of operations within gain (loss) on investment in affiliated entity. All intercompany accounts and transactions have been eliminated upon consolidation.

**Variable Interest Entities**

In June 2009, the FASB issued authoritative guidance that requires companies to perform a qualitative analysis to determine whether a variable interest in another entity represents a controlling financial interest in a variable interest entity. A controlling financial interest in a variable interest entity is characterized by having both the power to direct the most significant activities of the entity and the obligation to absorb losses or the right to receive benefits of the entity. This guidance also requires on-going reassessments of variable interests based on changes in facts and circumstances. This guidance became effective for fiscal years beginning after November 15, 2009. The Company adopted the provisions of the guidance in the first quarter of 2010 and determined that none of the entities with which the Company currently conducts business and collaborations are variable interest entities, except VGXI (a wholly-owned subsidiary of VGX Int 1). The Company determined that they are not the primary beneficiary and therefore are not required to consolidate VGXI.

**5. Investments**

Investments consist of certificates of deposit, mutual funds, and municipal bonds at September 30, 2012 and December 31, 2011. The Company classifies all investments as available-for-sale, as the sale of such investments may be required prior to maturity to implement management strategies. These investments are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) until realized. A decline in the market value of any investment below cost that is determined to be other-than-temporary will result in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the investment is established. No such impairment charges were recorded during the three and nine months ended September 30, 2012.

The following is a summary of investments as of September 30, 2012 and December 31, 2011:

Contractual Maturity (in years)	Cost	As of September 30, 2012		Fair Market Value
		Gross Unrealized Gains	Gross Unrealized Losses	

Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

Mutual funds	Less than 1	\$ 6,000,000	\$ 101,043	\$	\$ 6,101,043
Certificates of deposit	Less than 1	2,750,000	10	(342)	2,749,668
Municipal bonds	Less than 1	1,711,145		(6,890)	1,704,255
Total		\$ 10,461,145	\$ 101,053	\$ (7,232)	\$ 10,554,966

**Table of Contents**

	Contractual Maturity (in years)	Cost	As of December 31, 2011		Fair Market Value
			Gross Unrealized Gains	Gross Unrealized Losses	
Mutual funds	Less than 1	\$ 6,000,000	\$ 37,115	\$	\$ 6,037,115
Certificates of deposit	Less than 1	5,771,000		(2,696)	5,768,304
Municipal bonds	Less than 1	1,056,614	1,387		1,058,001
Total		\$ 12,827,614	\$ 38,502	\$ (2,696)	\$ 12,863,420

**6. Marketable Securities and Fair Value Measurements**

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

The following table presents the Company's financial assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2012:

	Total	Fair Value Measurements at September 30, 2012		
		Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Using Significant Other Observable Inputs (Level 2)	Using Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market funds	\$ 2,141,745	\$ 2,141,745	\$	\$
Mutual funds	6,101,043		6,101,043	
Certificates of deposit	2,749,668		2,749,668	
Municipal bonds	1,704,255		1,704,255	
Investment in affiliated entity	8,253,717	8,253,717		
Investment in common stock warrants	520,600			520,600
Total Assets	\$ 21,471,028	\$ 10,395,462	\$ 10,554,966	\$ 520,600
<b>Liabilities:</b>				
Common stock warrants	\$ 6,162,948	\$	\$	\$ 6,162,948
Total Liabilities	\$ 6,162,948	\$	\$	\$ 6,162,948

The following table presents the Company's financial assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2011:

	Total	Fair Value Measurements at December 31, 2011		
		Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Using Significant Other Unobservable Inputs (Level 2)	Using Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market funds	\$ 16,330,885	\$ 16,330,885	\$	\$

Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

Mutual funds	6,037,115		6,037,115	
Certificates of deposit	5,768,304		5,768,304	
Municipal bonds	1,058,001		1,058,001	
Investment in affiliated entity	9,071,513	9,071,513		
Investment in common stock warrants	100,000			100,000
<b>Total Assets</b>	<b>\$ 38,365,818</b>	<b>\$ 25,402,398</b>	<b>\$ 12,863,420</b>	<b>\$ 100,000</b>
<b>Liabilities:</b>				
Common stock warrants	\$ 5,176,319	\$	\$	\$ 5,176,319
<b>Total Liabilities</b>	<b>\$ 5,176,319</b>	<b>\$</b>	<b>\$</b>	<b>\$ 5,176,319</b>



**Table of Contents**

Level 1 assets at September 30, 2012 and December 31, 2011 include money market funds held by the Company that are valued at quoted market prices, as well as the Company's investment in VGX Int 1, for which the fair value is based on the market value of 8,220,775 common shares, listed on the Korean Stock Exchange. Due to the volatility of VGX Int 1 common stock, we have elected to account for our investment at fair value on a recurring basis which will better reflect the valuation of our investment.

Level 2 assets at September 30, 2012 and December 31, 2011 include mutual funds, certificates of deposit and municipal bonds 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. We obtain the fair value of our 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. Our professional pricing service gathers quoted market prices and observable inputs for all of our mutual funds, certificates of deposit and municipal bonds from a variety of industry data providers. The valuation techniques used to measure the fair value of our 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. We validate the quoted market prices provided by our primary pricing service by comparing their assessment of the fair values of our investment portfolio balance against the fair values of our investment portfolio balance obtained from an independent source, which may include our investment managers.

Level 3 assets at September 30, 2012 and December 31, 2011 include two warrants received by the Company to purchase shares of common stock of OncoSec Medical Incorporated ( OncoSec ), in connection with the first and second amendments to the Asset Purchase Agreement between the Company and OncoSec signed in September 2011 and March 2012, respectively. The first warrant to purchase 1,000,000 shares of common stock of OncoSec has a contractual life of five years with an exercise price of \$1.20 per share. The second warrant to purchase 3,000,000 shares of common stock of OncoSec has a contractual life of five years with an exercise price of \$1.00 per share.

There have been no transfers of assets or liabilities between the fair value measurement classifications.

As of September 30, 2012 the Company recorded a long-term asset of \$521,000 associated with the warrants received to purchase common stock of OncoSec. The Company valued the warrants received in March 2012 as of the issuance date using the Black Scholes pricing model and recorded a \$501,000 gain on sale of assets within the condensed consolidated statement of operations. Inputs used in the pricing model include estimates of OncoSec stock price volatility, expected warrant life and risk-free interest rate. The Company develops its estimates based on publicly available historical data. The Company reassesses the fair value of the warrants at each reporting date. The assumptions used to estimate the fair values of the OncoSec common stock warrants at September 30, 2012 are presented below:

Risk-free interest rate	0.37%
Expected volatility	125%
Expected life in years	4.0-4.5
Dividend yield	

As a result of these calculations, the Company recorded an increase (decrease) in fair value of the two warrants of \$11,000 and (\$80,000), respectively, for the three and nine months ended September 30, 2012. The change in fair value is reflected in the Company's condensed consolidated statement of operations as a component of change in fair value of common stock warrants.

The following table presents a summary of changes in fair value of the Company's total Level 3 financial assets for the nine months ended September 30, 2012:

Balance at January 1, 2012	\$ 100,000
Common stock warrant recorded at fair value upon acquisition in March 2012	501,000
Decrease in fair value included in change in fair value of common stock warrants	(80,400)
Balance at September 30, 2012	\$ 520,600

**Table of Contents**

Level 3 liabilities held as of September 30, 2012 and December 31, 2011 consist of common stock warrant liabilities associated with warrants to purchase the Company's common stock issued in July 2009, January 2011 and December 2011. If unexercised, the warrants will expire at various dates between July 2014 and December 2016.

As of September 30, 2012 the Company recorded a \$6.2 million common stock warrant liability. The Company reassesses the fair value of the common stock warrants at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of stock price volatility, expected warrant life and risk-free interest rate. The Company develops its estimates based on historical data. The range of assumptions used to estimate the fair values of common stock warrants at September 30, 2012 are presented below:

Risk-free interest rate	0.18%-0.37%
Expected volatility	63%-127%
Expected life in years	1.75-4.19
Dividend yield	

As a result of these calculations, the Company recorded an increase in fair value of \$1.1 million and \$987,000 for the three and nine months ended September 30, 2012, respectively, and a decrease in fair value of \$347,000 and \$7.6 million for the three and nine months ended September 30, 2011, respectively. The change in fair value is reflected in the Company's condensed consolidated statement of operations as a component of change in fair value of common stock warrants.

The following table presents the changes in fair value of the Company's total Level 3 financial liabilities for the nine months ended September 30, 2012:

Balance at January 1, 2012	\$ 5,176,319
Increase in fair value included in change in fair value of common stock warrants	986,629
Balance at September 30, 2012	\$ 6,162,948

**7. Goodwill and Intangible Assets**

In accordance with the guidance regarding goodwill and other intangible assets, the Company's goodwill is not amortized, but is subject to an annual impairment test, which the Company performs as of November each year or sooner if indicators of impairment exist. The following sets forth the intangible assets by major asset class:

	Useful Life (Yrs)	September 30, 2012			December 31, 2011		
		Gross	Accumulated Amortization	Net Book Value	Gross	Accumulated Amortization	Net Book Value
<b>Non-Amortizing:</b>							
Goodwill(a)		\$ 10,113,371	\$	\$ 10,113,371	\$ 10,113,371	\$	\$ 10,113,371
<b>Amortizing:</b>							
Patents	8 - 17	5,802,528	(4,775,995)	1,026,533	5,802,528	(4,526,488)	1,276,040
Licenses	8 - 17	1,323,761	(1,039,683)	284,078	1,323,761	(1,018,122)	305,639
CELLECTRA®(b)	5 - 11	8,106,270	(4,031,844)	4,074,426	8,106,270	(3,124,680)	4,981,590
GHRH(b)	11	335,314	(105,610)	229,704	335,314	(81,848)	253,466
Other(c)	18	4,050,000	(1,725,000)	2,325,000	4,050,000	(1,556,250)	2,493,750
<b>Total intangible assets</b>		<b>19,617,873</b>	<b>(11,678,132)</b>	<b>7,939,741</b>	<b>19,617,873</b>	<b>(10,307,388)</b>	<b>9,310,485</b>
Total goodwill and intangible assets		\$ 29,731,244	\$ (11,678,132)	\$ 18,053,112	\$ 29,731,244	\$ (10,307,388)	\$ 19,423,856

- (a) Goodwill was recorded from the Inovio AS acquisition in January 2005 and from the acquisition of VGX in June 2009 for \$3.9 million and \$6.2 million, respectively.
- (b) CELLECTRA<sup>®</sup> and GHRH are developed technologies that were recorded from the acquisition of VGX.
- (c) Other intangible assets represent the fair value of acquired contracts and intellectual property from the Inovio AS acquisition.

**Table of Contents**

Aggregate amortization expense on intangible assets for the three and nine months ended September 30, 2012 was \$453,000 and \$1.4 million, respectively. Aggregate amortization expense on intangible assets for the three and nine months ended September 30, 2011 was \$466,000 and \$1.4 million, respectively. Estimated aggregate amortization expense for each of the five succeeding fiscal years is \$449,000 for the remainder of fiscal year 2012, \$1.8 million for 2013, \$943,000 for 2014, \$870,000 for 2015, \$816,000 for 2016 and \$775,000 for 2017.

**8. Stockholders Equity**

The following is a summary of the Company's authorized and issued common and preferred stock as of September 30, 2012 and December 31, 2011:

	Authorized	Issued	Outstanding as of	
			September 30, 2012	December 31, 2011
Common Stock, par \$0.001	300,000,000	137,055,380	137,055,380	134,968,394
Series A Preferred Stock, par \$0.001	1,000	817		
Series B Preferred Stock, par \$0.001	1,000	750		
Series C Preferred Stock, par \$0.001	1,091	1,091	26	26
Series D Preferred Stock, par \$0.001	1,966,292	1,966,292		

**Common Stock**

In June 2012, the Company entered into a sales agreement (the "Sales Agreement") with an outside placement agent (the "Placement Agent") to sell shares of its common stock with aggregate gross proceeds of up to \$25.0 million from time to time, through an at-the-market equity offering program under which the Placement Agent will act as sales agent. Under the Sales Agreement, the Company will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. The Sales Agreement provides that the Placement Agent will be entitled to compensation for its services in an amount equal to 3.0% of the gross proceeds from the sales of shares sold through the Placement Agent under the Sales Agreement. The Company has no obligation to sell any shares under the Sales Agreement, and may at any time suspend solicitation and offers under the Sales Agreement.

During the three and nine months ended September 30, 2012, the Company sold a total of 2,086,986 shares of common stock under the Sales Agreement. The sales were made at a weighted average price of \$0.61 per share with net proceeds to the Company of \$1.2 million.

In December 2011, the Company completed an underwritten public offering relating to the sale and issuance of 7,699,712 units to certain institutional investors, consisting of 7,699,712 shares of common stock and warrants to purchase an aggregate of up to 5,774,784 additional shares of common stock. These units, which were purchased for \$0.5195 per unit, include the partial exercise of the underwriter's overallotment option of 962,465 additional units at the public offering price. The units consist of one share of common stock and 0.75 of a warrant to purchase one share of common stock. The warrants have a term of five years and an exercise price of \$0.65 per share. The Company may call the warrants if the closing bid price of the common stock has been at least \$1.30 over 20 trading days and certain other conditions are met. The Company received net proceeds from the transaction of approximately \$3.7 million, after deducting the underwriter's discounts and other offering expenses payable by the Company. The Company valued the registered warrants issued in connection with the December 2011 financing as of the issuance date using the Black Scholes pricing model and recorded a current liability on the consolidated balance sheet. The warrants were subsequently revalued and the Company recorded the change in fair value of \$635,000 and \$751,000 to "Change in fair value of common stock warrants" on the condensed consolidated statement of operations for the three and nine months ended September 30, 2012, respectively. As of September 30, 2012, none of these warrants had been exercised.

In January 2011, the Company entered into investor purchase agreements with investors relating to the issuance and sale of (a) 21,130,400 shares of common stock, and (b) warrants to purchase a total of 10,565,200 shares of common stock with an exercise price of \$1.40 per share, for an aggregate purchase price of approximately \$24.3 million. The shares of common stock and warrants were sold in units, consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at a purchase price of \$1.15 per unit. The Warrants have a five-year term from the date of issuance and are first exercisable commencing on the 180th day after the date of issuance. The Company may call the warrants if the closing bid price of the common stock has been at least \$2.80 over 20 trading days and certain other conditions are met. The Company received net proceeds from the transaction of

**Table of Contents**

approximately \$23.0 million, after deducting the placement agent's fee and estimated offering expenses payable by the Company. The Company valued the registered warrants issued in connection with the January 2011 financing as of the issuance date using the Black Scholes pricing model and recorded a current liability on the condensed consolidated balance sheet. The warrants were subsequently revalued and the Company recorded the change in fair value of \$488,000 and \$277,000 to Change in fair value of common stock warrants on the condensed consolidated statement of operations for the three and nine months ended September 30, 2012, respectively. As of September 30, 2012, none of these warrants had been exercised.

The Company accounts for registered common stock warrants issued in July 2009, January 2011 and December 2011 under the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the registered warrants require the issuance of registered securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. The Company classifies registered warrants on the condensed consolidated balance sheet as a current liability which is revalued at each balance sheet date subsequent to the initial issuance. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. The Company develops its estimates based on historical data. A small change in the estimates used may have a relatively large change in the estimated valuation. The Company uses the Black-Scholes pricing model to value the registered warrants. Changes in the fair market value of the warrants are reflected in the condensed consolidated statement of operations as Change in fair value of common stock warrants.

**Warrants**

The following table summarizes the warrants outstanding as of September 30, 2012 and December 31, 2011:

Issued in Connection With:	Exercise Price	Expiration Date	As of September 30, 2012		As of December 31, 2011	
			Number of Warrants	Common Stock Warrant Liability	Number of Warrants	Common Stock Warrant Liability
December 2011 financing	\$ 0.65	December 6, 2016	5,774,784	\$ 2,714,148	5,774,784	\$ 1,963,427
January 2011 financing	\$ 1.40	January 27, 2016	10,565,200	3,446,367	10,565,200	3,169,560
July 2009 financing	\$ 3.38	July 1, 2014	333,333	2,433	333,333	43,332
Warrants assumed in June 2009 Merger	\$ 0.05-1.28	March 24, 2013-April 28, 2016	4,920,527		4,920,527	
August 2007 consulting services	\$ 3.00	August 3, 2012			150,000	
Total			21,593,844	\$ 6,162,948	21,743,844	\$ 5,176,319

In August 2012, warrants expired to purchase 150,000 shares of our common stock issued in connection with consulting services received in August 2007.

In October 2011, warrants expired to purchase 2,364,394 shares of our common stock issued in connection with our October 2006 registered offering with foreign investors.

**Stock Options**

The Company has one active stock and cash-based incentive plan, the Amended and Restated 2007 Omnibus Incentive Plan (the Incentive Plan), pursuant to which the Company has granted stock options and restricted stock awards to executive officers, directors and employees. The plan was adopted on March 31, 2007, approved by the stockholders on May 4, 2007, approved by the stockholders as amended on May 2, 2008, and approved by the stockholders as amended and restated on August 25, 2009 and May 14, 2010. On May 14, 2010 the stockholders approved to increase the aggregate number of shares available for grant under the Incentive Plan by 2,000,000 shares and to provide that the aggregate number of shares available for grant under the plan will automatically increase on January 1 of each year beginning in 2011 by a number of shares equal to the lesser of (1) 2,055,331 shares or (2) such lesser number of shares as the Board of Directors may determine. On January 1, 2012 the number of securities available for future issuance increased by 2,055,331 shares. At September 30, 2012, the Incentive Plan reserved 9,860,662 shares of common stock for issuance upon exercise of incentive awards granted and to be granted at future dates. At September 30, 2012, the Company had 1,800,414 shares of common stock available for future grants under the plan, and 240,000 shares of vested restricted stock and options to purchase 7,505,035 shares of common stock outstanding under the plan. The awards granted and available for future grant under the Incentive Plan generally vest over three years and have a maximum contractual term of ten years. The Incentive Plan terminates by its

terms on March 31, 2017.

The Incentive Plan supersedes all of the Company's previous stock option plans, which include the Amended 2000 Stock Option Plan and the VGX Equity Compensation Plan, under which the Company had options to purchase 1,456,434 and 7,577,516 shares of common stock outstanding, respectively, at September 30, 2012. The terms and conditions of the options outstanding under these plans remain unchanged.

**Table of Contents****9. Net loss per share**

Basic net loss per share is computed by dividing the net loss for the year by the weighted average number of common shares outstanding during the year. Diluted loss per share is calculated in accordance with the treasury stock method and reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted to common stock. Since the effect of the assumed exercise of common stock options and other convertible securities was anti-dilutive for all periods presented, basic and diluted loss per share are the same.

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

	As of September 30, 2012	As of September 30, 2011
<b>Common Stock Equivalents</b>		
Options to purchase common stock	16,538,985	14,419,591
Warrants to purchase common stock	21,593,844	18,333,454
Convertible preferred stock	38,233	38,233
 Total	 38,171,062	 32,791,278

**10. Stock-Based Compensation**

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 highly subjective assumptions, including the expected stock price volatility and expected option life. The Company amortizes the fair value of the awards expected to vest on a straight-line basis. All option grants are amortized over the requisite service 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 forfeiture rate is based on historical data, and the Company records stock-based compensation expense only for those awards that are expected to vest. The dividend yield is based on the fact that no dividends have been paid historically and none are currently expected to be paid.

The weighted average assumptions used to estimate the fair value of stock options granted to employees and directors for the three and nine month periods ended September 30, 2012 and 2011 are presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Risk-free interest rate	0.33%	0.57% - 1.32%	0.36%	0.57% - 1.89%
Expected volatility	129%	132%	131%	132% - 134%
Expected life in years	4	4	4	4
Dividend yield				
Forfeiture rate	8%	11%	8%	11%

Total compensation cost for the Company's stock plan that has been recognized in the condensed consolidated statement of operations for the three and nine months ended September 30, 2012 was \$253,000 and \$1.0 million, respectively, of which \$117,000 and \$477,000 were included in research and development expenses and \$136,000 and \$551,000 were included in general and administrative expenses, respectively.

Total compensation cost for the Company's stock plan that has been recognized in the condensed consolidated statement of operations for the three and nine months ended September 30, 2011 was \$261,000 and \$1.4 million, respectively, of which \$103,000 and \$388,000 were included in research and development expenses and \$158,000 and \$1.0 million were included in general and administrative expenses, respectively.

As of September 30, 2012, there was \$1.1 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements for Inovio stock options, which the Company expects to recognize over a weighted-average period of one year.

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

The weighted average grant date fair value per share was \$0.44 and \$0.47 for employee and director stock options granted during the three and nine months ended September 30, 2012, respectively, and \$0.53 and \$0.91 for employee and director stock options granted during the three and nine months ended September 30, 2011, respectively.

The fair value of options granted to non-employees at the measurement dates were estimated using the Black-Scholes pricing model. Total stock-based compensation for options granted to non-employees for the three and nine months ended September 30, 2012 was \$46,000 and \$149,000, respectively. Total stock-based compensation for options granted to non-employees for the three and nine months ended September 30, 2011 was \$21,000 and \$22,000, respectively.



**Table of Contents**

**11. Related-Party Transactions**

***VGX International Inc.***

The Company conducts transactions with its affiliated entity, VGX Int'l.

In July 2011 the Company purchased an additional 145,000 shares of VGX Int'l at a price of approximately \$0.71 per share in connection with a common stock rights offering. The rights offering, however, reduced the Company's ownership percentage to approximately 16.1%.

On October 7, 2011, the Company entered into a Collaborative Development and License Agreement (the Agreement) with VGX Int'l. Under the Agreement, the Company and VGX Int'l will co-develop the Company's SynCom therapeutic vaccines for hepatitis B and C infections (the Products). Under the terms of the Agreement, VGX Int'l will receive marketing rights for the Products in Asia, excluding Japan, and in return will fully fund IND-enabling and initial Phase I and II clinical studies with respect to the Products. The Company will receive from VGX Int'l payments based on the achievement of clinical milestones and royalties based on sales of the Products in the licensed territories, retaining all commercial rights to the Products in all other territories.

On March 24, 2010, the Company entered into a Collaboration and License Agreement (the VGX Int'l Agreement) with VGX Int'l. Under the VGX Int'l Agreement, the Company granted VGX Int'l an exclusive license to Inovio's SynCom universal influenza vaccine delivered with electroporation to be developed in certain countries in Asia (the Product). As consideration for the license granted to VGX Int'l, the Company received payment of \$3.0 million, and will receive research support, annual license maintenance fees and royalties on net Product sales. The Company recorded the \$3.0 million as deferred revenue from affiliated entity, and will recognize it as revenue over the eight year expected period of the Company's performance obligation. In addition, contingent upon achievement of clinical and regulatory milestones, the Company will receive development payments over the term of the VGX Int'l Agreement. The VGX Int'l Agreement also provides Inovio with exclusive rights to supply devices for clinical and commercial purposes (including single use components) to VGX Int'l for use in the Product. The term of the VGX Int'l Agreement commenced upon execution and will extend on a country by country basis until the last to expire of all Royalty Periods for the territory (as such term is defined in the VGX Int'l Agreement) for any Product in that country, unless the VGX Int'l Agreement is terminated earlier in accordance with its provisions as a result of breach, by mutual agreement, or by VGX Int'l's right to terminate without cause upon prior written notice.

Under these Agreements, the future event based payments do not meet the criteria of a milestone in accordance with the authoritative guidance as they are solely based on the performance of the collaborators.

For the three and nine months ended September 30, 2012, the Company recognized revenue from VGX Int'l of \$222,000 and \$435,000, respectively, which consisted of licensing, collaborative research and development arrangements and other fees. Operating expenses related to VGX Int'l for the three and nine months ended September 30, 2012 include \$288,000 and \$616,000, respectively, related to biologics manufacturing. At September 30, 2012 and December 31, 2011 we had an accounts receivable balance of \$116,000 and \$20,000, respectively, from VGX Int'l and its subsidiaries.

For the three and nine months ended September 30, 2011, the Company recognized revenue from VGX Int'l of \$106,000 and \$305,000 respectively, which consisted of licensing fees. Operating expenses related to VGX Int'l for the three and nine months ended September 30, 2011 include \$2.5 million and \$4.9 million, respectively, related to biologics manufacturing and engineering services.

***OncoSec Medical Incorporated***

On March 24, 2011, the Company completed the sale of certain assets related to certain non-DNA vaccine technology and intellectual property relating to selective electrochemical tumor ablation (SECTA) to OncoSec Medical Incorporated, or OncoSec, pursuant to an Asset Purchase Agreement dated March 14, 2011 by and between the Company and OncoSec.

The Company's Chairman, Dr. Avtar Dhillon, is the non-executive Chairman of OncoSec.

At September 30, 2012 and December 31, 2011 the Company had an accounts receivable balance of \$18,000 from OncoSec.

The Company has received payment of \$1,000,000 from OncoSec as of September 30, 2012 and will receive an additional \$2.0 million in scheduled payments over a period of approximately three years from the closing date and a royalty on any potential commercial product sales related to the SECTA technology if and when a product is approved. No receivable has been recorded for the \$2.0 million due from OncoSec as collection of the funds is not reasonably assured.



**Table of Contents**

On September 28, 2011, the Company signed an amended agreement with OncoSec extending the term of the second payment owed to the Company in exchange for a warrant to purchase 1,000,000 shares of common stock of OncoSec. The warrant received was a five-year warrant with an exercise price of \$1.20 per share. (See Note 6 for further discussion.)

On March 24, 2012, the Company signed a second amended agreement with OncoSec further extending the term of the payments owed to the Company in exchange for a warrant to purchase 3,000,000 shares of common stock of OncoSec. The warrant received was a five-year warrant with an exercise price of \$1.00 per share. (See Note 6 for further discussion.)

**12. Subsequent Events**

Between October 1, 2012 and October 15, 2012, the Company sold an additional 2,308,400 shares of common stock under its Sales Agreement for net proceeds of \$1.5 million.

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

*This report contains forward-looking statements, as defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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, 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 consolidated financial statements and the related notes and other financial information appearing elsewhere in this Quarterly Report. 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 caption Risk Factors and under the captions Management's Discussion and Analysis of Financial Condition and Results of Operations, and Risk Factors and in our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2011.*

*Risk factors that could cause actual results to differ from those contained in the forward-looking statements include but are not limited to: our history of losses; our lack of products that have received regulatory approval; uncertainties inherent in clinical trials and product development programs, including but not limited to the fact that pre-clinical and clinical results may not be indicative of results achievable in other trials or for other indications, that the studies or trials may not be successful or achieve desired results, that pre-clinical studies and clinical trials may not commence 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 electroporation technology and DNA vaccines may fail to show the desired safety and efficacy traits in clinical trials; the availability of funding; the ability to manufacture vaccine 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; 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 proposals.*

**General**

We are engaged in the discovery, development, and delivery of a new generation of vaccines, called synthetic vaccines, focused on cancers and infectious diseases. Our SynCon® technology enables the design of universal vaccines capable of providing cross-protection against new, unmatched strains of pathogens such as influenza. Our electroporation DNA delivery technology uses brief, controlled electrical pulses to increase cellular DNA vaccine uptake. Initial human data has shown this method can safely and significantly increase gene expression and immune responses. Our clinical programs include HPV/cervical cancer (therapeutic), avian influenza (preventive), prostate cancer (therapeutic), leukemia (therapeutic), HCV and HIV vaccines. We are advancing preclinical research for a universal seasonal/pandemic influenza vaccine as well as other products. Our partners and collaborators include University of Pennsylvania, Drexel University, National Microbiology Laboratory of the Public Health Agency of Canada, Program for Appropriate Technology in Health/Malaria Vaccine Initiative ( PATH or MVI ), National Institute of Allergy and Infectious Diseases ( NIAID ), Merck, ChronTech, University of Southampton, United States Military HIV Research Program ( USMHRP ), U.S. Army Medical Research Institute of Infectious Diseases ( USAMRIID ), HIV Vaccines Trial Network ( HVTN ) and Department of Homeland Security ( DHS ).

All of our potential human products are in research and development phases. We have not generated any revenues from the sale of any such products, and we do not expect to generate any such revenues for at least the next several years. We earn revenue from license fees and milestone revenue, collaborative research and development agreements, grants and government contracts. Our product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product 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.

---

## **Table of Contents**

### *Recent Developments*

On December 6, 2011, we completed an underwritten public offering relating to the sale and issuance of 7,699,712 units to certain institutional investors, consisting of 7,699,712 shares of common stock and warrants to purchase an aggregate of up to 5,774,784 additional shares of common stock. These units include the partial exercise of the underwriter's overallotment option of 962,465 additional units at the public offering price. The units consist of one share of common stock and 0.75 of a warrant to purchase one share of common stock, at a purchase price of \$0.5195 per unit. The warrants have a term of five years and an exercise price of \$0.65 per share. We may call the warrants if the closing bid price of our common stock has been at least \$1.30 over 20 trading days and certain other conditions are met. We received net proceeds from the transaction of approximately \$3.7 million, after deducting the underwriter's discounts and other offering expenses payable.

On October 7, 2011, we entered into a Collaborative Development and License Agreement (the "Agreement") with VGX Int'l. Under the Agreement, we will co-develop with VGX Int'l our SynCon® therapeutic vaccines for hepatitis B and C infections (the "Products"). Under the terms of the agreement, VGX Int'l will receive marketing rights for the Products in Asia, excluding Japan, and in return will fully fund IND-enabling and initial Phase I and II clinical studies with respect to the Products. We will receive from VGX Int'l payments based on the achievement of clinical milestones and royalties based on sales of the Products in the licensed territories, retaining all commercial rights to the Products in all other territories.

As of September 30, 2012, we had an accumulated deficit of \$229.1 million. We expect to continue to incur substantial operating losses in the future due to our commitment to our research and development programs, the funding of preclinical studies, clinical trials and regulatory activities and the costs of general and administrative activities.

### *Critical Accounting Policies*

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and require management's judgment. Our discussion and analysis of our financial condition and results of operations is based on our audited consolidated financial statements, which have been prepared in accordance with U.S. GAAP. There have been no significant changes to our critical accounting policies during the three and nine months ended September 30, 2012. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. We base our estimates on experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates. Our critical accounting policies include:

#### *Revenue Recognition.*

##### Grant revenue

We receive non-refundable grants under available government programs. Government grants towards current expenditures are recorded as revenue when there is reasonable assurance that we have complied with all conditions necessary to receive the grants, collectability is reasonably assured, and as the expenditures are incurred.

##### License fee and milestone revenue

We have adopted a strategy of co-developing or licensing our gene delivery technology for specific genes or specific medical indications. Accordingly, we have entered into collaborative research and development agreements and have received funding for pre-clinical research and clinical trials. Prior to the adoption of the Financial Accounting Standards Board's (FASB) Accounting Standards Update (ASU) No. 2009-13, Revenue Recognition (Topic 605): *Multiple-Deliverable Revenue Arrangements*, we analyzed our multiple element arrangements to determine whether the identified deliverables could be accounted for individually as separate units of accounting. The delivered item(s) were considered a separate unit of accounting if all of the following criteria were met: (1) the delivered item(s) has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. If these criteria were not met, the deliverable was combined with other deliverables in the arrangement and accounted for as a combined unit of accounting.

For new collaborative agreements or material modifications of existing collaborative agreements entered into after December 31, 2010, we follow the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent separable units of accounting. Analyzing the arrangement to identify

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. A delivered item is considered a separate unit of accounting when the delivered item has value to the collaborator on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement.

## Table of Contents

Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence ( VSOE ), of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement.

Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, our price to the collaborator is fixed or determinable, and collectability is reasonably assured. Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

Prior to the adoption of ASU No. 2010-17, Revenue Recognition (Topic 605): *Milestone Method of Revenue Recognition* ( Milestone Method ), we recognized non-refundable milestone payments upon the achievement of specified milestones upon which we had earned the milestone payment, provided the milestone payment was substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement. We deferred payments for milestone events that were reasonably assured and recognized them ratably over the minimum remaining period of our performance obligations. Payments for milestones that were not reasonably assured were treated as the culmination of a separate earnings process and were recognized as revenue when the milestones were achieved.

Effective January 1, 2011, we adopted on a prospective basis the Milestone Method of ASU No. 2010-17. Under the Milestone Method, we will recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

1. The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone,
2. The consideration relates solely to past performance, and
3. The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company.

*Research and Development Expenses.* Since our inception, virtually all of our activities have consisted of research and development efforts related to developing our electroporation technologies and DNA vaccines. Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred.

*Valuation and Impairment Evaluations of Goodwill and Intangible Assets.* Goodwill represents the excess of acquisition cost over the fair value of the net assets of acquired businesses. As of September 30, 2012, our intangible assets resulting from the acquisition of VGX and Inovio AS, and additional intangibles including previously capitalized patent costs and license costs, net of accumulated amortization, totaled \$7.9 million. Intangible assets are amortized over their estimated useful lives ranging from 5 to 18 years. We are concurrently conducting pre-clinical, Phase I, and Phase II trials using acquired intangibles, and we have entered into certain significant licensing agreements for use of these acquired intangibles.

Historically we have recorded patents at cost and amortized these costs using the straight-line method over the expected useful lives of the patents or 17 years, whichever is less. Patent costs consist of the consideration paid for patents and related legal costs. Effective June 1, 2009, in connection with our acquisition of VGX, all new patent costs are being expensed as incurred. Patent costs currently capitalized will continue to be amortized over the expected life of the patent. The effect of this change was immaterial to prior periods. We record license costs based on the

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

fair value of consideration paid and amortize using the straight-line method over the shorter of the expected useful life of the underlying patents or the term of the related license agreement.

The determination of the value of such intangible assets requires management to make estimates and assumptions that affect our consolidated financial statements. We assess potential impairments to intangible assets when there is evidence that events or changes



**Table of Contents**

in circumstances indicate that the carrying amount of an asset may not be recovered. Our judgments regarding the existence of impairment indicators and future cash flows related to intangible assets are based on operational performance of our acquired businesses, market conditions and other factors. If impairment is indicated, we reduce the carrying value of the intangible asset to fair value. While our current and historical operating and cash flow losses are potential indicators of impairment, we believe the future cash flows to be received from our intangible assets will exceed the intangible assets' carrying value, and accordingly, we have not recognized any impairment losses through September 30, 2012.

Goodwill and intangible assets with indefinite lives are not amortized but instead are measured for impairment annually, or when events indicate that impairment exists. Our accounting policy with respect to reviewing goodwill for impairment is a two step process. The first step of the impairment test compares the fair value of our reporting unit with its carrying value including allocated goodwill. If the carrying value of our reporting unit exceeds its fair value, then the second step of the impairment test is performed to measure the impairment loss, if any. We test goodwill for impairment at the entity level, which is considered our reporting unit. Our estimate of fair value is determined using both the Discounted Cash Flow method of the Income Approach and the Guideline Public Company method of the Market Approach. The Discounted Cash Flow method estimates future cash flows of our business for a certain discrete period and then discounts them to their present value. The Guideline Public Company method computes value indicators ( multiples ) from the operating data of the selected publicly traded guideline companies. After these multiples were evaluated, appropriate value indicators were selected and applied to the operating statistics of the reporting unit to arrive at indications of value. Specifically, we relied upon the application of Total Invested Capital based valuation multiples for each guideline company. In applying the Income and Market Approaches, premiums and discounts were determined and applied to estimate the fair values of the reporting unit. To arrive at the indicated value of equity under each approach, we then assigned a relative weighting to the resulting values from each approach to determine whether the carrying value of the reporting unit exceeds its fair value, thus requiring step two of the impairment test.

We conduct the impairment test annually on November 30th for each fiscal year for which goodwill is evaluated for impairment. We are also aware of the requirement to evaluate goodwill for impairment at other times should circumstances arise. To date, we have concluded that the fair value of the reporting unit significantly exceeded the carrying value and therefore, step two of the impairment test has never been performed.

Although there are inherent uncertainties in this assessment process, the estimates and assumptions we use are consistent with our internal planning. If these estimates or their related assumptions change in the future, we may be required to record an impairment charge on all or a portion of our goodwill and intangible assets. Furthermore, we cannot predict the occurrence of future impairment-triggering events nor the impact such events might have on our reported asset values. Future events could cause us to conclude that impairment indicators exist and that goodwill or other intangible assets associated with our acquired businesses are impaired. Any resulting impairment loss could have an adverse impact on our results of operations.

*Stock-based Compensation.* We have equity incentive plans under which we have granted incentive stock options, restricted stock units and non-qualified stock options.

Our employee stock-based compensation cost is estimated at the grant date based on the fair-value of the award and is recognized as an expense ratably over the requisite service period of the award. Determining the appropriate fair-value model and calculating the fair value of stock-based awards at the grant date requires considerable judgment, including estimating stock price volatility, expected option life and forfeiture rates. We develop our estimates based on historical data. If factors change and we employ different assumptions in future periods, the compensation expense that we record may differ significantly from what we have recorded in the current period. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value stock option awards. We recognize compensation expense using the straight-line amortization method.

Our non-employee stock-based compensation awards are measured at either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured at each reporting date using the stock price and other measurement assumptions as of the earlier of (i) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached, or (ii) the date at which the counterparty's performance is completed.

*Registered Common Stock Warrants.* We account for registered common stock warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the registered warrants require the issuance of registered securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. We classify registered warrants on the condensed consolidated balance sheet as a current liability, which is revalued at each balance sheet date subsequent to the initial issuance. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment including estimating stock price volatility and expected warrant life. We develop our estimates based on historical data. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value the registered warrants. Changes in the fair market value of the warrants are reflected in the condensed consolidated statement of operations as Change in fair value of common stock warrants.



## **Table of Contents**

### ***Adoption of Recent Accounting Pronouncements***

We describe below recent pronouncements that may have a significant effect on our financial statements. We do not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to our financial condition, results of operations, or related disclosures.

***Accounting Standards Update, ( ASU ), No. 2011-04*** In May 2011, the Financial Accounting Standards Board ( FASB ) issued an ASU, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards , or IFRS. This update amends Accounting Standards Codification Topic 820, Fair Value Measurement and Disclosure. ASU 2011-04 clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. We have adopted ASU 2011-04 as of January 1, 2012 and it has not had a significant impact on our financial position, results of operations or cash flows but on presentation and disclosure only.

***ASU No. 2011-05*** In June 2011, the FASB issued an ASU, Presentation of Comprehensive Income . ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders' equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We have adopted ASU 2011-05 as of January 1, 2012 and it has not had an impact on our financial position, results of operations or cash flows but on presentation and disclosure only.

***ASU No. 2011-08*** In September 2011, the FASB issued an ASU, Goodwill Impairment Testing . For entities testing goodwill for impairment, ASU 2011-08 allows the option of performing a qualitative assessment before calculating the fair value of a reporting unit in step 1 of the impairment test. The two-step impairment test would be required only if the fair value of a reporting unit is qualitatively determined to be more likely than not less than the carrying amount. We have adopted the amendment provisions of ASU 2011-08 as of January 1, 2012 and it has not had an impact on our financial condition, results of operations or cash flows.

### ***Results of Operations***

***Revenue.*** We had total revenue of \$855,000 and \$3.0 million for the three and nine months ended September 30, 2012, respectively, as compared to \$2.6 million and \$8.2 million for the three and nine months ended September 30, 2011, respectively. Revenue primarily consists of license fees, revenue under collaborative research and development arrangements and grants and government contracts.

Revenue from license fees and milestone revenue was \$129,000 and \$387,000 for the three and nine months ended September 30, 2012, respectively, as compared to \$183,000 and \$435,000 for the three and nine months ended September 30, 2011, respectively. The decrease for the three and nine-month periods was primarily due to lower revenue recognized from various smaller license agreements.

Revenue under collaborative research and development arrangements was \$116,000 for the three and nine months ended September 30, 2012, as compared to no such revenue for the three and nine months ended September 30, 2011. The increase in 2012 was related to work performed under our Collaborative Development and License Agreement with VGX Int'l. Under the Agreement, we will co-develop with VGX Int'l our SynCon® therapeutic vaccines for hepatitis B and C infections.

During the three and nine months ended September 30, 2012, we recorded grant and miscellaneous revenue of \$610,000 and \$2.5 million, respectively, as compared to \$2.5 million and \$7.7 million for the three and nine months ended September 30, 2011, respectively. The decrease was primarily due to the timing of scheduled contract payments which resulted in lower revenues of \$1.4 million and \$4.2 million recognized from our contract with the NIAID for the three and nine months ended September 30, 2012, as compared to the same periods in 2011, respectively. The NIAID contract, which was modified in September 2011, has an initial term of five years with two one-year options (period of performance is September 30, 2008 – September 29, 2015 including the two options). The current approved funding of the contract for the five years is \$23.0 million with option years six and seven valued at \$1.3 million and \$1.0 million, respectively, for a total potential value of \$25.3 million, and will fund research and development for HIV DNA-based vaccines delivered via our proprietary electroporation system. These decreases were also attributable to no revenue recognized under our PATH Malaria Vaccine Initiative ( MVI ) contract during the three and nine months ended September 30, 2012 as compared to \$316,000 and \$715,000 for the same periods in 2011, respectively. PATH is an international nonprofit organization funded by private donors. We have a research program and agreement with the PATH MVI to evaluate in a preclinical feasibility study our SynCon® DNA vaccine development platform to target antigens from *Plasmodium* species and deliver them intradermally using the CELLECTRA® electroporation device. The initial agreement with MVI was for \$685,000 and was completed in February 2010. In September 2010 we entered into an amended agreement with PATH to further this study in non-human primates.



**Table of Contents**

The amended agreement had a total value of \$804,000 and was completed in August 2011. In October 2012 we entered into a third amendment with PATH MVI for a total value of \$887,000 for the conduct of feasibility studies, process development activities, and manufacture of cell banks to be utilized in Phase 1 clinical trials. The overall decrease in grants and miscellaneous revenue was also due to lower revenue of \$193,000 and \$372,000 recognized from our subcontracts with Drexel University for the three and nine months ended September 30, 2012 as compared to the same periods in 2011, respectively.

*Research and Development Expenses.* Research and development expenses for the three and nine months ended September 30, 2012, were \$5.0 million and \$13.5 million, respectively, as compared to \$7.0 million and \$15.9 million for the three and nine months ended September 30, 2011, respectively. The decrease for the three-month period year over year was primarily due to \$1.3 million in lower direct costs related to work performed for the NIAID contract, \$648,000 in lower clinical expenses related to biologics manufacturing and laboratory processing and \$599,000 in lower outside service expense related to various research and development arrangements. These decreases were partially offset by \$315,000 in higher compensation and related expenses due to increased employee headcount, \$107,000 in higher engineering and manufacturing contract labor expenses, higher expensed inventory of \$64,000 related to the purchase of devices to support on-going clinical trials and \$62,000 in higher engineering and professional services for device improvements, among other variances. The decrease for the nine-month period year over year was primarily due to \$2.7 million in lower direct costs related to work performed for the NIAID contract, \$905,000 in lower clinical expenses related to biologics manufacturing and laboratory processing and \$600,000 in lower outside services related to various research and development arrangements. These decreases were partially offset by \$1.2 million in higher compensation and related expenses due to increased employee headcount and \$199,000 in higher engineering and professional services for device improvements, as well as an increase in facilities expense, employee stock-based compensation, contract labor and shipping expense of \$135,000, \$89,000, \$85,000 and \$80,000, respectively, among other variances.

*General and Administrative Expenses.* General and administrative expenses, which include business development expenses and the amortization of intangible assets, for the three and nine months ended September 30, 2012, were \$2.7 million and \$7.9 million, respectively, as compared to \$2.3 million and \$8.7 million for the three and nine months ended September 30, 2011, respectively. The increase for the three-month period year over year was primarily due to an increase in legal expenses, travel expenses, accounting fees and franchise taxes and registration payments of \$145,000, \$52,000, \$46,000 and \$35,000, respectively, among other variances. The decrease for the nine-month period year over year, was primarily due to a \$607,000 decrease in severance expenses, a \$471,000 decrease in employee stock-based compensation due to no severance related stock option expense, and a \$365,000 decrease in compensation and related expenses. These decreases were partially offset by an increase in legal expenses, investor relations outside services, accounting fees and consultant stock-based compensation of \$211,000, \$141,000, \$140,000 and \$126,000, respectively, among other variances.

*Stock-based Compensation.* Stock-based compensation cost is measured at the grant date, based on the fair value of the award reduced by estimated forfeitures, and is recognized as expense over the employee's requisite service period. Total compensation cost for our stock plans for the three and nine months ended September 30, 2012 was \$253,000 and \$1.0 million, respectively. From these amounts, \$117,000 and \$477,000 were included in research and development expenses and \$136,000 and \$551,000 were included in general and administrative expenses, for the three and nine months ended September 30, 2012, respectively. Total compensation cost for our stock plans for the three and nine months ended September 30, 2011 was \$261,000 and \$1.4 million, respectively. From these amounts, \$103,000 and \$388,000 were included in research and development expenses and \$158,000 and \$1.0 million were included in general and administrative expenses, for the three and nine months ended September 30, 2011, respectively. The decrease for the three-month period year over year was primarily due to a lower valuation of the employee stock options granted during the period. The decrease for the nine-month period year over year was primarily due to a lower valuation of the employee stock options granted during the period and no severance related stock-based compensation expense recognized in 2012.

*Interest and Other Income, net.* Interest and other income, net, for the three and nine months ended September 30, 2012 was \$37,000 and \$110,000, respectively, as compared to \$6,000 and \$15,000 for the three and nine months ended September 30, 2011, respectively. The increase was primarily due to a higher interest rate earned on our short-term investment accounts.

*Change in fair value of common stock warrants.* The change in fair value of common stock warrants for the three and nine months ended September 30, 2012 was (\$1.1 million) and (\$1.1 million), respectively, as compared to \$347,000 and \$7.6 million for the three and nine months ended September 30, 2011, respectively. The variance is primarily due to the revaluation of registered common stock warrants issued by us in January 2011 and December 2011. We revalue warrants at each balance sheet date to fair value.

*Gain (Loss) from investment in affiliated entity.* Gain (loss) is a result of the change in the fair market value of the investment as of September 30, 2012.

---

## **Table of Contents**

### ***Liquidity and Capital Resources***

Historically, our primary uses of cash have been to finance research and development activities including clinical trial activities in the oncology, DNA vaccines and other immunotherapy areas of our business. Since inception, we have satisfied our cash requirements principally from proceeds from the sale of our company equity securities and government grants.

#### ***Working Capital and Liquidity***

As of September 30, 2012, we had working capital of \$5.7 million, as compared to \$20.9 million as of December 31, 2011. The decrease in working capital during the nine months ended September 30, 2012 was primarily due to expenditures related to our research and development activities and various general and administrative expenses related to legal, consultants, accounting and audit, and corporate development.

Net cash used in operating activities was \$16.8 million and \$15.3 million for the nine months ended September 30, 2012 and 2011, respectively.

Net cash provided by (used in) investing activities was \$2.8 million and \$(3.8 million) for the nine months ended September 30, 2012 and 2011, respectively. The variance was primarily the result of timing differences in short-term investment purchases, sales and maturities as well as the increase in proceeds received from Oncosec.

Net cash provided by financing activities was \$1.2 million and \$24.3 million for the nine months ended September 30, 2012 and 2011, respectively. The decrease was due to less financing activity during the period. Financing activities for the nine months ended September 30, 2011 included our January 2011 financing as well as our At-The-Market Equity Distribution Agreement.

In June 2012, we entered into a sales agreement (the "Sales Agreement") with an outside placement agent (the "Placement Agent") to sell shares of our common stock with aggregate gross proceeds of up to \$25.0 million from time to time, through an "at-the-market" equity offering program under which the Placement Agent will act as sales agent. As of September 30, 2012 we have sold 2,086,986 shares of common stock under the Sales Agreement for net proceeds of \$1.2 million.

In December 2011, we completed an underwritten public offering relating to the sale and issuance of 7,699,712 units to certain institutional investors, consisting of 7,699,712 shares of common stock and warrants to purchase an aggregate of up to 5,774,784 additional shares of common stock. These units include the partial exercise of the underwriter's overallotment option of 962,465 additional units at the public offering price. The units consist of one share of common stock and 0.75 of a warrant to purchase one share of common stock, at a purchase price of \$0.5195 per unit. The warrants have a term of five years and an exercise price of \$0.65 per share. We may call the warrants if the closing bid price of our common stock has been at least \$1.30 over 20 trading days and certain other conditions are met. We received net proceeds from the transaction of approximately \$3.7 million, after deducting the underwriter's discounts and other offering expenses payable.

In January 2011, we entered into investor purchase agreements with investors relating to the issuance and sale of (a) 21,130,400 shares of common stock, and (b) warrants to purchase a total of 10,565,200 shares of common stock with an exercise price of \$1.40 per share, for an aggregate purchase price of approximately \$24.3 million. The shares of common stock and warrants were sold in units, consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at a purchase price of \$1.15 per unit. We received net proceeds from the transaction of approximately \$23.0 million, after deducting the placement agent's fee and offering expenses payable.

As of September 30, 2012, we had an accumulated deficit of \$229.1 million. We have operated at a loss since 1994, and we expect to continue to operate at a loss for some time. The amount of the accumulated deficit will continue to increase, as it will be expensive to continue research and development efforts. If these activities are successful and if we receive approval from the FDA to market our DNA vaccine products, then we will need to raise additional funding to market and sell the approved vaccine products and equipment. We cannot predict the outcome of the above matters at this time. We are evaluating potential collaborations as an additional way to fund operations. We believe that current cash and cash equivalents plus short-term investments are sufficient to meet planned working capital requirements into the third quarter of 2013. We will continue to rely on outside sources of financing to meet our capital needs beyond this time.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk** ***Interest Rate Risk***

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

Market risk represents the risk of loss that may impact our consolidated financial position, results of operations or cash flows due to adverse changes in financial and commodity market prices and rates. We are exposed to market risk primarily in the area of changes in United States interest rates and conditions in the credit markets, and the recent fluctuations in interest rates and availability of funding in the credit markets primarily impact the performance of our investments. We do not have any material foreign currency or other derivative financial instruments. 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 investment grade securities.

## **Table of Contents**

### ***Fair Value measurements***

We account for our common stock warrants pursuant to the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the registered warrants require the issuance of registered securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. We classify registered warrants on the consolidated balance sheet as a current liability that is revalued at each balance sheet date subsequent to the initial issuance.

The investment in affiliated entity represents our ownership interest in the Korean based company, VGX Int'l. We report this investment at fair value on the consolidated balance sheet using the closing price of VGX Int'l's shares of common stock as listed on the Korean Stock Exchange.

Common stock warrants that we have received to purchase shares of OncoSec are classified on the consolidated balance sheet as a long-term asset that is revalued at each balance sheet date subsequent to the initial receipt.

### ***Foreign Currency Risk***

We have operated primarily in the United States and most transactions during the three and nine months ended September 30, 2012, have been made in United States dollars. Accordingly, we have not had any material exposure to foreign currency rate fluctuations, with the exception of the valuation of our equity investment in VGX Int'l which is denominated in South Korean Won. We do not have any foreign currency hedging instruments in place.

Certain transactions related to us are denominated primarily in foreign currencies, including Euros, British Pounds, Canadian Dollars and South Korean Won. 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, including the impact of the existing crisis in the global financial markets in such countries and the impact on both the United States dollar and the noted foreign currencies.

We do not use derivative financial instruments for speculative purposes. We do not engage in exchange rate hedging or hold or issue foreign exchange contracts for trading purposes. Currently, we do not expect the impact of fluctuations in the relative fair value of other currencies to be material in 2012.

## **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 Securities and Exchange Commission'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.

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 September 30, 2012.

### ***Changes in Internal Control Over Financial Reporting***

There have not been any changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the quarter ended September 30, 2012, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



---

**Table of Contents**

**Part II. Other Information**

**Item 1. Legal Proceedings**

Not applicable.

**Item 1A. Risk Factors**

*The following Risk Factors do not reflect any material changes to the Risk Factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, which we filed with the Securities and Exchange Commission on March 15, 2012. 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, 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 annual report on Form 10-K for the year ended December 31, 2011.*

**Risks Related to Our Business and Industry**

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

We have experienced significant operating losses to date; as of September 30, 2012 our accumulated deficit was approximately \$229.1 million. We have generated limited revenues, primarily consisting of license and grant revenue, 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 vaccine product candidates or electroporation-based synthetic vaccine delivery technology and thus may never have any significant future revenues or achieve and sustain profitability. We believe that current cash and cash equivalents plus short-term investments are sufficient to meet planned working capital requirements into the third quarter of 2013. We will continue to rely on outside sources of financing to meet our capital needs beyond this time.

*We have limited sources of revenue and our success is dependent on our ability to develop our vaccine and other product candidates and electroporation equipment.*

We do not sell any products and may not have any other products commercially available for several years, if at all. Our ability to generate future revenues depends heavily on our success in:

developing and securing United States and/or foreign regulatory approvals for our product candidates, including securing regulatory approval for conducting clinical trials with product candidates;

developing our electroporation-based DNA delivery technology; and

commercializing any products for which we receive approval from the FDA and foreign regulatory authorities.

Our electroporation equipment and product 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 electroporation equipment and product 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 electroporation equipment and products, and we may not be able to continue our operations.

*None of our human vaccine product candidates has been approved for sale, and we may not develop commercially successful vaccine products.*

Our human vaccine programs are in the early stages of research and development, and currently include vaccine product candidates in discovery, pre-clinical studies and Phase I and II clinical studies. There are limited data regarding the efficiency of synthetic vaccines compared with conventional vaccines, and we must conduct a substantial amount of additional research and development before any regulatory authority will approve any of our vaccine product candidates. The success of our efforts to develop and commercialize our vaccine product candidates could fail for a number of reasons. For example, we could experience delays in product development and clinical trials. Our vaccine product candidates could be found to be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances. The products, if safe and effective, could be difficult to manufacture on a large scale or uneconomical to market, or our competitors could develop superior vaccine products more quickly and efficiently or more effectively market their competing products.

In addition, adverse events, or the perception of adverse events, relating to vaccines and vaccine delivery technologies may negatively impact our ability to develop commercially successful vaccine products. For example, pharmaceutical companies have

## **Table of Contents**

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 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 will need substantial additional capital to develop our synthetic vaccine and electroporation delivery technology and other product candidates and for our future operations.*

Conducting the costly and time consuming research, pre-clinical and clinical testing necessary to obtain regulatory approvals and bring our vaccine delivery technology and product candidates 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 products and product candidates;

the cost of prosecuting, enforcing and defending against patent infringement claims and other intellectual property rights;

competing technological and market developments; and

our ability and 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 been experiencing heightened volatility and turmoil, making it more difficult to raise capital through the issuance of equity securities. Furthermore, as a result of the recent volatility in the capital markets, the cost and availability of credit has been and may continue to be adversely affected by 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, 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. Fluctuating 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.

*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 product candidates.*

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

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 product candidates.

*We face intense and increasing competition and many of our competitors have significantly greater resources and experience.*

Many other companies are pursuing other forms of treatment or prevention for diseases that we target. For example, many of our competitors are working on developing and testing H5N1, H1N1 and universal influenza vaccines, and several H1N1 vaccines developed by our competitors have been approved for human use. Our competitors and potential competitors include large pharmaceutical and medical device companies and more established biotechnology companies. 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, pre-clinical 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. Small 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

## **Table of Contents**

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.

*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, or may 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 a license and collaboration agreement with Merck. The amount and timing of resources applied by our collaborators are largely outside of our control.

Wyeth terminated one of our existing collaboration agreements. If any of our other 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. 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 enter into agreements with other highly-regarded 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 and implement 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.

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

We currently derive, and in the past we have derived, a significant portion of our revenue from a limited number of licensing partners and government grants and contracts. For example, during the year ended December 31, 2011, the NIAID and the PATH Malaria Vaccine Initiative (MVI) accounted for approximately 80% and 8%, of our consolidated revenue, respectively. 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 cancelled and we fail to replace the contract with new business, our revenue would be adversely affected.

*We have agreements with government agencies, which are subject to termination and uncertain future funding.*

We have entered into agreements with government agencies, such as the NIAID and the US Army, and we intend to continue entering into these agreements 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.

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.

*Our quarterly operating results may fluctuate significantly.*

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

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 electroporation equipment, product candidates or future development programs;

expenses related to corporate transactions, including ones not fully completed;

## **Table of Contents**

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 electroporation equipment and product candidates or those of our competitors;

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 products receives 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.

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

We need FDA approval prior to marketing our electroporation equipment and products in the United States. If we fail to obtain FDA approval to market our electroporation equipment and product 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 pre-clinical 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 electroporation equipment and product candidates are both safe and effective for each indication for which approval is sought. 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 electroporation equipment and any of our product 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 electroporation equipment and product candidates. If the FDA does not consider or approve our application, it may require that we conduct additional clinical, pre-clinical 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 products 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.

***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.***

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

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 pre-clinical studies and early clinical trials of our products 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 product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical 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.



**Table of Contents**

Our products 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 electroporation equipment and a product candidate are safe and effective for any indication;

the results of clinical trials may not meet the level of 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 electroporation equipment and a product candidate's clinical and other benefits outweigh its safety risks;

we may be unable to demonstrate that our electroporation equipment and a 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 pre-clinical studies or clinical trials;

the data collected from clinical trials of our product 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 the manufacturing processes or facilities of us or 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 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 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. 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;

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

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 gene based therapy clinical trials;

manufacturing sufficient quantities of our electroporation equipment and product candidates for use in clinical trials;

obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;

slower than expected recruitment and enrollment of patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for similar indications;

conducting clinical trials with sites internationally due to regulatory approvals and meeting international standards;

retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up; and

collecting, reviewing and analyzing our clinical trial data.

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.

---

## **Table of Contents**

If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our electroporation equipment and our product candidates may be harmed and our ability to generate product revenues will be delayed. 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 or completion of clinical trials may adversely affect the trading price of our common stock.

***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 product 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 electroporation equipment and product 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 product 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 product candidates. As a result, our financial results and the commercial prospects for our product 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.

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

Even if United States regulatory approval is obtained, the FDA 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, recordkeeping and submission of safety and other post-market information. 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 product candidates or the manufacturing facilities for our product 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 approval;

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.

***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.***

In order to market any electroporation equipment and product 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. 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. Regulatory

## **Table of Contents**

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 product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on their commercial potential or require costly, post-marketing follow-up studies.

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

The use of our electroporation equipment and synthetic vaccine 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, health care 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 product 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.

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

We currently do not have a sales organization for the marketing, sales and distribution of our electroporation equipment and product candidates. In order to commercialize any products, 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 our own sales force to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will 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 addition, we may have little or no control over the sales efforts of third parties involved in our commercialization efforts. In the event we are unable to 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 product candidates which would negatively impact our ability to generate product revenues.

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

The commercial success of our electroporation equipment and product 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 product 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;

**Table of Contents**

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;

our ability to obtain sufficient third-party coverage or reimbursement; and

the willingness of patients to pay out of pocket in the absence of third-party coverage.

If our electroporation equipment and product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care 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 product candidates may require significant resources and may never be successful.

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

Our ability to commercialize our electroporation equipment and product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors establish appropriate coverage and reimbursement levels for our product candidates and related treatments. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not be able to obtain third-party coverage or reimbursement for our products in whole or in part.

***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 recently passed healthcare reform legislation, the Patient Protection and Affordable Care Act, or the ACA. The provisions of the ACA are effective on various dates over the next several years. While many of the details regarding the implementation of the ACA are yet to be determined, we believe there will be continuing trends towards expanding coverage to more individuals, containing health care costs and improving quality. At the same time, the rebates, discounts, taxes and other costs associated with the ACA are expected to be a significant cost to the pharmaceutical industry.

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 and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights may be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business, without limitation. 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 either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

The ACA expands the government's investigative and enforcement authority and increases the penalties for fraud and abuse, including amendments to both the False Claims Act and the Anti-Kickback Statute to make it easier to bring suit under those statutes;



---

**Table of Contents**

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the Federal Food, Drug, and Cosmetic Act, 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; and

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, 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.

Additionally, the compliance environment is changing, with more states, such as California and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, Maine, and Minnesota requiring reporting to state governments of gifts, compensation, and other remuneration to physicians. Under the ACA, starting in 2012, pharmaceutical companies will be required to record any transfers of value made to doctors and teaching hospitals and to disclose such data to HHS, with initial disclosure to HHS due in 2013. These laws all provide for penalties for non-compliance. 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.

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 penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations 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. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

***If we and the contract manufacturers upon whom we rely fail to produce our systems and product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations, we may face delays in the development and commercialization of our electroporation equipment and product candidates.***

We manufacture some components of our electroporation systems and utilize the services of contract manufacturers to manufacture the remaining components of these systems and our product supplies for clinical trials. The manufacture of our systems and product supplies 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 product 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 electroporation equipment to our partners and products to patients in our clinical trials or to commercially launch a product would be jeopardized. Any delay or interruption in the supply of clinical trial supplies 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 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.

## **Table of Contents**

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.

***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 product 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 may be subject to stockholder litigation, which would harm our business and financial condition.***

We may have actions brought against us by stockholders relating to the Merger, past transactions, changes in our stock price or other matters. Any such actions could give rise to substantial damages, and thereby have a material adverse effect on our consolidated financial position, liquidity, or results of operations. Even if an action is not resolved against us, the uncertainty and expense associated with stockholder actions could harm our business, financial condition and reputation. Litigation can be costly, time-consuming and disruptive to business operations. The

defense of lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business.

***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. Recently, concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the United States mortgage market and a declining residential real estate market in the United States have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession. Domestic and international capital markets have also been experiencing heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing 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 in 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. Given the current instability of financial institutions, we may experience losses on these deposits.

## **Table of Contents**

### **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 electroporation equipment and product 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 has evolved over recent years and continues to undergo review and revision, both in the United States. 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;

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 product 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's various provisions will go into effect over an 18-month period. The Act changes 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 creates a procedure to challenge newly issued patents in the patent office via

## **Table of Contents**

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.

### **Risks Related to Our Common Stock**

*The price of our common stock is expected 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 is expected to be highly volatile and can 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, in addition to the other risk factors described in this annual 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:

## Edgar Filing: INOVIO PHARMACEUTICALS, INC. - Form 10-Q

developments concerning any research and development, clinical trials, manufacturing, and marketing efforts or collaborations;

fluctuating public or scientific interest in the potential for influenza pandemic or other applications for our vaccine or other product 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;

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;



**Table of Contents**

regulatory developments in the United States and other countries;

negative perception 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;

sales or other transactions by executive officers or directors involving our common stock;

changes in accounting principles;

global unrest, terrorist activities, and economic and other external factors; and

catastrophic weather and/or global disease pandemics.

The stock market in general has recently experienced relatively large price and volume fluctuations. 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 the common stock, which could cause a decline in the value of the common stock. In addition, price volatility may increase if the trading volume of our common stock remains limited or declines.

***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 your sole source of potential gain for the foreseeable future.

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

None.

**Item 3. Default Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

(a) Exhibits

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
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.
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.
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.*
Exhibit 101.INS XBRL Instance Document	
Exhibit 101.SCH XBRL Taxonomy Extension Schema Document	
Exhibit 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document	
Exhibit 101.LAB XBRL Taxonomy Extension Label Linkbase Document	
Exhibit 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document	

\* 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 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filings.

Table of Contents

**INOVIO PHARMACEUTICALS, INC.**

**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: November 7, 2012

By: */s/ J. JOSEPH KIM*  
**J. Joseph Kim**  
**President, Chief Executive Officer and Director**  
**(Principal Executive Officer)**

Date: November 7, 2012

By: */s/ PETER KIES*  
**Peter Kies**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**