ONCOSEC MEDICAL Inc
Form 10-Q
December 08, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended October 31, 2014

OR

o 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 000-54318

ONCOSEC MEDICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Nevada	**98-0573252**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

9810 Summers Ridge Road, Suite 110, San Diego, CA 92121

(Address of principal executive offices) (zip code)

855.662.6732

(Registrant s telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, 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 x No o

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 (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files) Yes x No o

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 the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company o

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

246,596,076 shares of the registrant s common stock were issued and outstanding as of December 2, 2014.

Table of Contents

OncoSec Medical Incorporated

Form 10-Q

for the Quarterly Period Ended October 31, 2014

Table of Contents

OncoSec Medical Incorporated

Condensed Balance Sheet and Condensed Consolidated Balance Sheet

	(unaudited) October 31, 2014	July 31, 2014
Assets		
Current assets		
Cash and cash equivalents	$ 33,989,597	$ 37,852,694
Prepaid expenses and other current assets	432,159	466,483
Total Current Assets	34,421,756	38,319,177
Property and equipment, net	974,746	581,054
Intangible assets, net	290,433	464,693
Other long-term assets	30,685	26,685
Total Assets	$ 35,717,620	$ 39,391,609
Liabilities and Stockholders Equity		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	$ 1,047,684	$ 1,236,352
Accrued other	51,754	87,199
Total Liabilities	1,099,438	1,323,551
Commitments and Contingencies		
Stockholders Equity		
Common stock authorized - 3,200,000,000 common shares with a par value of $0.0001, common stock issued and outstanding 244,631,076 and 244,631,076 common shares as of October 31, 2014 and July 31, 2014, respectively	24,463	24,463
Additional paid-in capital	56,692,715	56,081,475
Warrants issued and outstanding 37,647,790 and 37,647,790 warrants as of October 31, 2014 and July 31, 2014, respectively	7,325,152	7,325,152
Accumulated deficit	(29,424,148)	(25,363,032)
Total Stockholders Equity	34,618,182	38,068,058
Total Liabilities and Stockholders Equity	$ 35,717,620	$ 39,391,609

The accompanying notes are an integral part of these condensed financial statements

Table of Contents

OncoSec Medical Incorporated

Condensed Statement of Operations and Condensed Consolidated Statement of Operations (unaudited)

	Three Months Ended October 31, 2014	Three Months Ended October 31, 2013
Revenue	$	$
Expenses:		
Research and development	2,501,268	773,958
General and administrative	1,558,938	1,214,535
Loss from operations	(4,060,206)	(1,988,493)
Other income (expense):		
Non-cash interest expense		(12,293)
Net loss before income taxes	(4,060,206)	(2,000,786)
Provision for income taxes	910	50,700
Net loss, net of tax	$ (4,061,116)	$ (2,051,486)
Basic and diluted net loss per common share	$ (0.02)	$ (0.01)
Weighted average shares used in computing basic and diluted net loss per common share	244,631,076	144,247,064

The accompanying notes are an integral part of these condensed financial statements

Table of Contents

OncoSec Medical Incorporated

Condensed Statement of Cash Flows and Condensed Consolidated Statement of Cash Flows (unaudited)

	Three Months Ended October 31, 2014	Three Months Ended October 31, 2013
Operating activities		
Net loss	$ (4,061,116)	$ (2,051,486)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	211,347	190,453
Loss on disposal of fixed assets	2,635	
Non-cash interest expense		12,293
Stock-based compensation	611,240	70,410
Common stock issued for services		50,000
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other current assets	30,324	(547,804)
Increase (decrease) in accounts payable and accrued liabilities	(188,667)	220,311
Increase (decrease) in accrued other	(35,445)	824
Net cash used in operating activities	(3,429,682)	(2,054,999)
Investing activities		
Purchases of property and equipment	(433,415)	(11,454)
Net cash used in investing activities	(433,415)	(11,454)
Financing activities		
Proceeds from issuance of common stock and warrants		11,948,000
Payment of financing and offering costs		(836,360)
Proceeds from exercise of warrants and stock options		1,178,398
Net cash provided by financing activities		12,290,038
Net (decrease) increase in cash	(3,863,097)	10,223,585
Cash and cash equivalents, at beginning of period	37,852,694	4,970,175
Cash and cash equivalents, at end of period	$ 33,989,597	$ 15,193,760
Supplemental disclosure for cash flow information:		
Cash paid during the period for:		
Interest	$	$
Income taxes	$ 910	$ 1,600
Noncash investing and financing transaction:		
Fair value of placement agent warrants issued in the public offering	$	$ 410,535

The accompanying notes are an integral part of these condensed financial statements

Table of Contents

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

Note 1 Nature of Operations and Basis of Presentation

OncoSec Medical Incorporated (the Company) was incorporated under the name of Netventory Solutions Inc., in the state of Nevada on February 8, 2008 to pursue the business of inventory management solutions. On March 1, 2011, Netventory Solutions Inc. completed a merger with its subsidiary OncoSec Medical Incorporated and changed its name to OncoSec Medical Incorporated. On March 24, 2011, the Company completed the acquisition of certain technology and related assets from Inovio Pharmaceuticals, Inc. (Inovio) pursuant to an Asset Purchase Agreement (the Asset Purchase Agreement) dated March 14, 2011. The acquired technology and related assets relate to the use of drug-medical device combination products for the treatment of various cancers. Since this acquisition, the Company has focused its efforts in the biotechnology industry and abandoned its efforts in the online inventory services industry. Prior to the acquisition of the assets from Inovio, the Company had been inactive since March 2010 and had no continuing operations other than those of a company seeking a business opportunity.

The Company has not produced any revenues from the assets it acquired from Inovio and the Company has not commenced planned principal operations. The Company is a hybrid device and gene-therapy biotechnology company focused on the discovery, the design, the development and the commercialization of innovative and proprietary medical approaches (principally immunotherapy) for the treatment of cancer where currently approved therapies are inadequate based on their efficacy or side effects. The Company s technology includes intellectual property relating to certain delivery technologies, which the Company refers to as ImmunoPulse (ImmunoPulse), a therapeutic approach that is based on the use of an electroporation delivery device in combination with DNA-encoded immune targets to treat cancer. The Company s ImmunoPulse product candidates are based on the Company s proprietary DNA-based immunotherapy technology, which is designed to stimulate the human immune system, resulting in systemic anti-tumor immune responses.

During the quarter, the Company expanded its research capabilities to further assist in the research of next-generation devices, novel electroporation technologies and combination studies to facilitate the advancement of ImmunoPulse and the pursuit of other potential future product candidates. The Company s research and development activities are subject to significant risks and uncertainties, including failing to secure additional funding to continue the advancement of its product candidates and failing to commercialize its product candidates before similar or competing technology is developed by competitors.

Effective October 28, 2014, OncoSec Medical Therapeutics Incorporated (OncoSec Medical Therapeutics), which was acquired on June 3, 2011 for a total purchase price of $1,000 and incorporated in Delaware on July 2, 2010, was dissolved. There were no significant transactions related to this subsidiary since its inception.

The accompanying unaudited condensed financial statements of the Company 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 balance sheet as of October 31, 2014, condensed statement of operations for the three months ended October 31, 2014 and condensed consolidated statement of operations for October 31, 2013, condensed statement of cash flow for the three months ended October 31, 2014 and the condensed consolidated statement of cash flows for the three months ended October 31, 2013, 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 October 31, 2014 shown herein are not

necessarily indicative of the results that may be expected for the year ending July 31, 2015, 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 July 31, 2014, included in the Company s Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on October 10, 2014. The consolidated balance sheet at July 31, 2014 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

Note 2 Significant Accounting Policies

Segment Reporting

The Company operates in a single industry segment the discovery and development of novel immunotherapeutic product to improve treatment options for patients and physicians, intended to treat a wide range of oncology indications.

Table of Contents

Concentrations and Credit Risk

The Company maintains cash balances at a single financial institution and such balance commonly exceeds the $250,000 amount insured by the Federal Deposit Insurance Corporation. The Company has not experienced any losses in such accounts and management believes that the Company does not have significant credit risk with respect to such cash and cash equivalents.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts in the financial statements and disclosures made in the accompanying notes to the financial statements. The Company s significant estimates pertain to stock-based compensation expense see Footnote 8. Actual results could differ materially from the estimates.

Recent Accounting Pronouncements

Recent pronouncements that are not anticipated to have an impact on or are unrelated to the Company s financial condition, results of operations, or related disclosures are not discussed.

In June 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in the ASU remove all incremental financial reporting requirements from U.S. GAAP for development stage entities. In addition, the ASU: (*a*) adds an example disclosure in Topic 275, *Risks and Uncertainties*, to illustrate one way that an entity that has not begun planned principal operations could provide information about the risks and uncertainties related to the company s current activities; and (*b*) removes an exception provided to development stage entities in Topic 810, *Consolidation*, for determining whether an entity is a variable interest entity. The Company adopted this standard in the first quarter of fiscal year 2015, enhancing the disclosure in Footnote 1 to discuss the activities the Company is engaged in and the associated risks and uncertainties of these activities. The adoption of this standard did not have an impact on the financial condition of the Company.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*, which is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures. This ASU provides guidance to an organization s management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company does not intend to early adopt this standard. The adoption of this standard will not have an impact on the financial condition of the Company.

Note 3 Cash and Cash Equivalents and Liquidity

The Company considers all liquid investments with maturities of ninety days or less when purchased to be cash equivalents. As of October 31, 2014 and July 31, 2014, cash and cash equivalents were comprised of cash in checking accounts.

The Company s activities to date have been supported by equity and debt financing. It has sustained losses in previous reporting periods with an inception to date loss of $29,424,148 as of October 31, 2014.

As of October 31, 2014, the Company had cash and cash equivalents of approximately $34.0 million. The Company believes its cash resources are sufficient to meet its anticipated needs during the next twelve months. The Company will require additional financing to fund its future planned operations, including research and development and clinical trials and commercialization of its product candidate. In addition, the Company will require additional financing in order to seek to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. Additional financing may not be available to the Company when needed or, if available, it may not be obtained on commercially reasonable terms. If the Company is not able to obtain the necessary additional financing on a timely basis, the Company will be forced to delay or scale down some or all of its development activities or perhaps even cease the operation of its business. Historically, the Company has funded its operations primarily through equity financings and it expects that it will continue to fund its operations through equity and debt financing. If the Company secures additional financing by issuing equity securities, its existing stockholders ownership will be diluted. Obtaining commercial loans, assuming those loans would be available, will increase the Company s liabilities and future cash commitments. The Company also expects to pursue non-dilutive financing sources. However, obtaining such financing would require significant efforts by the Company s management team, and such financing may not be available, and if available, could take a long period of time to obtain.

Table of Contents

Note 4 Stockholders Equity

A summary of the changes in stockholders equity is provided below:

	October 31, 2014	October 31, 2013
Stockholders equity at beginning of period	$ 38,068,058	$ 4,739,124
Net loss	(4,061,116)	(2,051,486)
Stock-based compensation	611,240	70,410
Common stock issued for services		150,000
Exercise of common stock warrants		1,178,398
Public offering on September 18, 2013, net of issuance costs of $836,360		11,111,640
Stockholders equity at end of period	$ 34,618,182	$ 15,198,086

Note 5 Intangible Asset Acquisition and Cross License Agreement

On March 14, 2011, the Company entered into the Asset Purchase Agreement with Inovio, whereby the Company agreed to purchase certain assets of Inovio related to certain non-DNA vaccine and selective electrochemical tumor ablation (SECTA) technology, including, among other things: (a) certain patents, including patent applications, and trademarks related to the SECTA technology; (b) certain equipment, machinery, inventory and other tangible assets related to the technology; (c) certain engineering and quality documentation related to the technology; and (d) the assignment of certain contracts related to the technology. In return, the Company agreed to pay Inovio $3,000,000 in scheduled payments and a royalty on commercial product sales related to the SECTA technology. The transaction closed on March 24, 2011. The Asset Purchase Agreement has been amended by the parties to modify the schedule of payments to Inovio (see Note 6).

In connection with the closing of the Asset Purchase Agreement, the Company entered into a cross-license agreement with Inovio. Under the terms of the agreement, the Company granted Inovio a fully paid-up, exclusive, worldwide license to certain of the acquired SECTA technology patents in the field of use of electroporation. No consideration was received by the Company, nor will Inovio be liable for future royalty fees related to this arrangement. Inovio also granted the Company a non-exclusive, worldwide license to certain non-SECTA technology patents held by it in consideration for the following: (a) a fee for any sublicense of the Inovio technology, not to exceed 10%; (b) a royalty on net sales of any business the Company develops with the Inovio technology, not to exceed 10%; and (c) payment to Inovio of any amount Inovio pays to one licensor of the Inovio technology that is a direct result of the license. In addition, the Company agreed not to transfer this non-exclusive license apart from the assigned intellectual property.

The purchase price was allocated to the identified tangible and intangible assets acquired based on their relative fair values, which were derived from their individual estimated fair values of $38,000 and $3,000,000, respectively. Included in the estimated fair value of the intangible assets is the value associated with the engineering and quality documentation acquired, which was determined to have no stand-alone value apart from the patents. The relative fair value of the intangible assets of $2,962,000 was reduced by a discount of approximately $174,000 recorded for the

acquisition obligation. The relative fair value of the tangible assets of $38,000 was expensed to research and development as of the acquisition date.

Patents are stated net of accumulated amortization of approximately $2,497,000 and $2,323,000 as of October 31, 2014 and July 31, 2014, respectively. The patents are amortized on a straight-line basis over the estimated remaining useful lives of the assets, determined as four years from the date of acquisition. Amortization expense for the three-month periods ended October 31, 2014 and 2013 was approximately $174,000 and $174,000, respectively.

Table of Contents

Note 6 Acquisition Obligation

On March 24, 2011, the Company recorded an acquisition obligation for amounts due to Inovio in accordance with the Asset Purchase Agreement (see Note 5). On September 28, 2011, the Company entered into a First Amendment to Asset Purchase Agreement (the First Amendment). The First Amendment modified the payment of $750,000 due to Inovio by September 24, 2011, requiring the Company to make a payment of $100,000 to Inovio on September 30, 2011, with the remaining $650,000 to be paid to Inovio on or before March 31, 2012. On March 24, 2012, the Company entered into a Second Amendment to Asset Purchase Agreement (the Second Amendment). The Second Amendment further modified the payment terms for the $1,150,000 scheduled payments due to Inovio in March 2012 by requiring the Company to make a payment of $150,000 on March 31, 2012, with the remaining $1,000,000 to be paid to Inovio on December 31, 2013. As consideration for the First Amendment, the Company issued to Inovio a warrant to purchase 1,000,000 shares of common stock. As consideration for the Second Amendment, the Company issued to Inovio a warrant to purchase 3,000,000 shares of common stock.

The scheduled payments for the $3,000,000 obligation under this arrangement, as amended, were as follows:

- $ 250,000 - Upon the closing of the Asset Purchase Agreement
- $ 100,000 - September 30, 2011
- $ 150,000 - March 31, 2012
- $ 500,000 - September 24, 2012
- $ 1,000,000 - March 31, 2013
- $ 1,000,000 - December 31, 2013

The Company has made all scheduled payments under this arrangement.

Note 7 Recent Other Equity and Common Stock Transactions

At October 31, 2014, the Company had outstanding warrants to purchase 37,647,790 shares of common stock, with exercise prices ranging from $0.26 to $1.20, all of which were classified as equity instruments. These warrants expire at various times between March 2016 and June 2019.

The Company has not adopted any policy regarding payment of dividends. No dividends have been paid during the periods presented.

Note 8 Stock-Based Compensation

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period are defined pursuant to the terms of the consulting agreement. Share-based compensation expense for awards granted during the three-month periods ended October 31, 2014 and 2013, were based on the grant date fair value estimated using the Black-Scholes Option Pricing Model. Share-based compensation expense related to stock option grants to consultants, in which the grant was not entirely vested at the grant date, are marked-to-market each month. The Company s expected volatility is derived from the historical daily change in the market price of its common stock since it exited shell status, as well as the historical daily changes in the market price for the peer group as determined by the Company. The Company uses the simplified method to calculate the expected term of options issued to employees and directors. The Company s estimation of the expected term for stock options granted to parties other than employees or directors is the contractual term of the option award. The risk-free interest rate used in the Black-Scholes calculation is based on the prevailing U.S. Treasury yield in effect at the time of grant, commensurate with the expected term. Stock-based compensation expense recognized in the Company s condensed statements of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. The Company has never paid any dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future.

During the three months ended October 31, 2014, the Company granted options to purchase 2,150,000 and 500,000 shares of the Company s common stock to employees and consultants under the Company s 2011 Stock Incentive Plan (the 2011 Plan), respectively. The options issued to employees within the 2011 Plan have a ten-year term, vest over a range of two to three years, and have exercise prices ranging from $0.44 to $0.52. The options issued to consultants have one- to three-year terms, vest in accordance with the terms of the applicable consulting agreement, and have exercise prices ranging from $0.39 to $0.43.

During the three months ended October 31, 2013, the Company granted an option to purchase 500,000 shares of the Company s common stock to a consultant under the 2011 Plan. The option issued to the consultant has a three-year term, vests in accordance with the terms of the applicable consulting agreement, and has an exercise price of $0.26.

Table of Contents

The following assumptions were used to calculate the fair value of share-based compensation during the three months ended October 31, 2014 and 2013:

	October 31, 2014	October 31, 2013
Expected volatility	88.82% - 92.83%	83.62%
Risk-free interest rate	0.36% - 2.13%	0.69%
Expected forfeiture rate	0.00%	0.00%
Expected dividend yield		
Expected term	2- 7 years	3 years

Stock-based compensation expense recorded in the Company s condensed statement of operations for the three months ended October 31, 2014 resulting from stock-based compensation awarded to the Company s employees, directors and consultants was approximately $611,000. Of this balance, $316,000 was recorded to research and development, and $295,000 was recorded in general and administrative in the Company s condensed statement of operations for the period ended October 31, 2014.

Stock-based compensation expense recorded in the Company s condensed consolidated statement of operations for the three months ended October 31, 2013 resulting from stock-based compensation awarded to the Company s employees, directors and consultants was approximately $70,000. Of this balance, $8,000 was recorded to research and development, and $62,000 was recorded in general and administrative in the Company s condensed consolidated statement of operations for the period ended October 31, 2013.

The weighted-average grant date fair value of stock options granted during the three months ended October 31, 2014 and 2013 were $0.36 and $0.14, respectively.

Note 9 Commitments and Contingencies

In the ordinary course of business, the Company may become a party to lawsuits involving various matters. The Company is unaware of any such lawsuits presently pending against it which individually or in the aggregate, are deemed to be material to the Company s financial condition or results of operations.

Note 10 Related Party Transactions

The Company s Chairman of the Board of Directors is also a director and the Chairman (formerly Executive Chairman) of Inovio. The Company s Chairman abstained from all discussions and voting related to negotiations of the Asset Purchase Agreement disclosed in Note 5 and the amendments (and related warrants) disclosed in Note 6, while performing his duties as Executive Chairman of Inovio.

Note 11 Subsequent Events

Warrant Exercises

Subsequent to October 31, 2014 through December 2, 2014, the Company received approximately $700,000 in funds from the exercise of warrants.

Table of Contents

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

Cautionary Statement

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our Unaudited Condensed Financial Statements and the related notes thereto contained in Part I, Item 1 of this Report. The information contained in this Quarterly Report on Form 10-Q is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this Report and in our other reports filed with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for the fiscal year ended July 31, 2014, our subsequent quarterly reports on Form 10-Q and our subsequent reports on Form 8-K, which discuss our business in greater detail.

This quarterly report on Form 10-Q contains forward-looking statements that involve risks, uncertainties and assumptions. If such risks or uncertainties materialize or such assumptions prove incorrect, our results could differ materially from those expressed or implied by such forward-looking statements and assumptions. In some cases, you can identify forward-looking statements by terminology such as may , should , expects , plans , anticipates , believes , estimates , predicts , potential or continue or the negative of these terms or other comparable terminology. All statements made in this Form 10-Q other than statements of historical fact are statements that could be deemed forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled Risk Factors in Part II, Item IA of this Quarterly Report on Form 10-Q, and similar discussions in our other SEC filings. Risks that could cause actual results to differ from those contained in the forward-looking statements include but are not limited to risks related to: our ability to continue as a going concern; our need to raise additional capital and our ability to obtain financing; uncertainties inherent in pre-clinical studies and clinical trials and our ability to commercialize our products; our expected reliance on third parties; general economic and business conditions; our limited operating history; our ability to recruit and retain qualified personnel; competition we face within our industry; our ability to manage future growth; our ability to develop our planned products; our ability to protect our intellectual property; and various risks related to our common stock. These forward-looking statements speak only as of the date of this Form 10-Q, except as required by applicable law, we do not intend to update any of these forward-looking statements.

As used in this quarterly report on Form 10-Q and unless otherwise indicated, the terms the Company , we , us and our refer to OncoSec Medical Incorporated.

Company Overview

We were incorporated under the laws of the State of Nevada on February 8, 2008 under the name Netventory Solutions Inc. to pursue the business of inventory management solutions. Effective March 1, 2011, we consummated a 32-for-one forward stock split of our common stock and completed a merger with our subsidiary, OncoSec Medical Incorporated, a Nevada corporation which was incorporated solely to change our name to OncoSec Medical Incorporated .

Asset Purchase Agreement

We have acquired certain assets pursuant to our Asset Purchase Agreement with Inovio Pharmaceuticals, Inc. (Inovio), dated March 14, 2011 (as amended, the Asset Purchase Agreement). The acquired assets relate to certain non-DNA vaccine technology and intellectual property relating to selective tumor ablation technologies (SECTA).

We did not assume any of the liabilities of Inovio except liabilities under the assigned contracts and assigned intellectual property arising after the closing date of the Asset Purchase Agreement. We agreed to pay Inovio $3,000,000 in scheduled payments beginning on the closing date as well as certain royalties in the event we commercialize the acquired technology. We have entered into amendments to the Asset Purchase Agreement with Inovio in September 2011 (the First Amendment) and in March 2012 (the Second Amendment) to modify the terms of our payment obligations (among other modifications). We made a payment of $1,000,000 to Inovio in May 2013 and we made the final payment to Inovio of $1,000,000 in December 2013. As consideration for the First Amendment we issued to Inovio a warrant to purchase 1,000,000 shares of common stock with an exercise price of $1.20 per share. As consideration for the Second Amendment, we issued to Inovio a warrant to purchase 3,000,000 shares of our common stock with an exercise price of $1.00 per share. Each of the warrants is subject to a five year term. Each of the warrants also contains a mandatory exercise provision allowing us to request the exercise of the warrant in whole provided that our daily market price (as defined in the warrant) is equal to or greater than $2.40 for twenty consecutive trading days. We completed an evaluation of the warrants issued to Inovio and determined the warrants should be classified as equity within our balance sheet.

Table of Contents

We are also party to a cross-license agreement with Inovio, which we entered into concurrently with the closing of our asset acquisition. This agreement provides for the exclusive license to Inovio of rights related to certain SECTA patents in the field of gene or nucleic acids, outside of those encoding cytokines, delivered by electroporation and for the non-exclusive cross-license by Inovio to us of rights related to certain non-SECTA patents in our field in exchange for specified sublicensing and other licensing fees and royalties.

We are a hybrid device and gene-therapy biotechnology company focused on the discovery, the design, the development and the commercialization of innovative and proprietary medical approaches (principally immunotherapy) for the treatment of cancer where currently approved therapies are inadequate based on their efficacy or side effects. Our technology includes intellectual property relating to certain delivery technologies, which we refer to as ImmunoPulse (ImmunoPulse), a therapeutic approach that is based on the use of an electroporation delivery device in combination with DNA-encoded immune targets to treat cancer. Our ImmunoPulse product candidates are based on our proprietary DNA-based immunotherapy technology, which is designed to stimulate the human immune system, resulting in systemic anti-tumor immune responses. Because our candidate therapeutics are plasmid constructs, we expect to benefit from a simpler, more consistent and scalable manufacturing process in comparison to therapies based on patient-derived cells or recombinant proteins. In addition, our portfolio includes an asset that utilizes electroporation delivery with a small-molecule drug, which we refer to as NeoPulse. Our mission is to enable people with cancer to live longer with a better quality of life than otherwise possible or available with existing therapies.

Recent Events

June 2014 Public Offering

On June 6, 2014, we closed a registered public offering of an aggregate of 22,535,212 shares of our common stock and warrants to purchase an aggregate of 7,887,325 shares of common stock for gross proceeds to us of approximately $16.0 million (the June 2014 Public Offering). The warrants have an exercise price of $0.90 per share, are exercisable immediately upon issuance, and have a term of exercise equal to five years from the date of issuance of the warrants. After deducting for fees and expenses, the aggregate net proceeds from the sale of the common stock and the warrants in the June 2014 Public Offering were approximately $14.9 million. In connection with the June 2014 Public Offering, we paid placement agent fees consisting of (i) a cash fee equal to 6% of the gross proceeds of the offering, as well as a non-accountable expense allowance equal to 1% of the gross proceeds and (ii) warrants to purchase up to an aggregate of 6% of the aggregate number of shares of common stock sold in the offering, or 1,352,113 shares of our common stock. These warrants have substantially the same terms as the warrants issued to the purchasers in the June 2014 Public Offering, except that the warrants expire on May 12, 2019.

Proceeds from Warrant and Option Exercises

As discussed in more detail in Liquidity and Capital Resources, from November 1, 2014 through December 2, 2014, we have received approximately $0.7 million in cash from the exercise of warrants.

Critical Accounting Policies

Accounting for Long-Lived Assets / Intangible Assets

We assess the impairment of long-lived assets, consisting of property and equipment, and finite-lived intangible assets, whenever events or circumstances indicate that the carrying value may not be recoverable. Examples of such circumstances include: (1) loss of legal ownership or title to an asset; (2) significant changes in our strategic business objectives and utilization of the assets; and (3) the impact of significant negative industry or economic trends.

Recoverability of assets to be held and used in operations is measured by a comparison of the carrying amount of an asset to the future net cash flows expected to be generated by the assets. The factors used to evaluate the future net cash flows, while reasonable, require a high degree of judgment and the results could vary if the actual results are materially different than the forecasts. In addition, we base useful lives and amortization or depreciation expense on our subjective estimate of the period that the assets will generate revenue or otherwise be used by us. If such assets are considered impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less selling costs.

We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the technologies. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

Table of Contents

Stock-Based Compensation

We grant equity-based awards under our stock-based compensation plan. We estimate the fair value of stock-based payment awards using the Black-Scholes option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected life of the option. Stock-based compensation expense is based on awards ultimately expected to vest, and therefore is reduced by expected forfeitures. Stock-based compensation expense related to stock option grants issued to consultants not entirely vested at grant date are marked-to-market each month. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Results of Operations for the Three Months Ended October 31, 2014 Compared to the Three Months Ended October 31, 2013

The unaudited financial data for the three-month periods ended October 31, 2014 and October 31, 2013 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	October 31, 2014 ($)	October 31, 2013 ($)	Increase/ (Decrease) ($)	Increase/ (Decrease) %
Revenue				
Operating expenses				
Research and development	2,501,268	773,958	1,727,310	**
General and administrative	1,558,938	1,214,535	344,403	28.4
Loss from operations	(4,060,206)	(1,988,493)	(2,071,713)	**
Other income (expense)				
Interest expense non-cash and other		(12,293)	12,293	**
Net loss before income taxes	(4,060,206)	(2,000,786)	(2,059,420)	**
Tax provision	910	50,700	(49,790)	**
Net loss	(4,061,116)	(2,051,486)	(2,009,630)	**

** Percentage increase/(decrease) is greater than 100%.

Operational Milestones and Research and Development Expenses

The $1,727,000 increase in research and development expenses for the three-month period ended October 31, 2014, as compared to the three-month period ended October 31, 2013 is primarily the result of an increase of $950,000 in salary related expenses, inclusive of stock-based compensation due to hiring additional R&D personnel as we further expand our internal research capabilities, an increase of $300,000 in other outside services to further assist in the research of next-generation devices, novel electroporation technologies and combination studies, an increase of $200,000 in engineering and lab supplies and an increase of $200,000 in additional R&D related expenses consisting primarily of rent, conference fees and travel .

We expect to use our working capital for the advancement of our operational milestones. Our significant milestones currently include expanding our internal research capabilities and collaborations regarding next-generation devices, novel electroporation technologies and combination studies in pursuit of drug/device combination therapies in furtherance of our ImmunoPulse and any other potential future product candidates we may develop or acquire.

Activities related to the above milestones are particularly focused in our Engineering, Clinical and R&D departments. We estimate we may incur during our current fiscal year ending July 31, 2015 (Fiscal 2015), Engineering costs of $2,100,000, inclusive of $400,000 of personnel costs, Clinical costs of $6,400,000, inclusive of $1,400,000 of personnel costs and R&D costs of $5,800,000, inclusive of personnel costs of $1,700,000.

General and Administrative

The $344,000 increase in general and administrative expenses for the three-month period ended October 31, 2014, as compared to the three-month period ended October 31, 2013, was primarily the result of an increase of $450,000 in salary related costs, inclusive of stock-based compensation due to hiring additional personnel to support the growth in our operations, offset by a decrease of $100,000 in outside legal services fees related to general corporate matters and regulatory filings.

Other Income (Expense)

The $12,000 decrease in other expense for the three-month period ended October 31, 2014, as compared to the comparable three-month period ended October 31, 2013, was due to the decrease in non-cash interest expense related to our payment obligations to Inovio pursuant to the Asset Purchase Agreement which was fully paid in December 2013.

Table of Contents

Liquidity and Capital Resources

Working Capital

Our working capital as of October 31, 2014 and July 31, 2014 is summarized as follows:

	At October 31, 2014 ($)	At July 31, 2014 ($)
Current assets	34,421,756	38,319,177
Current liabilities	1,099,438	1,323,551
Working capital	33,322,318	36,995,626

Current Assets

Current assets as of October 31, 2014 decreased to approximately $34,422,000, in comparison to our approximate current assets of $38,320,000 as of July 31, 2014. This decrease in our current assets was primarily due to a decrease in cash from $37,853,000 as of July 31, 2014, to $33,990,000 as of October 31, 2014, which is attributable to the cash used in operations during the three-month period ended October 31, 2014.

Current Liabilities

Current liabilities as of October 31, 2014 decreased to approximately $1,099,000, in comparison to our approximate current liabilities of $1,324,000 as of July 31, 2014. This decrease was primarily due to a decrease in our accounts payables and accrued liabilities as a result of ordinary course disbursements made within their respective due dates.

Cash Flow

Cash Used in Operating Activities

Cash used in operating activities for the three-month period ended October 31, 2014 was $3,430,000, as compared to $2,055,000 for the three-month period ended October 31, 2013. This increase was primarily related to research and development efforts related to next-generation devices, novel electroporation technologies and combination studies, and an increase in salary related expenses as a result of hiring additional personnel to support the growth in our operations.

Cash Used in Investing Activities

Cash used in investing activities for the three-month period ended October 31, 2014 was $433,000, as compared to $11,000 for the three-month period ended October 31, 2013. This increase was primarily related to the purchase of property and equipment.

Cash Flow Provided by Financing Activities

Cash provided by financing activities was $0 for the three-month period ended October 31, 2014, as compared to $12,290,000 for the comparable three-month period ended October 31, 2013. There were no exercises of stock options, exercise of warrants or financings completed during the three-month period ended October 31, 2014.

Recent Equity Financings

On September 18, 2013, we closed a public offering of 47,792,000 shares of our common stock and warrants to purchase an aggregate of 23,896,000 shares of common stock, for gross proceeds of approximately $11.95 million. The warrants have an exercise price of $0.35 per share, are exercisable immediately upon issuance and have a term of exercise equal to four years from the date of issuance. We paid placement agent fees consisting of (i) $836,360 in cash fees and expenses and (ii) issued warrants to purchase 2,389,600 shares of our common stock on terms substantially similar to the warrants issued in the offering. After deducting for fees and expenses, the aggregate net proceeds from the offering were approximately $11.1 million.

Table of Contents

On June 6, 2014, we closed the June 2014 Public Offering in which we sold an aggregate of 22,535,212 shares of our common stock and warrants to purchase an aggregate of 7,887,325 shares of our common stock for gross proceeds of approximately $16.0 million. The warrants have an exercise price of $0.90 per share, are exercisable immediately upon issuance, and have a term of exercise equal to five years from the date of issuance of the warrants. We paid placement agent fees consisting of (i) $1,145,000 in cash fees and expenses and (ii) warrants to purchase 1,352,113 shares of our common stock on terms substantially similar to the warrants issued to investors in the June 2014 Public Offering. After deducting for fees and expenses, the aggregate net proceeds from the sale of the common stock and the warrants in the June 2014 Public Offering were approximately $14.9 million.

Cash Requirements

Our primary objectives for Fiscal 2015 are to continue the advancement of our operations milestones, focusing on Engineering, Clinical and R&D. We continuously search for industry experts to expand our management team and better position our company. In addition, we expect to pursue raising sufficient capital to fund our operations and to acquire and develop additional assets and technology consistent with our business objectives.

We continue to estimate our aggregate operating expenses and working capital requirements for Fiscal 2015 (inclusive of the three-month period ended October 31, 2014) to be approximately $19.5 million, although our estimates for certain categories of operating expenses and working capital requirements for Fiscal 2015 may vary by classification. As of October 31, 2014, we estimate the components of our operating expenses and working capital requirements for Fiscal 2015 (inclusive of the three month period ended October 31, 2014) to be approximately as follows:

Cash Requirements		**Amount**
Product development	$	10,900,000
Employee compensation		5,900,000
General and administration		2,200,000
Professional services fees		500,000
	$	19,500,000

Subsequent to October 31, 2014, we have received approximately $700,000 from the exercise of warrants as of December 2, 2014. During the three-month period ended October 31, 2014, our operating cash outflow was approximately $3,400,000. Based on our current operating costs and our operational goals, we expect our monthly cash outflows for the remainder of FY2015 to range from approximately $1,400,000 to $2,400,000 per month. In general, our cash outflows for future periods may increase as we expand our business, increase our headcount and further our development activities. We expect our current funds to be sufficient to allow us to continue to operate our business for at least the next twelve months.

If the investors who hold our outstanding warrants choose to exercise their remaining warrants in full on a cash basis, we would receive approximately $14.2 million. However, the warrant holders may choose not to exercise their warrants or, alternatively, may choose to net exercise their warrants as provided in such warrants under certain limited circumstances. As our stock price continues to fluctuate in the market, the exercise prices of the outstanding warrants issued in each such offering may or may not exceed the current market price of our common stock on the OTCQB Marketplace. As a result, we may never receive any proceeds from the exercise of our outstanding warrants.

Since inception we have funded our operations primarily through equity financings and we expect to fund our operations through equity and debt financings in the future. If we obtain additional financing by issuing equity securities, our existing stockholders ownership will be diluted. Obtaining commercial loans, assuming those loans would be available, will increase our liabilities and future cash commitments. We may be unable to maintain operations at a level sufficient for investors to obtain a return on their investments in our common stock. Further, we may continue to be unprofitable.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

Table of Contents

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, or SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

As required by Rule 13a-15(b) under the Exchange Act, our management conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing evaluation, our Chief Executive Officer and our Chief Financial Officer, in their capacities as our principal executive officer and our principal financial officer, concluded that as of the end of the period covered by this report our disclosure controls and procedures were effective.

Changes in Our Controls

There were no changes in our internal controls over financial reporting during our fiscal quarter ended October 31, 2014 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings that arise in the ordinary course of business. The impact and outcome of litigation, if any, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are not currently a party to any proceedings the adverse outcome of which, individually or in the aggregate, would have a material adverse effect on our financial position or results of operations.

ITEM 1A. RISK FACTORS

You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q. If any of the following events, described as risks, actually occur, either alone or taken together, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment in our securities. An investment in our securities is speculative and involves a high degree of risk. You should not invest in our securities if you cannot bear the economic risk of your investment for an indefinite period of time and cannot afford to lose your entire investment. There may be additional risks that we do not presently know of or that we currently believe are immaterial which could also impair our business and financial position.

We will likely need to raise additional capital in future periods to continue operating our business, and such additional funds may not be available on acceptable terms or at all.

We do not generate, and may never generate, any cash from operations and will likely need to raise additional funds in future periods in order to continue operating our business. We estimate our cash requirements for Fiscal 2015 to be approximately $19.5 million. As of October 31, 2014, we had cash and cash equivalents of approximately $34.0 million.

We have a history of raising funds through offerings of our common stock, and we may in the future raise additional funds through public or private equity offerings, debt financings, grants, corporate collaborations or licensing arrangements. We expect to continue to fund our operations primarily through equity and debt financings in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely. We will require additional financing to fund our planned operations, including developing and commercializing our intellectual property, seeking to license or acquire new assets, researching and developing any potential patents, related compounds and other intellectual property, funding potential acquisitions, and supporting clinical trials and seeking regulatory approval relating to our assets and any assets we may acquire in the future. Additional financing may not be available to us when needed or, if available, may not be available on commercially reasonable terms. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments.

Table of Contents

We may not be able to obtain additional financing if the volatile conditions in the capital and financial markets, and more particularly the market for early-development-stage biotechnology company stocks, persist. Weak economic and capital markets conditions could result in increased difficulties in raising capital for our operations. We may not be able to raise money through the sale of our equity securities or through borrowing funds on terms we find acceptable. If we cannot raise the funds that we need, we will be unable to continue our operations, and our stockholders could lose their entire investment in our Company.

We have never generated revenue from our operations.

We have not generated any revenue from operations since our inception. During our quarter ended October 31, 2014, we incurred a net loss of approximately $4.1 million. From inception through October 31, 2014, we have incurred an aggregate net loss of approximately $29.4 million. We expect that our operating expenses will continue to increase as we expand our current headcount, further our development activities, and continue to pursue FDA approval for our product candidates.

We are an early-stage company with a limited operating history, which may hinder our ability to successfully meet our objectives.

We are an early-stage company with only a limited operating history upon which to base an evaluation of our current business and future prospects and how we will respond to competitive, financial, or technological challenges. Only recently have we explored opportunities in the biotechnology industry. As a result, the revenue and income potential of our business is unproven. In addition, because of our limited operating history, we have limited insight into trends that may emerge and affect our business. Errors may be made in predicting and reacting to relevant business trends and we will be subject to the risks, uncertainties, and difficulties frequently encountered by early-stage companies in evolving markets. We may not be able to successfully address any or all of these risks and uncertainties. Failure to adequately do so could cause our business, results of operations, and financial condition to suffer or fail.

We have not commercialized any of our product candidates and we cannot predict if or when we will become profitable.

We have not commercialized any of our product candidates. Our ability to generate revenues from any of our product candidates will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals, and negotiate arrangements with third parties to help finance the development of, and market and distribute, any product candidate that receives regulatory approval. In addition, even if we achieve regulatory approval for one or more of our product candidates, we will be subject to the risk that the marketplace may not accept our products in sufficient levels for us to achieve profitability, or at all.

Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict the extent of our future losses or when or if we will become profitable, and it is possible we will never commercialize any of our product candidates or become profitable. Our failure to obtain regulatory approval and successfully commercialize any of our product candidates would have a material adverse effect on our business, results of operations, financial condition, and prospects and could result in our inability to continue operations.

If we are unable to successfully recruit and retain qualified personnel, we may not be able to continue our operations.

In order to successfully implement and manage our business plan, we will depend upon, among other things, successfully recruiting and retaining qualified executives, managers and other employees having relevant experience in the biotechnology industry. Competition for qualified individuals is intense, particularly in our geographical location where there are several larger, more established biotechnology companies that compete with us for talent. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are not able to find, attract, and retain qualified personnel on acceptable terms and in a timely manner to coincide with our growth, we may not be able to successful grow or maintain our business and our business operations and prospects could suffer.

Additionally, although we have employment agreements with each of our executive officers, these agreements are terminable by them at will and we may not be able to retain any one or more of our executives. The loss of the services of any one or more members of our senior management team could (i) disrupt or divert our focus from pursuing our business plan while we seek to recruit other executives, (ii) impact the perceptions of our employees, partners and investors regarding our business and prospects and (iii) delay or prevent the development and commercialization of our product candidates. These and other potential consequences could cause significant harm to our business to the extent that we are not able to recruit suitable replacements in a timely manner.

Table of Contents

Future growth could strain our resources, and if we are unable to manage our growth, we may not be able to successfully implement our business plan.

Our business plan includes the continued growth of our operations at an accelerated pace, which will place a significant strain on our management, administrative, operational, and financial infrastructure. Our future success will depend in part upon the ability of our executive officers to manage growth effectively. This will require that we hire and train additional personnel to support our expanding operations. In addition, we must continue to improve our operational, financial, and management controls and our reporting systems and procedures. If we fail to successfully manage our growth, we may be unable to execute upon our business plan.

We may be unable to successfully develop and commercialize the assets we have acquired, or acquire, or develop and commercialize new assets and product candidates.

Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize our product candidates, including the assets we acquired from Inovio related to certain non-DNA vaccine technology and intellectual property relating to solid tumor treatments. In addition, we plan to expand our clinical pipeline and to build our product portfolio through the acquisition or licensing of new assets, product candidates or approved products. There are numerous difficulties inherent in acquiring, developing and commercializing new products and product candidates, including difficulties related to:

- successfully identifying potential product candidates;
- developing potential product candidates;
- difficulties in conducting or completing clinical trials, including receiving incomplete, unconvincing, or equivocal clinical trials data;
- obtaining requisite regulatory approvals for such products in a timely manner or at all;
- acquiring, developing, testing, and manufacturing products in compliance with regulatory standards in a timely manner or at all;
- being subject to legal actions brought by our competitors, which may delay or prevent the development and commercialization of new products;
- delays or unanticipated costs; and
- significant and unpredictable changes in the payor landscape, coverage, and reimbursement for any products we develop.

As a result of these and other difficulties, we may be unable to develop potential product candidates using our intellectual property, and our potential products in development may not receive regulatory approvals in a timely manner or at all. If we do not acquire or develop product candidates, if any of our product candidates are not approved in a timely manner or at all, or if any of our product candidates, when acquired or developed and approved, cannot be successfully manufactured and commercialized, our operating results would be adversely affected. In addition, we may not recoup our investment in developing products, even if we are successful in commercializing those products. Our business expenditures may not result in the successful acquisition, development, or commercialization of products that will prove to be commercially

successful or result in the long-term profitability of our business.

Certain of our intellectual property is licensed from Inovio pursuant to a non-exclusive license.

As we describe elsewhere in this Quarterly Report, we have acquired certain technology and related assets from Inovio pursuant to the Asset Purchase Agreement. In connection with the closing of the Asset Purchase Agreement, we entered into a cross-license agreement with Inovio. Under the terms of the cross-license agreement, Inovio granted to us a non-exclusive, worldwide license to certain non-SECTA technology patents held by Inovio, and we granted to Inovio a limited, exclusive license to our acquired SECTA technology. While we do not currently rely on the intellectual property we have licensed from Inovio pursuant to this non-exclusive license, our product candidates may in the future utilize this intellectual property. Because the license is non-exclusive, Inovio may use its technology to compete with us. In addition, there are no restrictions on Inovio s ability to license their technology to others. As a result Inovio could license to others, including our competitors, the intellectual property rights covered by their license to us, including any of our improvements to the licensed intellectual property. In addition, either party may terminate the cross-license agreement with 30 days notice if they no longer utilize or sublicense the patent rights they have acquired pursuant to the cross-license. If either party were to terminate the cross-license agreement, we would no longer have the right to use Inovio s intellectual property that is subject to the cross license.

Table of Contents

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

Our business plan includes the expansion of our clinical pipeline and our product portfolio through the acquisition, in-license, development and/or marketing of additional products and product candidates. The success of our efforts to expand our clinical pipeline and to build our product portfolio will depend in significant part on our ability to successfully 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 can be lengthy and complex. Other companies, including many of our competitors with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. Our experience in making acquisitions, entering collaborations and in-licensing product candidates is limited, and 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. We may incorrectly judge the value or worth of an acquired or in-licensed product candidate, approved product or other asset. 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 business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership; and
- inability to retain key employees of any acquired business.

Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future product candidates.

We may seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our current and potential future product candidates, including our pursuit of combination trials to develop and commercialize our product candidates as combination products. Drug/device combination products are particularly complex, expensive and time-consuming to develop due to the number of variables involved in the final product design, including ease of patient and doctor use, maintenance of clinical efficacy, reliability and cost of manufacturing, regulatory approval requirements and standards and other important factors. There continues to be substantial and unpredictable risk and uncertainty related to manufacturing and supply until such time as the commercial supply chain is validated and proven.

We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators.

Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Table of Contents

Regulatory authorities may not approve our product candidates or the approvals we secure may be too limited for us to earn sufficient revenues.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of our product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. The FDA and other foreign regulatory agencies can delay approval of or refuse to approve our product candidates for a variety of reasons, including failure to meet safety and efficacy endpoints in our clinical trials. Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, may disagree with our or our partners trial design and our interpretation of data from preclinical studies and clinical trials. Clinical trials of our product candidates may not demonstrate that they are safe and effective to the extent necessary to obtain regulatory approvals. We have initiated Phase 2 clinical trials to assess our ImmunoPulse technology in patients with metastatic melanoma, Merkel cell carcinoma and cutaneous T-cell lymphoma. We currently plan to initiate a Phase l study for a new solid tumor indication and an additional Phase 2b pivotal trial for metastic melanoma. If we cannot adequately demonstrate through the clinical trial process that a therapeutic product we are developing is safe and effective, regulatory approval of that product would be delayed or prevented, which would impair our reputation, increase our costs and prevent us from earning revenues. Even if a product candidate is approved, it may be approved for fewer or more limited indications than requested or the approval may be subject to the performance of significant post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any limitation, condition or denial of approval would have an adverse affect on our business, reputation and results of operations.

As part of our asset acquisition in March 2011, we acquired from Inovio an extensive clinical database from existing clinical trials utilizing the NeoPulse technology. We must initiate or complete new pivotal clinical studies to support or expand upon our clinical database for our NeoPulse technology, either internally or in collaboration with a strategic partner, if we were to seek to commercialize the NeoPulse technology. We or any strategic partner that we engage may not be successful in initiating or completing any such new pivotal clinical studies.

Delays in the commencement or completion of clinical testing for product candidates based on our technology could result in increased costs to us and delay or limit our ability to pursue regulatory approval or generate revenues.

Clinical trials are very expensive, time-consuming, and difficult to design and implement. Even if the results of our current and proposed clinical trials are favorable, clinical trials for product candidates based on our technology will continue for several years and may take significantly longer than expected to complete.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs and business plan. We do not know whether our Phase 2 clinical trials will be completed on schedule, if at all. In addition, we do not know whether any other pre-clinical or clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining clearance from the FDA or respective international regulatory equivalent to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, clinical investigators, and trial sites;
- obtaining institutional review board, or IRB, approval to initiate and conduct a clinical trial at a prospective site;

- identifying, recruiting and training suitable clinical investigators;

- identifying, recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for similar indications; and

- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy, personal issues, or for any other reason they choose, or who are lost to further follow-up.

We believe that we have planned and designed an adequate development strategy for our electroporation technology. However, the FDA could determine that it is not satisfied with our plan or the details of our pivotal clinical trial protocols and designs.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our product candidates may be harmed, which may have a material adverse effect on our business, results of operations, financial condition and prospects.

Table of Contents

We must rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We expect to enter into agreements with third-party CROs to conduct our planned clinical trials and anticipate that we may enter into other such agreements in the future regarding any future product candidates. We currently rely on these parties for the execution of our clinical and pre-clinical studies, and control only certain aspects of their activities. We, and our CROs, are required to comply with the current FDA Code of Federal Regulations for Conducting Clinical Trials and GCP and ICH guidelines. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators, CRO trial sites, laboratories, and any entity having to do with the completion of the study protocol and processing of data. If we, or our CROs, fail to comply with applicable GCP regulations, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA and similar foreign regulators may determine that our clinical trials are not compliant with GCP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. 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 or 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 results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate additional revenues could be delayed.

We may participate in clinical trials conducted under an approved investigator-sponsored investigational new drug (IND) application and correspondence and communication with the FDA pertaining to these trials will strictly be between the investigator and the FDA.

We have in the past, and may in the future, participate in clinical trials conducted under an approved investigator-sponsored investigational new drug (IND) application. Regulations and guidelines imposed by the FDA with respect to IND applications include a requirement that the sponsor of a clinical trial provide ongoing communication with the agency as it pertains to safety of the treatment. This communication can be relayed to the agency in the form of safety reports, annual reports, or verbal communication at the request of the FDA. Accordingly, it is the responsibility of each investigator (as the sponsor of the trial) to be the point of contact with the FDA. The communication and information provided by the investigator may not be appropriate and accurate, and the investigator has the ultimate responsibility and final decision-making authority with respect to submissions to the FDA. This may result in reviews, audits, delays, or clinical holds by the FDA ultimately affecting the timelines for these studies and potentially risking the completion of these trials.

We may incur liability if our promotions of product candidates are determined, or are perceived, to be inconsistent with regulatory guidelines.

The FDA provides guidelines with respect to appropriate product promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General: U.S. Department of Health and Human Services may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management s attention could be diverted and our reputation could be damaged.

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 currently assemble certain 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. We expect to increase our reliance on third party manufacturers if and when we commercialize our product candidates and systems. 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.

Table of Contents

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, assuming we are successful in commercializing one or more of our product candidates, 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.

If any product candidate for which we receive regulatory approval does not achieve broad market acceptance or coverage by third-party payors, our revenues may be limited.

The commercial success of any potential product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by physicians, patients, healthcare payors, and the medical community. Coverage and reimbursement of our approved product by third-party payors is also necessary for commercial success. The degree of market acceptance of any potential product candidates for which we may receive regulatory approval will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the prevalence and severity of adverse side effects;
- limitations or warnings contained in a product s FDA-approved labeling;
- the clinical indications for which the product is approved;
- availability and perceived advantages of alternative treatments;
- any negative publicity related to our or our competitors products;
- the effectiveness of our or any current or future collaborators sales, marketing, and distribution strategies;
- pricing and cost effectiveness;
- our ability to obtain sufficient third-party payor coverage or reimbursement; and
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage.

Our efforts to educate the medical community and third-party payors on the benefits of any of our potential product candidates for which we obtain marketing approval from the FDA or other regulatory authorities may require significant resources and may never be successful. If our potential products do not achieve an adequate level of acceptance by physicians, third-party payors, and patients, we may not generate sufficient revenue from these products to become or remain profitable.

We may not be successful in executing our strategy for the commercialization of our product candidates. If we are unable to successfully execute our commercialization strategy, we may not be able to generate significant revenue.

We intend to advance a commercialization strategy that leverages previous in-depth clinical experiences, previous CE (Conformité Européene) approvals for the electroporation-based devices, and late stage clinical studies in the United States. This strategy includes seeking approval from the FDA to initiate pivotal registration studies in the United States for select rare cancers that have limited, adverse, or no therapeutic alternatives. This strategy also includes expanding the addressable markets for our therapies through the addition of relevant indications. Our commercialization plan also includes partnering and/or co-developing our technology in developing geographic locations, such as Eastern Europe and Asia, where local resources are best leveraged and appropriate collaborators can be secured.

We may not be able to implement a commercialization strategy as we have planned. Further, we have little experience and have not proven our ability to succeed in the biotechnology industry and are not certain that our implementation strategy, if implemented correctly, would lead to significant revenue. If we are unable to successfully implement our commercialization plans and drive adoption by patients and physicians of our potential future products through our sales, marketing, and commercialization efforts, then we will not be able to generate significant revenue which will have a material adverse effect on our business, results of operations, financial condition, and prospects.

Table of Contents

In order to market our proprietary products, we may choose to establish our own sales, marketing, and distribution capabilities. We have no experience in these areas, and if we have problems establishing these capabilities, the commercialization of our products would be impaired.

We may choose to establish our own sales, marketing, and distribution capabilities to market products to our target markets. We have no experience in these areas, and developing these capabilities will require significan