

INOVIO PHARMACEUTICALS, INC.

Form 10-Q

May 17, 2010

[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 March 31, 2010**

**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)

**Inovio Biomedical Corporation**

(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):

Large accelerated filer ☐

Accelerated filer ☐

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 ☒

The number of shares outstanding of the registrant's Common Stock, par value \$0.001 per share, was 102,804,930 as of May 11, 2010.

**Table of Contents**

**INOVIO PHARMACEUTICALS, INC.**

**FORM 10-Q**

**For the Quarterly Period Ended March 31, 2010**

**INDEX**

|                |                                                                                                                               |           |
|----------------|-------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>Part I</b>  | <b><u>Financial Information</u></b>                                                                                           | <b>3</b>  |
| Item 1.        | <u>Financial Statements</u>                                                                                                   | 3         |
| a)             | <u>Condensed Consolidated Balance Sheets as of March 31, 2010 (Unaudited) and December 31, 2009</u>                           | 3         |
| b)             | <u>Condensed Consolidated Statements of Operations for each of the Three Months Ended March 31, 2010 and 2009 (Unaudited)</u> | 4         |
| c)             | <u>Condensed Consolidated Statements of Cash Flows for each of the Three Months Ended March 31, 2010 and 2009 (Unaudited)</u> | 5         |
| d)             | <u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>                                                       | 6         |
| Item 2.        | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                                  | 16        |
| Item 3.        | <u>Quantitative and Qualitative Disclosures About Market Risk</u>                                                             | 21        |
| Item 4.        | <u>Controls and Procedures</u>                                                                                                | 22        |
| <b>Part II</b> | <b><u>Other Information</u></b>                                                                                               | <b>24</b> |
| Item 1.        | <u>Legal Proceedings</u>                                                                                                      | 24        |
| Item 1A.       | <u>Risk Factors</u>                                                                                                           | 24        |
| Item 2.        | <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>                                                            | 38        |
| Item 3.        | <u>Default Upon Senior Securities</u>                                                                                         | 38        |
| Item 4.        | <u>(Removed and Reserved)</u>                                                                                                 | 38        |
| Item 5.        | <u>Other Information</u>                                                                                                      | 39        |
| Item 6.        | <u>Exhibits</u>                                                                                                               | 40        |
|                | <b><u>Signatures</u></b>                                                                                                      | <b>41</b> |

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

|                                                                 | <b>March 31,<br/>2010<br/>(Unaudited)</b> | <b>December 31,<br/>2009</b> |
|-----------------------------------------------------------------|-------------------------------------------|------------------------------|
| <b>ASSETS</b>                                                   |                                           |                              |
| <b>Current assets:</b>                                          |                                           |                              |
| Cash and cash equivalents                                       | \$ 17,710,983                             | \$ 30,296,215                |
| Short-term investments certificates of deposit                  | 8,000,000                                 |                              |
| Short-term investments auction rate securities                  | 10,836,476                                | 10,397,530                   |
| Auction rate security rights                                    | 2,706,210                                 | 3,145,156                    |
| Accounts receivable                                             | 344,061                                   | 259,207                      |
| Accounts receivable from affiliated entity                      | 3,061,207                                 | 58,853                       |
| Prepaid expenses and other current assets                       | 463,562                                   | 409,845                      |
| <b>Total current assets</b>                                     | <b>43,122,499</b>                         | <b>44,566,806</b>            |
| Fixed assets, net                                               | 339,984                                   | 343,457                      |
| Intangible assets, net                                          | 12,487,537                                | 12,968,934                   |
| Goodwill                                                        | 10,113,371                                | 10,113,371                   |
| Investment in affiliated entity                                 | 13,374,976                                | 12,330,802                   |
| Other assets                                                    | 283,478                                   | 305,547                      |
| <b>Total assets</b>                                             | <b>\$ 79,721,845</b>                      | <b>\$ 80,628,917</b>         |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>                      |                                           |                              |
| <b>Current liabilities:</b>                                     |                                           |                              |
| Accounts payable and accrued expenses                           | \$ 2,915,220                              | \$ 3,445,750                 |
| Accounts payable and accrued expenses due to affiliated entity  | 128,720                                   | 445,091                      |
| Accrued clinical trial expenses                                 | 299,313                                   | 299,261                      |
| Line of credit                                                  | 12,097,634                                | 12,114,760                   |
| Common stock warrants                                           | 1,718,492                                 | 2,774,850                    |
| Deferred revenue                                                | 151,532                                   | 270,326                      |
| Deferred revenue from affiliated entity                         | 375,000                                   |                              |
| Deferred rent                                                   | 1,917                                     |                              |
| <b>Total current liabilities</b>                                | <b>17,687,828</b>                         | <b>19,350,038</b>            |
| Deferred revenue, net of current portion                        | 72,580                                    | 82,594                       |
| Deferred revenue from affiliated entity, net of current portion | 2,617,944                                 |                              |
| Deferred rent, net of current portion                           | 23,844                                    | 11,338                       |
| <b>Total liabilities</b>                                        | <b>20,402,196</b>                         | <b>19,443,970</b>            |
| <b>Inovio Pharmaceuticals, Inc. stockholders equity:</b>        |                                           |                              |
| Common stock                                                    | 102,766                                   | 102,746                      |
| Additional paid-in capital                                      | 238,008,428                               | 237,577,970                  |
| Accumulated deficit                                             | (179,518,119)                             | (177,224,433)                |

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

|                                                                |                      |                      |
|----------------------------------------------------------------|----------------------|----------------------|
| Accumulated other comprehensive income                         | 110,656              | 105,796              |
| <b>Total Inovio Pharmaceuticals, Inc. stockholders' equity</b> | <b>58,703,731</b>    | <b>60,562,079</b>    |
| Non-controlling interest                                       | 615,918              | 622,868              |
| <b>Total stockholders' equity</b>                              | <b>59,319,649</b>    | <b>61,184,947</b>    |
| <b>Total liabilities and stockholders' equity</b>              | <b>\$ 79,721,845</b> | <b>\$ 80,628,917</b> |

See accompanying notes.

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

|                                                                                     | <b>Three Months Ended<br/>March 31,</b> |                       |
|-------------------------------------------------------------------------------------|-----------------------------------------|-----------------------|
|                                                                                     | <b>2010</b>                             | <b>2009</b>           |
| <b>Revenue:</b>                                                                     |                                         |                       |
| License fee and milestone revenue                                                   | \$ 73,610                               | \$ 213,098            |
| Revenue under collaborative research and development arrangements                   |                                         | 54,458                |
| Grant and miscellaneous revenue                                                     | 1,299,779                               | 101,894               |
| <b>Total revenue</b>                                                                | <b>1,373,389</b>                        | <b>369,450</b>        |
| <b>Operating expenses:</b>                                                          |                                         |                       |
| Research and development                                                            | 2,730,595                               | 963,733               |
| General and administrative                                                          | 3,050,158                               | 2,966,142             |
| <b>Total operating expenses</b>                                                     | <b>5,780,753</b>                        | <b>3,929,875</b>      |
| <b>Loss from operations</b>                                                         | <b>(4,407,364)</b>                      | <b>(3,560,425)</b>    |
| Interest income, net                                                                | 34,561                                  | 33,648                |
| Other income, net                                                                   | 1,027,993                               | 62,282                |
| Gain from investment in affiliated entity                                           | 1,044,174                               |                       |
| <b>Net loss</b>                                                                     | <b>(2,300,636)</b>                      | <b>(3,464,495)</b>    |
| Net loss attributable to non-controlling interest                                   | 6,950                                   |                       |
| <b>Net loss attributable to Inovio Pharmaceuticals, Inc.</b>                        | <b>\$ (2,293,686)</b>                   | <b>\$ (3,464,495)</b> |
| <b>Loss per common share basic and diluted:</b>                                     |                                         |                       |
| <b>Net loss per share attributable to Inovio Pharmaceuticals, Inc. stockholders</b> | <b>\$ (0.02)</b>                        | <b>\$ (0.08)</b>      |
| <b>Weighted average number of common shares outstanding basic and diluted</b>       | <b>102,757,083</b>                      | <b>44,035,480</b>     |

See accompanying notes.

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

|                                                                             | <b>Three Months<br/>Ended<br/>March 31,<br/>2010</b> | <b>Three<br/>Months<br/>Ended<br/>March 31,<br/>2009</b> |
|-----------------------------------------------------------------------------|------------------------------------------------------|----------------------------------------------------------|
| <b>Cash flows from operating activities:</b>                                |                                                      |                                                          |
| Net loss                                                                    | \$ (2,300,636)                                       | \$ (3,464,495)                                           |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                                      |                                                          |
| Depreciation                                                                | 41,244                                               | 46,029                                                   |
| Amortization of intangible assets                                           | 481,397                                              | 181,634                                                  |
| Change in value of common stock warrants                                    | (1,056,358)                                          | (63,953)                                                 |
| Gain on long-term investments                                               | 438,946                                              | (365,111)                                                |
| Loss on auction rate security rights                                        | (438,946)                                            | 365,111                                                  |
| Stock-based compensation                                                    | 429,477                                              | 160,719                                                  |
| Interest expense accrued on line of credit                                  | 34,368                                               |                                                          |
| Amortization of deferred tax liabilities                                    |                                                      | (15,750)                                                 |
| Deferred rent                                                               | 14,423                                               | (17,774)                                                 |
| Gain from investment in affiliated company                                  | (1,044,174)                                          |                                                          |
| Changes in operating assets and liabilities:                                |                                                      |                                                          |
| Accounts receivable                                                         | (84,854)                                             | 437,455                                                  |
| Accounts receivable from affiliated entity                                  | (3,002,354)                                          |                                                          |
| Prepaid expenses and other current assets                                   | (53,717)                                             | 35,619                                                   |
| Other assets                                                                | 22,069                                               |                                                          |
| Accounts payable and accrued expenses                                       | (530,478)                                            | 494,751                                                  |
| Accounts payable due to affiliated entity                                   | (316,371)                                            |                                                          |
| Deferred revenue                                                            | (128,808)                                            | (79,998)                                                 |
| Deferred revenue from affiliated entity                                     | 2,992,944                                            |                                                          |
| <b>Net cash used in operating activities</b>                                | <b>(4,501,828)</b>                                   | <b>(2,285,763)</b>                                       |
| <b>Cash flows from investing activities:</b>                                |                                                      |                                                          |
| Purchase of short term investments                                          | (8,000,000)                                          |                                                          |
| Purchases of capital assets                                                 | (37,771)                                             | (1,094)                                                  |
| Additions to intangible assets and other assets                             |                                                      | (62,448)                                                 |
| <b>Net cash used in investing activities</b>                                | <b>(8,037,771)</b>                                   | <b>(63,542)</b>                                          |
| <b>Cash flows from financing activities:</b>                                |                                                      |                                                          |
| Proceeds from stock option exercises                                        | 1,001                                                |                                                          |
| Repayment of line of credit                                                 | (51,494)                                             | (37,016)                                                 |
| <b>Net cash used in financing activities</b>                                | <b>(50,493)</b>                                      | <b>(37,016)</b>                                          |
| Effect of exchange rate changes on cash and equivalents                     | 4,860                                                | (1,722)                                                  |
| <b>Decrease in cash and equivalents</b>                                     | <b>(12,585,232)</b>                                  | <b>(2,388,043)</b>                                       |
| Cash and cash equivalents, beginning of period                              | 30,296,215                                           | 14,115,281                                               |

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

|                                                 |               |               |
|-------------------------------------------------|---------------|---------------|
| <b>Cash and cash equivalents, end of period</b> | \$ 17,710,983 | \$ 11,727,238 |
|-------------------------------------------------|---------------|---------------|

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. Our SynCon 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 (preventative), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) vaccines. The Company is advancing preclinical research for a universal seasonal/pandemic influenza vaccine. The Company's partners and collaborators include University of Pennsylvania, National Microbiology Laboratory of the Public Health Agency of Canada, NIAID (NIH), Merck, ChronTech, University of Southampton, and HIV Vaccines Trial Network (HVTN).

All of the Company's potential human products are in research and development phases. No revenues have been generated from the sale of any such products, nor are any such revenues expected for at least the next several years. The Company earns revenue from license fees and milestone revenue, collaborative research and development agreements, grants and government contracts. The Company's product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that the Company advances to clinical testing will require regulatory approval prior to commercial use, and will require significant costs for commercialization. The Company may not be successful in its research and development efforts and the Company may never generate sufficient product revenue to be profitable.

On May 14, 2010, we amended our Certificate of Incorporation to change our name from Inovio Biomedical Corporation to Inovio Pharmaceuticals, Inc.

##### **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 March 31, 2010, condensed consolidated statements of operations for the three months ended March 31, 2010 and 2009, and the condensed consolidated statements of cash flows for the three months ended March 31, 2010 and 2009, 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 months ended March 31, 2010 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2010, 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, 2009, included in the Company's Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 26, 2010. The Company has evaluated subsequent events after the balance sheet date of March 31, 2010 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 net loss attributable to Inovio of \$2.3 million for the three months ended March 31, 2010. The Company had working capital of \$25.4 million and an accumulated deficit of \$179.5 million as of March 31, 2010. The Company's ability to continue its operations is dependent upon its ability to obtain additional capital in the future and achieve profitable operations. On July 31, 2009, Inovio closed a \$30.0 million offering of its shares of common stock and warrants to purchase shares of common stock. The Company received net proceeds from the transaction of approximately \$28.4 million, after deducting offering expenses. 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



**Table of Contents**

**INOVIO PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

business. The Company's unaudited interim condensed consolidated financial statements as of and for the period ended March 31, 2010 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. VGX Pharmaceuticals Business Acquisition**

On June 1, 2009 (the Acquisition Date) the Company completed the acquisition of VGX Pharmaceuticals, Inc. (VGX), a privately-held company, pursuant to the terms of an Amended and Restated Agreement and Plan of Merger dated December 5, 2008, as further amended on March 31, 2009 (the Merger Agreement) by and among Inovio, Inovio's wholly-owned subsidiary Inovio Acquisition, LLC and VGX (the Merger).

Upon the closing of the Merger, based on an exchange ratio of 0.9812 (the Merger Exchange Ratio), and on terms and conditions as set forth in the Merger Agreement,

all of the issued and outstanding shares of common stock of VGX were canceled and converted into the right to receive shares of common stock of Inovio,

all outstanding options to purchase shares of VGX common stock became exercisable for shares of Inovio's common stock,

all outstanding warrants to purchase shares of VGX common stock became exercisable for shares of Inovio's common stock, and

all outstanding convertible debt of VGX became debt convertible into Inovio's common stock on existing terms.

As of the Acquisition Date, an aggregate of 41,492,757 shares of Inovio's common stock were issued to the former stockholders of VGX, and an additional 18,794,187 shares of Inovio's common stock were reserved for issuance upon exercise of the assumed options and warrants and conversion of the principal of and maximum interest payable on the VGX convertible debt. Immediately following the Acquisition Date the continuing holders of Inovio securities owned approximately 51.59% of Inovio's issued and outstanding common stock and the former holders of VGX securities owned approximately 48.41% of Inovio's issued and outstanding common stock.

Upon the closing of the Merger, Inovio Acquisition, LLC succeeded to all of VGX's business, properties and assets and assumed its obligations (other than the outstanding options and warrants to purchase shares of VGX common stock that became exercisable to purchase shares of Inovio common stock), changed its name to VGX Pharmaceuticals, LLC, and remains a wholly-owned subsidiary of the Company, utilizing a single, integrated management team with Inovio.

Prior to the date of the Merger Agreement, Inovio's sole relationship with VGX was as a party to a licensing agreement with VGX, entered into in the ordinary course of business, and as a holder of 25,000 shares of VGX common stock acquired in relation to such agreement. The shares of VGX common stock held by Inovio were cancelled upon closing of the Merger.

After a review of relevant factors and in accordance with the guidance regarding business combinations, Inovio was determined to be the accounting acquirer. The Merger was accounted for using the purchase method of accounting for business combinations under U.S. GAAP. Accordingly, the historical consolidated financial statements of Inovio were carried forward at their historical cost and the purchase price allocated to VGX's identifiable assets and liabilities was based on their estimated fair values at the Acquisition Date.

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

The final determination of the purchase price allocation was based on the fair values of major classes of assets acquired, including identifiable intangibles, and the fair value of liabilities assumed as of the Acquisition Date. The excess purchase price of the acquired entity over the fair value of assets and liabilities was recognized by the Company as goodwill on the accompanying consolidated balance sheet.

As a result of the Merger, Inovio acquired VGX's developed technology, which consists of VGX's CELLECTRA<sup>®</sup> technology and GHRH technology.

The purchase price allocation for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective fair values. Additionally, the Company must determine whether an acquired entity is considered to be a business or a set of net assets, because a portion of the purchase price can only be allocated to goodwill in a business combination.

**Table of Contents****INOVIO PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)**

Management estimated the fair value of the VGX developed technology using reasonable assumptions based on historical experience. The valuation methodology used to estimate the value of the technologies was the excess earnings method. This method reflects the present value of the operating cash flows generated by the technologies after taking into account the cost to realize the revenue, and an appropriate discount rate to reflect the time value and risk associated with the assets. First, yearly revenues for each technology were forecasted for a projected period of time of 10 years. Related cost of sales and operating expenses were then deducted from the revenue stream. Next, in order to value the technology, the value and required rate of return for other assets that contribute to the generation of the revenue earned by that particular technology asset were determined. The required returns on these other assets (the other asset classes identified were: net working capital, fixed assets, and assembled workforce) were charged to (or rather deducted from) the future net operating income to determine the returns specifically earned by the technology. Then, a discount rate was applied that considered the reasonable expectation of the risk profile of the proprietary technology in order to bring the future income to a present value. In the case of CELLECTRA<sup>®</sup> technology, a discount rate of 45% was used for the core technology and 60% for the milestone and royalty; for the GHRH technology, a 45% discount rate was utilized.

There was no purchase price amount allocated to acquired in-process research and development.

The percentage of non-controlling ownership interest consists of 12% in VGX Animal Health ( VGX AH ) and 88% ownership by the Company. The estimated fair value utilized is based on the last round of financing by VGX AH in late 2007, in which that entity issued shares of its common stock to a third party. There have been no subsequent financing rounds. Inovio has updated the valuation model to reflect current assumptions and due to the fact that there have been no additional milestone events, such as additional marketing approval, significant licensing agreements, material adverse events, or large sales contracts that would have materially changed any of the key assumptions used in the last valuation of VGX AH, Inovio believes that the valuation used in the last round of financing continues to reflect current fair value.

The Company's investment in an affiliated entity represents the Company's ownership interest in VGX International, Inc. ( VGX Int'l ) and is measured at fair value. The fair market value of the Company's interest in VGX Int'l was determined using the closing price of VGX Int'l's shares of common stock as listed on the Korean Stock Exchange as of June 1, 2009. The fair value of the Company's investment in VGX Int'l and the Company's ownership percentage of VGX Int'l were \$21,575,416 and 19.65%, respectively, on June 1, 2009.

The total purchase price of the acquisition was estimated as follows:

|                                              |                      |
|----------------------------------------------|----------------------|
| Value of Inovio shares issued                | \$ 26,156,188        |
| Value of vested warrants and options assumed | 5,137,038            |
|                                              | <b>\$ 31,293,226</b> |

The fair value of the Inovio shares used in determining the purchase price was \$0.63 per share based on the closing price of Inovio common stock on June 1, 2009.

The purchase price has been allocated to each major class of identifiable assets acquired and liabilities assumed based on their fair values as of June 1, 2009. The allocation to identifiable assets and liabilities is summarized below:

|                                          | <b>Fair Value</b>    |
|------------------------------------------|----------------------|
| Identifiable assets acquired             | <b>\$ 25,012,941</b> |
| Intangible assets (developed technology) | 8,441,583            |
| Goodwill                                 | 6,212,658            |

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

|                                 |               |
|---------------------------------|---------------|
| Assumed liabilities             | (7,703,649)   |
| Assumed noncontrolling interest | (670,307)     |
| Total                           | \$ 31,293,226 |

The excess of the purchase price over the fair value of net assets acquired resulted in goodwill of approximately \$6.2 million.

The following unaudited pro forma financial information combines the results of operations of Inovio and VGX assuming the Merger was consummated on January 1, 2009. The pro forma results are not necessarily indicative of what would have occurred if the Merger had been in effect for the periods presented. In addition, they are not intended to be a projection of future results and do not reflect any synergies that might be achieved from combined operations.

**Table of Contents****INOVIO PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)**

|                                              | Three Months<br>Ended<br>March 31, 2010 | Three Months<br>Ended<br>March 31, 2009 |
|----------------------------------------------|-----------------------------------------|-----------------------------------------|
| Revenue                                      | \$ 1,373,389                            | \$ 1,756,678                            |
| Net loss attributable to common stockholders | \$ (2,293,686)                          | \$ (6,180,169)                          |
| Net loss per common share                    | \$ (0.02)                               | \$ (0.07)                               |

**4. Principles of Consolidation**

These unaudited condensed consolidated financial statements include the accounts of Inovio Pharmaceuticals, Inc. and its domestic and foreign subsidiaries. All intercompany accounts and transactions have been eliminated upon consolidation.

***Reorganization***

In April 2009, the Company's Board of Directors implemented a reduction in force which impacted our Norwegian operations. In connection with this decision, operations previously performed in Norway ceased as of July 31, 2009, and are continuing in the United States. As of March 31, 2010, both of our wholly-owned Norwegian subsidiaries, Inovio AS and Inovio Tec AS, have been dissolved.

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

The guidance regarding fair value measurements establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; 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 March 31, 2010:

|                                 |                      | Fair Value Measurements at<br>March 31, 2010                                     |                                                                   |                                                          |
|---------------------------------|----------------------|----------------------------------------------------------------------------------|-------------------------------------------------------------------|----------------------------------------------------------|
|                                 |                      | Using Quoted Prices<br>in Active Markets<br>for Identical<br>Assets<br>(Level 1) | Using Significant<br>Other<br>Unobservable<br>Inputs<br>(Level 2) | Using Significant<br>Unobservable<br>Inputs<br>(Level 3) |
|                                 | Total                |                                                                                  |                                                                   |                                                          |
| <b>Assets:</b>                  |                      |                                                                                  |                                                                   |                                                          |
| Money market funds              | \$ 11,288,517        | 11,288,517                                                                       |                                                                   |                                                          |
| Certificates of deposit         | 8,000,000            |                                                                                  | 8,000,000                                                         |                                                          |
| Auction rate securities         | 10,836,476           |                                                                                  |                                                                   | 10,836,476                                               |
| Auction rate securities rights  | 2,706,210            |                                                                                  |                                                                   | 2,706,210                                                |
| Investment in affiliated entity | 13,374,976           | 13,374,976                                                                       |                                                                   |                                                          |
| <b>Total Assets</b>             | <b>\$ 46,206,179</b> | <b>\$ 24,663,493</b>                                                             | <b>\$ 8,000,000</b>                                               | <b>\$ 13,542,686</b>                                     |

Liabilities:

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

|                       |              |    |    |              |
|-----------------------|--------------|----|----|--------------|
| Common stock warrants | \$ 1,718,492 |    |    | \$ 1,718,492 |
| Total Liabilities     | \$ 1,718,492 | \$ | \$ | \$ 1,718,492 |

Level 1 assets include money market funds held by the Company which are valued at quoted market prices, as well as the Company's investment in VGX International, Inc. (VGX Int'l), for which the fair value is based on the market value of 8,075,775 common shares on March 31, 2010 listed on the Korean Stock Exchange.



**Table of Contents****INOVIO PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)**

Level 2 assets include certificates of deposit held by the Company with maturities that range from 91 days to 12 months. The Company determines fair value through broker quotations with reasonable levels of price transparency. Our certificates of deposit have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, typically utilizing market observable data.

Level 3 assets held as of March 31, 2010 include municipal debt obligations known as auction rate securities ( ARS ). Due to conditions in the global credit markets, these securities, representing a par value of \$13.6 million, are currently not liquid. Level 3 liabilities held as of March 31, 2010 consist of common stock warrant liabilities associated with warrants to purchase the Company's common stock issued in October 2006, August 2007 and July 2009.

In December 2008, the Company, via its wholly-owned subsidiary Genetronics, Inc. ( Genetronics ), which holds the ARS, accepted an offer of ARS Rights from UBS. The ARS Rights permit the Company to require UBS to purchase the Company's ARS at par value at any time during the period of June 30, 2010 through July 2, 2012. If the Company does not exercise its ARS Rights, the ARS will continue to accrue interest as determined by the terms of the ARS. If the ARS Rights are not exercised before July 2, 2012 they will expire and UBS will have no further obligation to buy the Company's ARS. UBS has the discretion to purchase or sell the Company's ARS at any time without prior notice so long as the Company receives a payment at par upon any sale or disposition. UBS will only exercise its discretion to purchase or sell the Company's ARS for the purpose of restructurings, dispositions or other solutions that will provide the Company with par value for its ARS. As a condition to accepting the offer of ARS Rights, the Company released UBS from all claims except claims for consequential damages relating to its marketing and sales of ARS. The Company also agreed not to serve as a class representative or receive benefits under any class action settlement or investor fund.

While the Company continues to earn interest on its ARS at the maximum contractual rates, these investments are not currently trading and therefore do not currently have a readily determinable market value. Accordingly, the estimated fair value of the ARS no longer approximates par value. The Company has used a discounted cash flow model to determine the estimated fair value of its investment in ARS and its ARS Rights as of March 31, 2010. The assumptions used in preparing the discounted cash flow model include estimates for interest rates, timing and amount of cash flows and expected holding period of the ARS and ARS Rights.

As of March 31, 2010, these ARS investment securities and the ARS and Put option are recorded as current assets due to the time frame in which they can be readily convertible to cash.

The Company elected to measure the ARS Rights at fair value to mitigate volatility in reported earnings due to their linkage to the ARS. The ARS Rights will continue to be measured at fair value utilizing Level 3 inputs until the earlier of their maturity or exercise.

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

There were no changes in fair value of the Company's total Level 3 financial assets for the three months ended March 31, 2010 as shown in the following table:

|                                                 | <b>Auction Rate<br/>Securities</b> |
|-------------------------------------------------|------------------------------------|
| Balance at January 1, 2010                      | \$ 13,542,686                      |
| Change in value of auction rate security        | 438,946                            |
| Change in value of auction rate security rights | (438,946)                          |
| Balance at March 31, 2010                       | \$ 13,542,686                      |

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

As of March 31, 2010, the Company has a \$1.7 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. As a result of these calculations, the Company recorded a net gain of \$1.1 million for the three months ended March 31, 2010. The net gain is reflected in the Company's unaudited condensed consolidated statement of operations as a component of other income, net.

**Table of Contents****INOVIO PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)**

The following table presents the changes in fair value of the Company's total Level 3 financial liabilities for the three months ended March 31, 2010:

|                                             | <b>Common Stock<br/>Warrants</b> |
|---------------------------------------------|----------------------------------|
| Balance at January 1, 2010                  | \$ 2,774,850                     |
| Realized gain included in other income, net | (1,056,358)                      |
| Balance at March 31, 2010                   | \$ 1,718,492                     |

**6. Line of Credit**

On August 26, 2008, the Company received notice from UBS Bank USA ( "UBS" ) that the Company's application had been approved for a \$5.0 million uncommitted demand revolving line of credit ( "Line of Credit" ) secured by ARS held by the Company in an account with UBS Financial Services, Inc. (the "Collateral Account" ), to provide additional working capital. On December 19, 2008, the Company amended its existing loan agreement with UBS Bank USA, increasing the existing credit line up to \$12.1 million, with the ARS pledged as collateral. The Company fully drew down on the line of credit on December 23, 2008. Advances under the Line of Credit bear interest at LIBOR plus 1.00% (the "Spread Over LIBOR" ). UBS may change the Spread Over LIBOR at its discretion when the Collateral consisting of ARS may be sold, exchanged or otherwise conveyed by the Company for gross proceeds that are, in the aggregate, not less than the par value of such securities. The loan is treated as a "no net cost loan" , as it bears interest at a rate equal to the average rate of interest paid to the Company on the pledged ARS, and the net interest cost to the Company is zero.

**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 is performed by the Company as of November each year or sooner if indicators of impairment exist. The following sets forth the intangible assets by major asset class:

|                         | <b>Useful<br/>Life<br/>(Yrs)</b> | <b>Gross</b>  | <b>March 31, 2010<br/>Accumulated<br/>Amortization</b> | <b>Net Book<br/>Value</b> | <b>Gross</b>  | <b>December 31, 2009<br/>Accumulated<br/>Amortization</b> | <b>Net Book<br/>Value</b> |
|-------------------------|----------------------------------|---------------|--------------------------------------------------------|---------------------------|---------------|-----------------------------------------------------------|---------------------------|
| <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     | (3,838,037)                                            | 1,964,491                 | 5,802,528     | (3,727,747)                                               | 2,074,781                 |
| Licenses                | 8 - 17                           | 1,198,781     | (970,454)                                              | 228,327                   | 1,198,781     | (965,907)                                                 | 232,874                   |
| CELLECTRA®(b)           | 5 - 11                           | 8,106,270     | (1,007,962)                                            | 7,098,308                 | 8,106,270     | (705,573)                                                 | 7,400,697                 |
| GHRH(b)                 | 11                               | 335,314       | (26,403)                                               | 308,911                   | 335,314       | (18,482)                                                  | 316,832                   |
| Other(c)                | 18                               | 4,050,000     | (1,162,500)                                            | 2,887,500                 | 4,050,000     | (1,106,250)                                               | 2,943,750                 |
| Total intangible assets |                                  | 19,492,893    | (7,005,356)                                            | 12,487,537                | 19,492,893    | (6,523,959)                                               | 12,968,934                |

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

|                                      |               |                |               |               |                |               |
|--------------------------------------|---------------|----------------|---------------|---------------|----------------|---------------|
| Total goodwill and intangible assets | \$ 29,606,264 | \$ (7,005,356) | \$ 22,600,908 | \$ 29,606,264 | \$ (6,523,959) | \$ 23,082,305 |
|--------------------------------------|---------------|----------------|---------------|---------------|----------------|---------------|

- (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® and GHRH are developed technologies which 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.
- Aggregate amortization expense on intangible assets for the three months ended March 31, 2010 and 2009 was \$481,000 and \$182,000, respectively. Estimated aggregate amortization expense for each of the five succeeding fiscal years is \$1.4 million for the remainder of fiscal year 2010, \$1.9 million for 2011, \$1.8 million for 2012, \$1.8 million for 2013, and \$932,000 for 2014.

**Table of Contents****INOVIO PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)****8. Stockholders' Equity**

The following is a summary of the Company's authorized and issued common and preferred stock as of March 31, 2010 and December 31, 2009:

|                                       |             |             | Outstanding as of |                      |
|---------------------------------------|-------------|-------------|-------------------|----------------------|
|                                       | Authorized  | Issued      | March 31,<br>2010 | December 31,<br>2009 |
| Common Stock, par \$0.001             | 300,000,000 | 102,765,682 | 102,765,682       | 102,746,058          |
| 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   |                   |                      |

***Preferred Stock***

The following is a summary of changes in the number of outstanding shares of the Company's Series C preferred stock for the three months ended March 31, 2010 and 2009:

|                                          | Series C |
|------------------------------------------|----------|
| Shares Outstanding as of January 1, 2010 | 26       |
| Preferred Shares converted               |          |
| Shares Outstanding as of March 31, 2010  | 26       |
| Shares Outstanding as of January 1, 2009 | 71       |
| Preferred Shares converted               |          |
| Shares Outstanding as of March 31, 2009  | 71       |

***Common Stock***

In July 2009, the Company entered into a securities purchase agreement with certain institutional investors relating to the sale and issuance of (a) 11,111,110 shares of common stock and (b) warrants to purchase a total of 2,777,776 shares of common stock with an exercise price of \$3.50 per share, for an aggregate purchase price of approximately \$30 million. The warrants were exercisable beginning six months after issuance and expire six months from the date they are first exercisable. The shares of common stock and warrants were sold in units, consisting of one share of common stock and a warrant to purchase 0.25 of a share of common stock, at a purchase price of \$2.70 per unit. The Company received net proceeds from the transaction of approximately \$28.4 million, after deducting offering expenses. As of March 31, 2010, none of these warrants have been exercised.

Upon the closing of the Merger in June 2009, an aggregate of 41,492,757 shares of the Company's common stock were issued to the former stockholders of VGX, and an additional 18,794,187 shares of the Company's common stock were reserved for issuance upon exercise of the assumed options and warrants and conversion of the principal of and maximum interest payable on the VGX convertible debt. In August 2009, the VGX convertible debt was automatically converted into 4,600,681 shares of the Company's common stock. VGX warrants assumed were ten-year warrants to purchase an aggregate of 4,923,406 shares of the Company's common stock with an exercise price ranging from \$0.26 to

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

\$1.28 per share, exercisable at various dates from March 25, 2013 through April 28, 2016. As of March 31, 2010, none of these warrants have been exercised.

In August 2007, the Company entered into an agreement with an outside consulting advisor pursuant to which the Company issued 230,000 registered shares of common stock and registered warrants to purchase 150,000 shares of common stock, as payment of a non-refundable retainer in connection with the engagement of its services. The warrants issued have an exercise price of \$3.00 per share, and are exercisable through August 6, 2012. As of March 31, 2010, none of these warrants have been exercised.

In January 2007, the Company exchanged 2,201,644 restricted shares of common stock and warrants to purchase up to 770,573 restricted shares of common stock for 2,201,644 ordinary shares of its Singapore subsidiary Inovio Asia Pte. Ltd. (IAPL), pursuant to

**Table of Contents**

**INOVIO PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(Unaudited)**

the terms of the Securities Purchase and Exchange Agreement under which the ordinary shares were originally issued by IAPL in October 2006 for \$5.3 million. The warrants issued have an exercise price of \$2.87 per share and are exercisable through October 13, 2011. As of March 31, 2010, none of these warrants have been exercised.

The Company accounts for registered common stock warrants issued in October 2006, August 2007 and July 2009 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 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 Other income, net.

***Warrants***

In addition to warrants granted as discussed above, the Company has issued the following additional warrants.

Participants in our October 2006 registered offering with foreign investors received five-year warrants to purchase an aggregate of 1,593,821 shares of our common stock with an exercise price of \$2.87 per share, exercisable through October 13, 2011. As of March 31, 2010, none of these warrants have been exercised.

Participants in our December 2005 private placement were issued five-year warrants to purchase an aggregate of 3,462,451 shares of our common stock with an exercise price of \$2.93 per share, exercisable through December 30, 2010. As of March 31, 2010, none of these warrants have been exercised.

On September 15, 2000, the Company entered into an exclusive license agreement with the University of South Florida Research Foundation, Inc. (USF), whereby USF granted us an exclusive, worldwide license to USF's rights in patents and patent applications generally related to needle electrodes (License Agreement). Pursuant to the License Agreement, the Company granted USF and its designees warrants to acquire 150,000 common shares for \$9.00 per share until September 14, 2010. Of the total warrants granted, 75,000 vested at the date of grant and the remainder will vest upon the achievement of certain milestones. The remaining 75,000 warrants are forfeitable and will be valued at the fair value on the date of vesting using the Black-Scholes pricing model. As of March 31, 2010, no warrants issued in connection with this licensing agreement had been exercised.

***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. The Incentive Plan reserves 3,750,000 shares of common stock for issuance as or upon exercise of incentive awards granted and to be granted at future dates. At March 31, 2010, the Company had 147,626 shares of common stock available for future grant under the plan, and 240,000 shares of vested restricted stock and options to purchase 3,192,161 shares of common stock outstanding under the plan. The awards granted and available for future grant under the Incentive Plan generally have a term of ten years and generally vest over a period of three 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 includes the Amended 2000 Stock Option Plan, under which the Company had options to purchase 2,313,120 shares of common stock outstanding at March 31, 2010. The terms and conditions of the options outstanding under these plans remain unchanged.

**9. Net loss per share**

Basic 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 warrants was anti-dilutive for all periods presented in 2010 and 2009, there is no difference between basic and diluted loss per share.



**Table of Contents****INOVIO PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)****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 assumptions used to estimate the fair value of stock options granted for the three month periods ended March 31, 2010 and 2009 are presented below:

|                         | <b>Three Months Ended March 31,</b> |             |
|-------------------------|-------------------------------------|-------------|
|                         | <b>2010</b>                         | <b>2009</b> |
| Risk-free interest rate | 2.34%-2.64%                         | 1.37%       |
| Expected volatility     | 134%                                | 96%         |
| Expected life in years  | 4                                   | 4           |
| Dividend yield          |                                     |             |

Total compensation cost for the Company's stock plans that has been recognized in the condensed consolidated statement of operations for the three months ended March 31, 2010 and 2009 was \$293,000 and \$155,000, respectively, of which \$105,000 and \$32,000 was included in research and development expenses and \$188,000 and \$123,000 was included in general and administrative expenses, respectively.

As of March 31, 2010, there was \$1.4 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements for Inovio stock options, which is expected to be recognized over a weighted-average period of 2.5 years, as well as \$80,000 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements from VGX stock options assumed in the Merger, which is expected to be recognized over a weighted-average period of 8 months. All compensation expense related to Inovio stock options granted prior to the Merger was fully vested upon the Merger.

As of March 31, 2009, there was \$580,000 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements for Inovio stock options, which was expected to be recognized over a weighted-average period of nine months.

The weighted average grant date fair value per share was \$0.92 and \$0.34 for employee stock options granted during the three months ended March 31, 2010 and 2009, respectively, excluding VGX stock options assumed pursuant to the merger.

There was no restricted stock granted during the three months ended March 31, 2010 or 2009.

At March 31, 2010, there was no unrecognized compensation cost related to non-vested restricted stock as all restricted stock became vested upon the Merger. At March 31, 2009, there was \$141,000 of total unrecognized compensation cost related to non-vested restricted stock, which was expected to be recognized over a weighted-average period of one year.

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 months ended March 31, 2010 and 2009 was \$137,000 and \$5,000, respectively.

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

VGX AH, a majority owned subsidiary of VGX, has adopted a 2007 equity incentive plan for the issuance of options to employees and consultants. There were no options granted under this plan during the three months ended March 31, 2010 or 2009.

**Table of Contents****INOVIO PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Unaudited)****11. Comprehensive Loss**

Comprehensive loss for the three months ended March 31, 2010 and March 31, 2009 includes net loss and foreign currency translation adjustments. A summary of the Company's comprehensive loss is as follows:

|                                          | <b>Three Months Ended<br/>March 31,</b> |                |
|------------------------------------------|-----------------------------------------|----------------|
|                                          | <b>2010</b>                             | <b>2009</b>    |
| Comprehensive loss:                      |                                         |                |
| Net loss                                 | \$ (2,300,636)                          | \$ (3,464,495) |
| Foreign currency translation adjustments | 4,860                                   | 16,026         |
| Comprehensive loss                       | \$ (2,295,776)                          | \$ (3,448,469) |

**12. Supplemental Disclosures of Cash Flow Information**

|                                                | <b>Three Months Ended<br/>March 31,</b> |             |
|------------------------------------------------|-----------------------------------------|-------------|
|                                                | <b>2010</b>                             | <b>2009</b> |
| Supplemental schedule of financing activities: |                                         |             |
| Interest paid                                  | \$ 34,368                               | \$ 39,745   |

**13. Related-Party Transactions**

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

For the three months ended March 31, 2010, the Company recognized revenue from VGX Int'l of \$7,000 which consisted of licensing fees. Operating expenses related to VGX Int'l for the three months ended March 31, 2010 include \$132,000 related to manufacturing and engineering services as well as \$1,000 for regulatory and technical support and other consulting services received. At March 31, 2010 the Company had an accounts receivable balance of \$3.1 million from VGX Int'l and its subsidiaries.

For the three months ended March 31, 2010, the Company received sublease income from VGX Int'l of \$55,000 for the facility in The Woodlands, TX, which offset the Company's lease expense.

On March 24, 2010, the Company entered into a Collaboration and License Agreement (the "Agreement") with VGX Int'l. Under the Agreement, the Company granted VGX Int'l an exclusive license to Inovio's SynCov 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 will receive a payment of \$3.0 million as a research and development initiation fee which is reflected in the Company's accounts receivable from affiliated entity at March 31, 2010, as well as research support, annual license maintenance fees and royalties on net product sales. In addition, contingent upon achievement of clinical and regulatory milestones, the Company will receive development payments over the term of the Agreement. The 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 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 Agreement) for any Product in that country, unless the Agreement is terminated earlier in accordance with its provisions as a result of breach, by mutual agreement, or by VGX Int'l right to terminate

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

without cause upon prior written notice.

Dr. J. Joseph Kim, the Company's CEO, Young Park, the Company's corporate secretary and Bryan Kim, the Company's vice president of Asian operations, currently constitute three of the four members of VGX Int'l's board of directors and receive customary compensation from VGX Int'l for their service in such capacity. Dr. Kim also served as chief executive officer of VGX Int'l prior to our acquisition of VGX Pharmaceuticals, Inc. in June 2009. Bryan Kim currently serves as the president and chief executive officer of VGX Int'l.

## **Table of Contents**

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

*This report contains forward-looking statements. 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 which attempt to advise interested parties of the factors which 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, 2009.*

*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 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**

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. Our SynCon technology enables the design of universal DNA-based 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 human papillomavirus (HPV)/cervical cancer (therapeutic), avian influenza (preventative), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) vaccines. We are advancing preclinical research for a universal seasonal/pandemic influenza vaccine. Our partners and collaborators include University of Pennsylvania, National Microbiology Laboratory of the Public Health Agency of Canada, NIAID (NIH), Merck, ChronTech, University of Southampton, and HIV Vaccines Trial Network (HVTN).

On June 1, 2009, we completed our acquisition of VGX Pharmaceuticals, Inc. (VGX) whereby VGX became a wholly-owned subsidiary of Inovio (the Merger). We believe the Merger advances our ability to play a leadership role in the discovery, development, and delivery of DNA vaccines.

On May 14, 2010, we amended our Certificate of Incorporation to change our name from Inovio Biomedical Corporation to Inovio Pharmaceuticals, Inc.

## **Table of Contents**

### *Recent Developments*

On March 24, 2010, we entered into a Collaboration and License Agreement (the "Agreement") with VGX International ("VGX Int'l"). Under the Agreement, we granted VGX Int'l an exclusive license to Inovio's SynCom<sup>TM</sup> 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, we will receive a payment of \$3.0 million as a research and development initiation fee, as well as research support, annual license maintenance fees and royalties on net product sales. In addition, contingent upon achievement of clinical and regulatory milestones, we will receive development payments over the term of the Agreement. The 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 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 Agreement) for any Product in that country, unless the Agreement is terminated earlier in accordance with its provisions as a result of breach, by mutual agreement, or by VGX Int'l right to terminate without cause upon prior written notice.

In January 2010, we announced that we expanded our existing license agreement with the University of Pennsylvania, adding exclusive worldwide licenses for technology and intellectual property for novel DNA vaccines against pandemic influenza, Chikungunya, and foot-and-mouth disease. The amendment also encompasses new chemokine and cytokine molecular adjuvant technologies. The technology was developed in the University of Pennsylvania laboratory of Professor David B. Weiner, a pioneer in the field of DNA vaccines, and chairman of our scientific advisory board. Under the terms of the original license agreement completed in 2007, we obtained exclusive worldwide rights to develop multiple DNA plasmids and constructs with the potential to treat and/or prevent HIV, HCV, HPV and influenza and included molecular adjuvants. These prior and most recent agreements and amendments provide for royalty payments, based on future sales, to the University of Pennsylvania.

As of March 31, 2010, we had an accumulated deficit of \$179.5 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. generally accepted accounting principles ("U.S. GAAP"). 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.** License fees are comprised of initial fees and milestone revenue derived from collaborative licensing arrangements. We continue to recognize non-refundable milestone payments upon the achievement of specified milestones upon which we have earned the milestone payment, provided the milestone payment is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement. We defer payments for milestone events which are reasonably assured and recognize them ratably over the minimum remaining period of our performance obligations. Payments for milestones which are not reasonably assured are treated as the culmination of a separate earnings process and are recognized as revenue when the milestones are achieved.

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. Payments under these agreements, which are non-refundable, are recorded as revenue as the related research expenditures are incurred pursuant to the terms of the agreements and provided collectability is reasonably assured.

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.



## **Table of Contents**

*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. Intangible assets are amortized over their estimated useful lives ranging from 5 to 18 years. Acquired intangible assets are still being developed for the future economic viability contemplated at the time of acquisition. We are concurrently conducting Phase I and pre-clinical trials using the 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 cost consists of the consideration paid for patents and related legal costs. Effective June 1, 2009, in connection with our acquisition of VGX Pharmaceuticals, all new patent costs will be expensed as incurred. Patent cost currently capitalized will continue to be amortized over the expected life of the patent. The effect of this change was immaterial to prior periods. License costs are recorded based on the fair value of consideration paid and amortized 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. As of March 31, 2010, 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 \$12.5 million.

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 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 March 31, 2010.

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.

*Purchase Price Allocation.* The purchase price allocation for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because a portion of the purchase price can only be allocated to goodwill in a business combination.

*Stock-based Compensation.* 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.

*Auction Rate Securities and Auction Rate Securities Rights.* We account for Auction Rate Securities (ARS) under the authoritative guidance for certain investments in debt and equity securities and fair value measurements. We account for ARS Rights using the fair value option for financial assets and financial liabilities. Our investments in ARS and our ARS Rights are recorded at their estimated fair value as there is currently no liquid market which indicates value. We have used a discounted cash flow model to determine the estimated fair value of our investment in ARS and our ARS Rights as of March 31, 2010. The assumptions used in preparing the discounted cash flow model include estimates for interest rates, timing and amount of cash flows and expected holding period of the ARS and ARS Rights. Changes in the estimated fair value of the ARS and ARS Rights are reflected in the condensed consolidated statement of operations as Other income, net.





## **Table of Contents**

**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 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 Other income, net.

### ***Pending 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 2009-13** In September 2009, the Financial Accounting Standards Board ( FASB ) ratified the final consensus reached by the Emerging Issues Task Force ( EITF ) that revised the authoritative guidance for revenue arrangements with multiple deliverables. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The guidance will be effective for our fiscal year beginning January 1, 2011 with early adoption permitted. The guidance may be applied retrospectively or prospectively for new or materially modified agreements. We are currently evaluating early prospective adoption and determining the effects, if any, the adoption of the guidance will have on our condensed consolidated financial statements.

**Accounting Standards Update 2010-3** In March 2010, the FASB ratified the final consensus that offers an alternative method of revenue recognition for milestone payments. The guidance states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The guidance will be effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted, provided that the revised guidance is applied retrospectively to the beginning of the year of adoption. The guidance may be applied retrospectively or prospectively for milestones achieved after the adoption date. We are currently evaluating early prospective adoption and determining the effects, if any, the adoption of this guidance will have on our condensed consolidated financial statements.

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

**Revenue.** We had total revenue of \$1.4 million and \$369,000 for the three months ended March 31, 2010 and 2009, respectively. Revenue primarily consists of license fees, milestone revenue and amounts received from collaborative research and development agreements, grants and government contracts.

Revenue from license fees and milestone revenue was \$74,000 and \$213,000 for the three months ended March 31, 2010 and 2009, respectively. The decrease in revenue under license fees and milestone revenue for the three month period ended March 31, 2010, as compared to the comparable period in 2009, was mainly due to no revenues recognized under the Wyeth collaboration and licensing agreement as a result of the cancellation of the agreement in July 2009, as well as no royalties recognized from various smaller license agreements.

During the three months ended March 31, 2010, we recorded no revenue under collaborative research and development arrangements as compared to \$54,000 for the three months ended March 31, 2009. This decrease in revenue was primarily due to no revenues recognized under our research and collaboration agreement with Merck, as we have provided the majority of the required device development for use in their clinical trials. We believe that development activities will be limited until trial results are obtained.

During the three months ended March 31, 2010 and 2009, we recorded grant and miscellaneous revenue of \$1.3 million and \$102,000, respectively. The increase in grant and miscellaneous revenue for the three months ended March 31, 2010, as compared to the comparable period in 2009, was primarily due to revenues recognized from our contract with the National Institute of Allergy and

**Table of Contents**

Infectious Diseases ( NIAID ) and the PATH Malaria Vaccine Initiative ( MVI ) of \$835,000 and \$239,000, respectively, and from the Department of Defense ( U.S. Army ) grant of \$200,000 for the three months ended March 31, 2010. The NIAID contract is for five years with two one-year options (period of performance is September 30, 2008 – September 29, 2015 including the two options). The value for the five years is \$21.3 million with option years six and seven valued at \$1.2 million and \$1.1 million, respectively, for a total potential value of \$23.6 million, and will fund research and development for HIV DNA-based vaccines delivered via our proprietary electroporation system. 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 agreement with MVI was for \$685,000 and was completed in February 2010. The U.S. Army grant has a total value of \$933,000, will fund research and development of DNA-based vaccines delivered via our proprietary electroporation system and will run through May 2010. This project is focused on identifying DNA vaccine candidates with the potential to provide rapid, robust immunity to protect against bio-warfare and bioterror attacks.

*Research and Development Expenses.* Research and development expenses for the three months ended March 31, 2010 and 2009, were \$2.7 million and \$964,000, respectively. The increase in research and development expenses for the three months ended March 31, 2010, as compared to the comparable period in 2009, was primarily due to higher costs related to work performed for the NIAID and MVI contracts, higher other outside services and contract labor expenses related to research and development projects, higher outside engineering professional services related to CELLECTRA® development, higher clinical trial costs and higher personnel costs due to greater employee headcount on average throughout the quarter. The increase was partially offset by a decrease in research and development expenses incurred by Inovio AS and Inovio Tec as these entities ceased operations in late 2009.

*General and Administrative Expenses.* General and administrative expenses, which include business development expenses and the amortization of intangible assets, for the three months ended March 31, 2010 and 2009, were \$3.1 million and \$3.0 million, respectively. The increase in general and administrative expenses for the three months ended March 31, 2010, as compared to the comparable period in 2009, was primarily due to higher amortization expense as a result of the intangible assets that were acquired from VGX, higher personnel costs due to greater employee headcount on average throughout the quarter and higher consultant stock option expense as a result of the stock options that were acquired from VGX. The increase was partially offset by a decrease in legal and related fees associated with the Merger and other corporate matters.

*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 months ended March 31, 2010 and 2009 was \$293,000 and \$155,000, respectively. From these amounts, \$105,000 and \$32,000 was included in research and development expenses and \$188,000 and \$123,000 was included in general and administrative expenses, respectively. The increase in stock-based compensation cost for the three months ended March 31, 2010, as compared to the comparable period in 2009, was primarily due to an increase in total options granted during the quarter as well as the continued vesting of options granted to employees in 2009 after the merger.

*Interest Income, net.* Interest income, net, for the three months ended March 31, 2010 and 2009 was \$35,000 and \$34,000 respectively. The slight increase in interest income, net, for the first three months of 2010, as compared to 2009, was primarily due to a higher cash and investments balance.

*Other Income, net.* We recorded other income, net, for the three months ended March 31, 2010 and 2009 of \$1.0 million and \$62,000 respectively. The increase in other income, net, is primarily due to the revaluation of registered common stock warrants issued by us in October 2006, August 2007 and July 2009. We are required to revalue the warrants at each balance sheet date to fair value. If unexercised, the warrants will expire at various dates between August 2010 and July 2014.

*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 March 31, 2010.

***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 equity securities.



## **Table of Contents**

### *Working Capital and Liquidity*

As of March 31, 2010, we had working capital of \$25.4 million, as compared to \$25.2 million as of December 31, 2009. The increase in working capital during the three months ended March 31, 2010 was primarily due to the significant receivable balance of \$3.0 million due from VGX Int'l in connection with the March 2010 Collaboration and License Agreement, as well as a decrease in the valuation of registered common stock warrants and decrease in the accounts payable and accrued expenses balance. These increases were offset by expenditures related to our research and development activities, as well as various general and administrative expenses related to legal, consultants, accounting and audit, and corporate development. Based on management's projections and analysis, we believe that our cash and cash equivalents are sufficient to meet our planned working capital requirements through the second half of 2011.

Net cash used in operating activities was \$4.5 million and \$2.3 million for the three months ended March 31, 2010 and 2009, respectively. The increase in net cash used in operating activities for the three months ended March 31, 2010, compared with the prior year period, was primarily the result of increased spending by our post-Merger Company on clinical, engineering and other research and development activities to support our programs.

Our ARS are municipal debt obligations with an underlying long-term maturity. Due to conditions in the global credit markets these securities, representing a par value of \$13.6 million, are currently not liquid.

In December 2008, we, via our wholly-owned subsidiary Genetronics, which holds the ARS, accepted an offer of ARS Rights from UBS. The ARS Rights permit us to require UBS to purchase our ARS at par value at any time during the period of June 30, 2010 through July 2, 2012. If we do not exercise our ARS Rights, the ARS will continue to accrue interest as determined by the terms of the ARS. If the ARS Rights are not exercised before July 2, 2012 they will expire and UBS will have no further obligation to buy our ARS. UBS has the discretion to purchase or sell our ARS at any time without prior notice so long as we receive a payment at par upon any sale or disposition. UBS will only exercise its discretion to purchase or sell our ARS for the purpose of restructurings, dispositions or other solutions that will provide us with par value for our ARS. As a condition to accepting the offer of ARS Rights, we released UBS from all claims except claims for consequential damages relating to its marketing and sales of ARS. We also agreed not to serve as a class representative or receive benefits under any class action settlement or investor fund.

In conjunction with the acceptance of the ARS Rights, we also amended our existing loan agreement with UBS Bank USA, increasing the existing credit line up to \$12.1 million, with the ARS pledged as collateral. The loan is treated as a "no net cost loan", as it bears interest at a rate equal to the average rate of interest paid to Genetronics on the pledged ARS, and the net interest cost to Genetronics is zero. We fully drew down on the line of credit in December 2008.

Historically, the fair value of ARS approximated par value. While we continue to earn interest on our ARS at the maximum contractual rates, these investments are not currently trading and therefore do not currently have a readily determinable market value. Accordingly, the estimated fair value of the ARS no longer approximates par value. We have used a discounted cash flow model to determine the estimated fair value of our investment in ARS and our ARS Rights as of March 31, 2010. The assumptions used in preparing the discounted cash flow model include estimates for interest rates, timing and amount of cash flows and expected holding period of the ARS and ARS Rights.

As of March 31, 2010, we had an accumulated deficit of \$179.5 million. We have operated at a loss since 1994, and we expect this to continue 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 DNA vaccines and equipment, then even more funding will be required to market and sell the approved vaccine products and equipment. The outcome of the above matters cannot be predicted at this time. We are evaluating potential collaborations as an additional way to fund operations. We will continue to rely on outside sources of financing to meet our capital needs beyond mid-2011. We have on file an effective shelf registration statement that allows us to raise up to an additional \$45.0 million from the sale of common stock, preferred stock, debt securities and/or warrants.

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

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 U.S. interest rates and conditions in the credit markets, and the recent fluctuations in interest rates and availability of funding in the credit markets primarily impacts 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

## **Table of Contents**

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.

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

All of our investment securities are classified as trading securities and are reported on the consolidated balance sheet at market value. Our investment securities consist of auction rate securities ( ARS ) issued primarily by municipalities, with a par value of approximately \$13.6 million. As a result of the negative conditions in the global credit markets, our ARS are currently not liquid, and if we do not exercise our ARS Rights (discussed in the following paragraph) we could be required to hold them until they are redeemed by the issuer or to maturity. In the event we need to access the funds that are in an illiquid state, we will not be able to do so without a loss of principal, until the securities are redeemed by the issuer or they mature.

In December 2008, we, via our wholly-owned subsidiary Genetronics, which holds the ARS, accepted an offer of ARS Rights from our investment advisor, UBS Financial Services, Inc., a subsidiary of UBS AG, or UBS. The ARS Rights permit us to require UBS to purchase our ARS at par value at any time during the period of June 30, 2010 through July 2, 2012. If we do not exercise our ARS Rights, the ARS will continue to accrue interest as determined by the terms of the ARS. If the ARS Rights are not exercised before July 2, 2012 they will expire and UBS will have no further obligation to buy our ARS. UBS has the discretion to purchase or sell our ARS at any time without prior notice so long as we receive a payment at par upon any sale or disposition. UBS will only exercise its discretion to purchase or sell our ARS for the purpose of restructurings, dispositions or other solutions that will provide us with par value for our ARS. As a condition to accepting the offer of ARS Rights, we released UBS from all claims except claims for consequential damages relating to its marketing and sales of ARS. We also agreed not to serve as a class representative or receive benefits under any class action settlement or investor fund.

In conjunction with the acceptance of the ARS Rights, we also amended our existing loan agreement with UBS Bank USA, increasing the existing credit line up to \$12.1 million, with the ARS pledged as collateral. The loan is treated as a no net cost loan , as it bears interest at a rate equal to the average rate of interest paid to us on the pledged ARS, and our net interest cost will be zero. We fully drew down on the line of credit in December 2008.

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

We have operated primarily in the U.S. and most transactions during the year ended December 31, 2009, have been made in U.S. 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. We do not have any foreign currency hedging instruments in place.

We have conducted clinical trials in Europe in conjunction with several Clinical Research Organizations ( CRO s ), where we have clinical sites being monitored by Clinical Research Associates ( CRA s ). While invoices relating to these clinical trials are generally denominated in U.S. dollars, our financial results could be affected by factors such as inflation in foreign currencies, in relation to the U.S. dollar, in markets where these vendors have assisted us in conducting these clinical trials.

Certain transactions related to our Company and our subsidiary Inovio Asia Pte. Ltd. ( IAPL ), are denominated primarily in foreign currencies, including Euros, British Pounds, Canadian Dollars, and Singapore Dollars. Our equity investment in VGX Int l is denominated in 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 Inovio conducts business, including the impact of the existing crisis in the global financial markets in such countries and the impact on both the U.S. 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 2010.

## **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





**Table of Contents**

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 March 31, 2010.

***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 three months ended March 31, 2010, 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**

*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, 2009, which we filed with the Securities and Exchange Commission on March 26, 2010*

**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 March 31, 2010 our accumulated deficit was approximately \$179.5 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 DNA vaccine delivery technology and thus may never have any significant future revenues or achieve and sustain profitability.

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

Other than a DNA therapy for food animals, whose sales have not been significant, 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 U.S. 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;

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

developing a market for LifeTide and/or our other animal health product candidates.

## **Table of Contents**

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 clinical studies. There is limited data regarding the efficiency of DNA 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 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 electroporation-based DNA vaccine delivery technology and vaccine 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.

## **Table of Contents**

***If we are unable to attract and retain key personnel and advisors, it may adversely affect our ability to obtain financing, pursue collaborations or develop or market our product candidates.***

To pursue our business strategy, we will need to attract and retain qualified scientific 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 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, 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.

## **Table of Contents**

### ***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 quarter ended March 31, 2010, the National Institute of Allergy and Infectious Diseases (NIAID), the PATH Malaria Vaccine Initiative (MVI) and the Department of Defense (US Army grant) accounted for approximately 61%, 17% and 15% 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.***

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;

merger integration expenses;

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.

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

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

## **Table of Contents**

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.***

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.

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 is 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 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;



## **Table of Contents**

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;

adverse results from third party clinical trials involving gene based therapies and the regulatory response thereto;

reaching agreement on acceptable terms with prospective contract research organizations, or 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 enrolment of patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for similar indications;

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:

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

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues; and

lack of adequate funding to continue the clinical trial.

If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our 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.

## **Table of Contents**

***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 contract research organizations ( 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 U.S. 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

## **Table of Contents**

countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our 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 DNA 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.

In the United States, the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act") was created to provide a federal no-fault system for compensating certain vaccine-related injuries or death by establishing a claims procedure involving the United States Court of Federal Claims and special masters. Litigation is pending before the Supreme Court of the United States to decide whether the Vaccine Act categorically preempts all design-defect claims against vaccine manufacturers, or whether instead the preemption of particular design-defect claims must be decided on a case-by-case basis. If the Supreme Court holds that preemption under the Vaccine Act must be decided on a case-by-case basis, vaccine manufacturers will likely be exposed to greater litigation risk from plaintiffs alleging injuries from vaccines.

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

## **Table of Contents**

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 less 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;

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

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

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. While many of the details regarding the implementation of this legislation 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.

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

our ability to set a price we believe is fair for our products;



## **Table of Contents**

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, persons 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 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. Federal legislation, the Physician Payments Sunshine Act of 2009, has been proposed and is moving forward in Congress. This legislation would require disclosure to the federal government of payments to physicians. 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.



## **Table of Contents**

***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.

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;

## **Table of Contents**

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 U.S. and elsewhere around the world. Recently, concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. 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.

## **Risks Related to Our Intellectual Property**

***It is difficult and costly to 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. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date 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.

## **Table of Contents**

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. 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 disputes or invalidate the patents;

others may independently develop similar or alternative technologies or duplicate any of our products or technologies that may not be covered by our patents, or they may design around our patents;

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;

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.

***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, 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



## **Table of Contents**

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 proceedings in the U.S. Patent and Trademark Office to determine priority of 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 ultimately invalid or we are ultimately found to 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 ordered 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. The following factors, in addition to the other risk factors described in this quarterly report, and the potentially low volume of trades in our common stock, may have a significant impact on the market price of our common stock, some of which are beyond our control:

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

fluctuating public or scientific interest in the potential for 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;

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;

## **Table of Contents**

additions or departures of key personnel;

sales or other transactions involving our common stock;

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**

Not applicable.

## **Item 3. Default Upon Senior Securities**

Not applicable.

**Item 4. (Removed and Reserved)**

38

**Table of Contents****Item 5. Other Information*****Submission of Matters to a Vote of Security Holders***

On May 14, 2010, we held our annual meeting of stockholders, at which our stockholders (i) elected six directors to hold office until the next annual meeting of stockholders, (ii) ratified the appointment of Ernst & Young LLP as our independent registered public accounting firm for the year ending December 31, 2010, (iii) approved an amendment to our 2007 Omnibus Incentive Plan to (A) increase the aggregate number of shares available for grant under the plan by 2,000,000 and (B) provide that the aggregate number of shares available for grant under the plan will be increased on January 1 of each year beginning in 2011 by a number of shares equal to the lesser of (1) 2,055,331 or (2) such lesser number of shares as may be determined by the Board, and (iv) approved an amendment to our Certificate of Incorporation to change our name from Inovio Biomedical Corporation to Inovio Pharmaceuticals, Inc. . The vote on such matters was as follows:

**1. Election of Directors**

| <b>Director</b> | <b>Votes For</b> | <b>Votes Against</b> | <b>Votes Abstained</b> | <b>Broker Non-Votes</b> |
|-----------------|------------------|----------------------|------------------------|-------------------------|
| Avtar Dhillon   | 35,555,063       | 0                    | 448,537                | 26,096,608              |
| Joseph Kim      | 34,091,633       | 0                    | 1,911,967              | 26,096,608              |
| Simon X. Benito | 34,619,543       | 0                    | 1,384,057              | 26,096,608              |
| Morton Collins  | 34,616,244       | 0                    | 1,387,356              | 26,096,608              |
| David Williams  | 34,706,861       | 0                    | 1,296,739              | 26,096,608              |
| Keith Wells     | 34,181,772       | 0                    | 1,821,828              | 26,096,608              |

**2. Ratification of appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2010.**

| <b>For</b> | <b>Against</b> | <b>Abstain</b> | <b>Broker Non-Votes</b> |
|------------|----------------|----------------|-------------------------|
| 61,640,358 | 0              | 459,850        | 0                       |

3. Approval of an amendment to our 2007 Omnibus Incentive Plan to (i) increase the aggregate number of shares available for grant under the plan by 2,000,000 and (ii) provide that the aggregate number of shares available for grant under the plan will be increased on January 1 of each year beginning in 2011 by a number of shares equal to the lesser of (1) 2,055,331 or (2) such lesser number of shares as may be determined by the Board.

| <b>For</b> | <b>Against</b> | <b>Abstain</b> | <b>Broker Non-Votes</b> |
|------------|----------------|----------------|-------------------------|
| 31,254,645 | 4,748,955      | 0              | 26,096,608              |

4. Approval of an amendment to our Certificate of Incorporation to change our name from Inovio Biomedical Corporation to Inovio Pharmaceuticals, Inc.

| <b>For</b> | <b>Against</b> | <b>Abstain</b> | <b>Broker Non-Votes</b> |
|------------|----------------|----------------|-------------------------|
| 61,791,835 | 308,372        | 0              | 1                       |

***Amendment to Certificate of Incorporation***

On May 14, 2010, we amended our Certificate of Incorporation to change our name to Inovio Pharmaceuticals, Inc. The Certificate of Amendment to our Certificate of Incorporation effecting such change is filed herewith as Exhibit 3.1(d).

## **Table of Contents**

### **Item 6. Exhibits**

#### (a) Exhibits

| <b>Exhibit Number</b> | <b>Description of Document</b>                                                                                                                                                      |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1(d)                | Certificate of Amendment to the Certificate of Incorporation of Inovio Biomedical Corporation, filed with the Delaware Secretary of State on May 14, 2010.                          |
| 10.1#                 | Amended and Restated 2007 Omnibus Incentive Plan                                                                                                                                    |
| 10.2**                | License and Collaboration Agreement dated March 24, 2010 between Registrant and VGX International.                                                                                  |
| 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.* |

- \* 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.
- # Indicates management contract or compensatory plan.
- \*\* The company has applied with the Secretary of the Securities and Exchange Commission for confidential treatment of certain information pursuant to Rule 24b-2 of the Securities Exchange Act of 1934. Copies of the exhibits including all confidential portions have been filed separately with confidential treatment applications, which may be made available for public inspection pending the Securities and Exchange Commission's review of the application in accordance with Rule 24b-2.

**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: May 17, 2010

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

Date: May 17, 2010

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