

ONCOSEC MEDICAL Inc  
Form 10-Q  
June 09, 2015  
[Table of Contents](#)

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

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended April 30, 2015

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 000-54318

# ONCOSEC MEDICAL INCORPORATED

(Exact name of registrant as specified in its charter)

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

**98-0573252**  
(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  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 (§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  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 the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

**12,351,763 shares of the registrant's common stock were issued and outstanding as of June 5, 2015.**



Table of Contents

**OncoSec Medical Incorporated**

**Form 10-Q**

**for the Quarterly Period Ended April 30, 2015**

PART I FINANCIAL INFORMATION

Item 1.	Condensed Financial Statements and Condensed Consolidated Financial Statements: <u>Condensed Balance Sheet as of April 30, 2015 (unaudited) and Condensed Consolidated Balance Sheet as of July 31, 2014</u>	3
	<u>Condensed Statement of Operations for the three and nine months ended April 30, 2015 (unaudited) and Condensed Consolidated Statement of Operations for the three and nine months ended April 30, 2014 (unaudited)</u>	4
	<u>Condensed Statement of Cash Flows for the nine months ended April 30, 2015 (unaudited) and Condensed Consolidated Statement of Cash Flows for the nine months ended April 30, 2014 (unaudited)</u>	5
	<u>Notes to Condensed Financial Statements (unaudited)</u>	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	11
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosure about Market Risk</u>	18
<u>Item 4.</u>	<u>Controls and Procedures</u>	18

PART II OTHER INFORMATION

<u>Item 1.</u>	<u>Legal Proceedings</u>	19
<u>Item 1A.</u>	<u>Risk Factors</u>	19
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	32
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	32
<u>Item 5.</u>	<u>Other Information</u>	32
<u>Item 6.</u>	<u>Exhibits</u>	33

Table of Contents**OncoSec Medical Incorporated****Condensed Balance Sheet and Condensed Consolidated Balance Sheet**

	(unaudited) April 30 2015	July 31, 2014
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 25,439,188	\$ 37,852,694
Prepaid expenses and other current assets	879,445	466,483
<b>Total Current Assets</b>	<b>26,318,633</b>	<b>38,319,177</b>
Property and equipment, net	1,201,338	581,054
Intangible assets, net		464,693
Other long-term assets	123,308	26,685
<b>Total Assets</b>	<b>\$ 27,643,279</b>	<b>\$ 39,391,609</b>
<b>Liabilities and Stockholders Equity</b>		
<b>Liabilities</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 1,702,403	\$ 1,236,352
Accrued other	52,721	87,199
<b>Total Liabilities</b>	<b>1,755,124</b>	<b>1,323,551</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders Equity</b>		
Common stock authorized - 160,000,000 common shares with a par value of \$0.0001, common stock issued and outstanding 12,351,763 and 12,231,554 common shares as of April 30, 2015 and July 31, 2014, respectively (1)	24,701	24,463
Additional paid-in capital	58,760,949	56,081,475
Warrants issued and outstanding 1,771,647 and 1,882,390 warrants as of April 30, 2015 and July 31, 2014, respectively (1)	7,132,235	7,325,152
Accumulated deficit	(40,029,730)	(25,363,032)
<b>Total Stockholders Equity</b>	<b>25,888,155</b>	<b>38,068,058</b>
<b>Total Liabilities and Stockholders Equity</b>	<b>\$ 27,643,279</b>	<b>\$ 39,391,609</b>

---

(1) See Note 1, Reverse Stock Split

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 April 30, 2015	Three Months Ended April 30, 2014	Nine Months Ended April 30, 2015	Nine Months Ended April 30, 2014
Revenue	\$	\$	\$	\$
Expenses:				
Research and development	3,932,322	1,700,656	9,293,484	3,933,611
General and administrative	2,053,964	2,115,374	5,371,245	4,472,692
Loss from operations	(5,986,286)	(3,816,030)	(14,664,729)	(8,406,303)
Other income (expense):				
Non-cash interest expense				(20,684)
Net loss before income taxes	(5,986,286)	(3,816,030)	(14,664,729)	(8,426,987)
Provision (benefit) for income taxes	1,059	814	1,969	41,773
Net loss	\$ (5,987,345)	\$ (3,816,844)	\$ (14,666,698)	\$ (8,468,760)
Basic net loss per common share (1)	\$ (0.48)	\$ (0.37)	\$ (1.19)	\$ (0.96)
Diluted net loss per common share (1)	\$ (0.48)	\$ (0.37)	\$ (1.19)	\$ (0.96)
Weighted average shares used in computing basic net loss per common share (1)	12,349,693	10,364,406	12,347,450	8,789,111
Weighted average shares used in computing diluted net loss per common share (1)	12,349,693	10,364,406	12,347,450	8,789,111

---

(1) See Note 1, Reverse Stock Split

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)**

	<b>Nine Months Ended April 30, 2015</b>	<b>Nine Months Ended April 30, 2014</b>
<i>Operating activities</i>		
Net loss	\$ (14,666,698)	\$ (8,468,760)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	601,777	579,545
Loss on disposal of fixed assets	4,325	
Non-cash interest expense		20,684
Stock-based compensation	1,650,550	1,397,174
Common stock issued for services	59,250	150,000
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other current assets	(509,585)	(482,164)
Increase (decrease) in accounts payable and accrued liabilities	466,051	539,959
Increase (decrease) in accrued other	(34,478)	(5,005)
Net cash used in operating activities	(12,428,808)	(6,268,567)
<i>Investing activities</i>		
Purchases of property and equipment	(761,693)	(154,105)
Net cash used in investing activities	(761,693)	(154,105)
<i>Financing activities</i>		
Proceeds from issuance of common stock and warrants	776,995	11,948,000
Payment of financing and offering costs		(836,360)
Payment of amounts due under acquisition obligation		(1,000,000)
Proceeds from exercise of warrants and stock options		15,593,011
Net cash provided by financing activities	776,995	25,704,651
Net (decrease) increase in cash	(12,413,506)	19,281,979
Cash and cash equivalents, at beginning of period	37,852,694	4,970,175
Cash and cash equivalents, at end of period	\$ 25,439,188	\$ 24,252,154
Supplemental disclosure for cash flow information:		
Cash paid during the period for:		
Interest	\$	\$
Income taxes	\$ 1,969	\$ 22,837
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 period, the Company expanded its research capabilities in the areas 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 potentially failing to secure additional funding to continue the advancement of its product candidates and potentially failing to commercialize its product candidates before similar or competing technology is developed by competitors.

Effective October 28, 2014, OncoSec Medical Therapeutics Incorporated, 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 Company currently has no subsidiaries.

*Reverse Stock Split*

Effective May 18, 2015 and pursuant to the reverse stock split approved by our Board of Directors, each 20 shares of issued and outstanding common stock and warrants, respectively, were combined into and became one share of common stock and no fractional shares were issued. The accompanying financial statements and related disclosures give retroactive effect to the reverse stock split for all periods presented. Under Nevada



## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

law, because the reverse stock split was approved by the Board of Directors and (i) both the number of authorized shares of the common stock and the number of issued and outstanding shares of common stock were proportionally reduced as a result of the reverse stock split, (ii) the reverse stock split does not adversely affect any other class of stock of the Company and (iii) the Company did not pay money or issue scrip to stockholders who would otherwise be entitled to receive a fractional share as a result of the reverse stock split, stockholder approval was not required.

### *NASDAQ Listing*

Effective May 29, 2015, our common stock began trading on The NASDAQ Stock Market LLC's NASDAQ Capital Market tier, under the symbol ONCS.

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 April 30, 2015, condensed statement of operations for the three and nine months ended April 30, 2015 and condensed consolidated statement of operations for the three and nine months ended April 30, 2014, condensed statement of cash flow for the nine months ended April 30, 2015 and the condensed consolidated statement of cash flows for the nine months ended April 30, 2014, 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

Table of Contents

flows for the periods presented. The results of operations for the three and nine months ended April 30, 2015 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 products to improve treatment options for patients and physicians, intended to treat a wide range of oncology indications.

*Concentrations and Credit Risk*

The Company maintains cash balances at two financial institutions and such balances commonly exceed 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.

**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 April 30, 2015 and July 31, 2014, cash and cash equivalents were comprised of cash in checking accounts and a certificate of deposit.

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 approximately \$40.0 million as of April 30, 2015.

As of April 30, 2015, the Company had cash and cash equivalents of approximately \$25.4 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 for the nine months ended is provided below:

	April 30, 2015	April 30, 2014
Stockholders equity at beginning of period	\$ 38,068,058	\$ 4,739,124
Net loss	(14,666,698)	(8,468,760)
Stock-based compensation	1,650,550	1,397,174
Common stock issued for services	59,250	150,000
Exercise of common stock warrants	775,257	15,254,873
Exercise of stock options	1,738	338,138
Public offering on September 18, 2013, net of issuance costs of \$836,360		11,111,640
Stockholders equity at end of period	\$ 25,888,155	\$ 24,522,189

**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 \$2,788,000 and \$2,323,000 as of April 30, 2015 and July 31, 2014, respectively. The patents are fully amortized and were 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- and nine-month periods ended April 30, 2015 and 2014 were approximately \$116,000 and \$465,000, respectively, and \$174,000 and \$523,000, respectively.

#### **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 50,000 shares of common stock. As consideration for the Second Amendment, the Company issued to Inovio a warrant to purchase 150,000 shares of common stock.

Table of Contents

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 April 30, 2015, the Company had outstanding warrants to purchase 1,771,647 shares of common stock, with exercise prices ranging from \$5.20 to \$24.00, all of which were classified as equity instruments. These warrants expire at various times between March 2016 and June 2019.

During the nine months ended April 30, 2015, 110,750 warrants were exercised, with net proceeds of approximately \$775,000 received.

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- and nine-month periods ended April 30, 2015 and 2014, 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

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

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 April 30, 2015, the Company granted options to purchase 184,750 shares of the Company's common stock to employees under the Company's 2011 Stock Incentive Plan (the "2011 Plan"). The options issued under the 2011 Plan have a ten-year term, vest over three years, and have exercise prices ranging from \$6.60 to \$7.60.

During the nine months ended April 30, 2015, the Company granted options to purchase 338,500 and 30,000 shares of the Company's common stock to employees and consultants under the 2011 Plan, respectively. The options issued to employees within the 2011 Plan have a ten-year term, vest over a range of one to three years, and have exercise prices ranging from \$7.30 to \$10.60. 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 \$6.60 to \$8.60.

During the three month period ended April 30, 2014, the Company granted options to purchase 111,000 shares of the Company's common stock to employees and directors under the 2011 Plan. In addition, the Company granted options to purchase up to 200,000 shares of the Company's common stock outside the terms of the 2011 Plan to certain key employees and consultants. While such grants were made outside of the 2011 Plan, the terms of such grants are substantially similar to comparable grants made pursuant to the 2011 Plan. All of the foregoing options are subject to a ten year term, vest over two to three years in accordance with the terms of the applicable stock option agreement, and have exercise prices ranging from \$9.00 - \$16.10.

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

### Table of Contents

The following assumptions were used to calculate the fair value of stock-based compensation during the three months ended April 30, 2015 and 2014:

	April 30, 2015	April 30, 2014
Expected volatility	87.68%-117.51%	88.65%-91.96%
Risk-free interest rate	0.87%-1.86%	1.46%-2.78%
Expected forfeiture rate	0.00%	0.00%
Expected dividend yield		
Expected term	3-6.5 years	5-10 years

The following assumptions were used to calculate the fair value of stock-based compensation during the nine months ended April 30, 2015 and 2014:

	April 30, 2015	April 30, 2014
Expected volatility	87.68%-117.51%	83.62%-92.52%
Risk-free interest rate	0.40%-2.13%	0.69%-2.78%
Expected forfeiture rate	0.00%	0.00%
Expected dividend yield		
Expected term	2-6.5 years	3-10 years

Stock-based compensation expense recorded in the Company's condensed statement of operations for the three- and nine-month periods ended April 30, 2015 resulting from stock-based compensation awarded to the Company's employees, directors and consultants was approximately \$628,000 and \$1,700,000, respectively. Of this balance, \$279,000 and \$761,000 were recorded in research and development, respectively, and \$349,000 and \$949,000, respectively, were recorded in general and administrative in the Company's condensed statement of operations for the periods ended April 30, 2015.

Stock-based compensation expense recorded in the Company's condensed consolidated statements of operations for the three- and nine-month periods ended April 30, 2014 resulting from stock-based compensation awarded to the Company's employees, directors and consultants was approximately \$1,105,000 and \$1,397,000, respectively. Of this balance, \$374,000 and \$536,000 was recorded to research and development, and \$731,000 and \$861,000, was recorded in general and administrative in the Company's condensed consolidated statements of operations for the three- and nine-month periods ended April 30, 2014, respectively.

The weighted-average grant date fair value of stock options granted during the three- and nine-month periods ended April 30, 2015 and 2014 were \$6.20 and \$6.60, respectively, and \$11.40 and \$9.60, 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.



On December 31, 2014, the Company entered into a Lease Agreement (the "Lease Agreement"). Pursuant to the Lease Agreement, the Company has leased certain premises of approximately 33,928 rentable square feet located at 5820 Nancy Ridge Drive, San Diego, California (the "Premises") to serve as the Company's corporate headquarters and research and development laboratory. The term of the Lease Agreement is expected to commence on or about October 1, 2015 (the "Commencement Date"), and expires one hundred twenty (120) months after the Commencement Date (the "Term"). The Company has an option to extend the Term for an additional five (5) years, if notice is given within 12 months prior to the expiration of the Term. The Company also has the right to terminate the Lease ("Termination Right") with respect to the entire Premises only as of expiration of the 84th month after the Commencement Date ("Early Termination Date") so long as the Company delivers to the Landlord a written notice of its election to exercise its Termination Right no less than 12 months in advance of the Early Termination Date. The Lease Agreement provides for base rent at \$2.65 per rentable square feet, subject to a 3% rate increase on each annual anniversary of the first day of the first full month during the Term of the Lease Agreement. The Rent Commencement Date shall be the date that is 12 months after the Commencement Date. In addition, the Company is required to share in certain operating expenses of the Premises. In December 2014, pursuant to the Lease Agreement, the Company delivered a security deposit of approximately \$90,000.

On March 6, 2015, the Company entered into two Research and Development Services Agreements, one with Rev.1 Engineering Inc. ("Rev.1") and the other with Merlin CSI, LLC ("Merlin"). Each company has been engaged to perform research, development, testing, and regulatory filing services related to two engineering projects. The Company will own intellectual property related to any potential candidate device that is developed by either party in the performance of the services under these agreements. The estimated total cost of the Rev.1 agreement is \$3,383,000. The Company paid an initial deposit to Rev.1 of \$350,000 upon signing the agreement and Rev.1 will use this deposit to offset 10% of each monthly invoice under the agreement, reducing the outstanding deposit accordingly. If the Company exercises its right to terminate the Rev.1 agreement before the completion of the engineering projects, the Company will forfeit the outstanding deposit amount to Rev.1. The estimated total cost of the Merlin agreement is \$1,525,000. The Company may be responsible for additional costs, including the costs of preapproved expenses incurred by Merlin.

#### **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**

##### *June 2015 Public Offering*

On June 8, 2015, the Company closed a registered direct public offering of an aggregate of 2,469,091 shares of the Company's common stock at a purchase price of \$5.50 per share, for gross proceeds to the Company of approximately \$13.6 million (the "June 2015 Public Offering"). After deducting for fees and expenses, the aggregate net proceeds from the sale of the common stock in the June 2015 Public Offering were approximately \$12.6 million.

In connection with the June 2015 Public Offering, the Company 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 5% of the aggregate number of shares of common stock sold in the offering, or 123,455 shares of the Company's common stock (the "June 2015 Placement Agent Warrants"). The June 2015 Placement Agent Warrants will be exercisable as of December 8, 2015 and will expire on May 12, 2019.



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 product candidates; 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 current and any additional planned product candidates; 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.

Table of Contents

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.

Our lead product candidate, an investigational intratumoral plasmid IL-12 electroporation ( pIL-12 EP ) monotherapy ( ImmunoPulse IL-12 ), is being studied in a Phase II open label clinical trial. On December 5, 2014, we released top-line six-month data from the first Phase II trial of this product candidate in patients with stage III and IV metastatic melanoma, which was presented in an abstract at the Melanoma Bridge 2014 conference in Naples, Italy. In this Phase II study, 30 patients with stage III and IV melanoma received up to four cycles of pIL-12 EP into superficial cutaneous, subcutaneous and nodal lesions on days 1, 5 and 8 of each 12-week cycle. Tumor responses were evaluated using modified RECIST criteria for cutaneous lesions. The primary endpoint of the study was best overall response rate ( bORR ) by modified RECIST. In the 29 response-evaluable patients, bORR was 31% (9/29), with 14% (4/29) of patients achieving a complete response. Regression of at least one non-injected, non-electroporated lesion was observed in 50% (13/26) of patients. Patients are currently being enrolled into an extension arm of the Phase II trial to evaluate a new six-week treatment cycle. On November 25, 2014, we announced entering into a clinical collaboration with the University of California, San Francisco to initiate an investigator sponsored clinical trial to evaluate the safety, tolerability, and efficacy of the combination of KEYTRUDA® (pembrolizumab), Merck & Co.'s anti-PD-1 therapy, and OncoSec's ImmunoPulse IL-12 in metastatic melanoma. This is a multicenter study in which the University of California, San Francisco will be the first site of enrollment.

The safety and efficacy of intratumoral electroporation with plasmid IL-12 is also being tested in other cancer indications. On December 9, 2014, we announced plans to conduct a Phase II trial in head and neck squamous cell carcinoma ( HNSCC ) using our proprietary ImmunoPulse platform. This is a multicenter study in which the University of California, San Francisco will also be the first site of enrollment. The study will enroll patients with treatment-refractory metastatic and unresectable HNSCC, regardless of human papillomavirus status. Additionally, on January 12, 2015, we announced plans to initiate a pilot study to assess ImmunoPulse IL-12 in patients with triple negative breast cancer ( TNBC ). This pilot study, which will be conducted at Stanford University, is designed to assess whether ImmunoPulse IL-12 increases TNBC tumor immunogenicity by driving a pro-inflammatory cascade of events that leads to increases in cytotoxic tumor-infiltrating lymphocytes.

*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

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

Inovio of \$1,000,000 in December 2013. As consideration for the First Amendment we issued to Inovio a warrant to purchase 50,000 shares of common stock with an exercise price of \$24.00 per share. As consideration for the Second Amendment, we issued to Inovio a warrant to purchase 150,000 shares of our common stock with an exercise price of \$20.00 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 \$48.00 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.

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.

Table of Contents

**Recent Events**

*Lease Agreement*

On December 31, 2014, we entered into a Lease Agreement (the "Lease Agreement") to lease certain premises of approximately 33,928 rentable square feet located at 5820 Nancy Ridge Drive, San Diego, California (the "Premises") to serve as our corporate headquarters and research and development laboratory. The term of the Lease Agreement is expected to commence on or about October 1, 2015 (the "Commencement Date"), and expires one hundred twenty (120) months after the Commencement Date (the "Term"). We have an option to extend the Term for an additional five (5) years, if notice is given within 12 months prior to the expiration of the Term. We also have the right to terminate the Lease ("Termination Right") with respect to the entire Premises only as of expiration of the 84th month after the Commencement Date ("Early Termination Date") so long as the Company delivers to the landlord a written notice of our election to exercise our Termination Right no less than 12 months in advance of the Early Termination Date. The Lease Agreement provides for base rent at \$2.65 per rentable square feet, subject to a 3% rate increase on each annual anniversary of the first day of the first full month during the Term of the Lease Agreement. In addition, we are required to share in certain operating expenses of the Premises. In December 2014, pursuant to the Lease Agreement, we delivered a security deposit of approximately \$90,000.

*Development Agreements*

On March 6, 2015, we entered into two Research and Development Services Agreements, one with Rev.1 Engineering Inc. ("Rev.1") and the other with Merlin CSI, LLC ("Merlin"). Each company has been engaged to perform research, development, testing, and regulatory filing services related to two engineering projects. We will own intellectual property related to any potential candidate device that is developed by either party in the performance of the services under these agreements. The estimated total cost of the Rev.1 agreement is \$3,383,000. We paid an initial deposit to Rev.1 of \$350,000 upon signing the agreement and Rev.1 will use this deposit to offset 10% of each monthly invoice under the agreement, reducing the outstanding deposit accordingly. If we exercise our right to terminate the Rev.1 agreement before the completion of the engineering projects, we will forfeit the outstanding deposit amount to Rev.1. The estimated total cost of the Merlin agreement is \$1,525,000. We may be responsible for additional costs, including the costs of preapproved expenses incurred by Merlin.

*Reverse Stock Split*

Effective May 18, 2015 and pursuant to the reverse stock split approved by our Board of Directors, each 20 shares of issued and outstanding common stock and warrants, respectively, were combined into and became one share of common stock and no fractional shares were issued. Under Nevada law, because the reverse stock split was approved by our Board of Directors and (i) both the number of authorized shares of the common stock and the number of issued and outstanding shares of common stock were proportionally reduced as a result of the reverse stock split, (ii) the reverse stock split does not adversely affect any other class of stock of ours and (iii) we did not pay money or issue scrip to stockholders who would otherwise be entitled to receive a fractional share as a result of the reverse stock split, stockholder approval was not required.

*NASDAQ Listing*

Effective May 29, 2015, our common stock began trading on The NASDAQ Stock Market LLC's NASDAQ Capital Market tier, under the symbol ONCS.

*June 2015 Public Offering*

On June 8, 2015, we closed a registered direct public offering of an aggregate of 2,469,091 shares of our common stock at a purchase price of \$5.50 per share, for gross proceeds to us of approximately \$13.6 million (the June 2015 Public Offering). After deducting for fees and expenses, the aggregate net proceeds from the sale of the common stock in the June 2015 Public Offering were approximately \$12.6 million.

In connection with the June 2015 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 5% of the aggregate number of shares of common stock sold in the offering, or 123,455 shares of our common stock (the June 2015 Placement Agent Warrants). The June 2015 Placement Agent Warrants will be exercisable as of December 8, 2015 and will expire on May 12, 2019. We intend to use the net proceeds from the June 2015 Public Offering for general corporate purposes, including clinical trial expenses and research and development expenses.

Table of Contents

*June 2014 Public Offering*

On June 6, 2014, we closed a registered public offering of an aggregate of 1,126,761 shares of our common stock and warrants to purchase an aggregate of 394,368 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 \$18.00 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 67,606 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.

**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.

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,



## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

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 April 30, 2015 Compared to the Three Months Ended April 30, 2014

The unaudited financial data for the three-month periods ended April 30, 2015 and April 30, 2014 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	April 30, 2015 (\$)	April 30, 2014 (\$)	Increase/ (Decrease) (\$)	Increase/ (Decrease) %
<b>Revenue</b>				
<b>Operating expenses</b>				
Research and development	3,932,322	1,700,656	2,231,666	**
General and administrative	2,053,964	2,115,374	(61,410)	(3)
<b>Loss from operations</b>	(5,986,286)	(3,816,030)	2,170,256	57
<b>Other income (expense)</b>				
Interest expense non-cash and other				
<b>Net loss before income taxes</b>	(5,986,286)	(3,816,030)	2,170,256	57
<b>Tax provision (benefit)</b>	1,059	814	245	30
<b>Net loss</b>	(5,987,345)	(3,816,844)	2,170,501	57

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

Table of ContentsResearch and Development Expenses and Operational Milestones

The \$2,200,000 increase in research and development expenses for the three-month period ended April 30, 2015, as compared to the three-month period ended April 30, 2014 is primarily the result of an increase of \$800,000 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 \$700,000 in other outside services to further assist in the research of next-generation devices, novel electroporation technologies and combination studies, an increase of \$400,000 in engineering and lab supplies as we continue to prepare to undertake our internal R&D projects, an increase in clinical studies costs of \$200,000 due primarily to the progression of the metastatic melanoma extension study and an increase of \$100,000 in additional R&D related expenses consisting primarily of rent, conference fees and travel.

We expect research and development expenses to continue to increase and to use our working capital for the advancement of our operational milestones, inclusive of 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.

General and Administrative

The \$60,000 decrease in general and administrative expenses for the three-month period ended April 30, 2015, as compared to the three-month period ended April 30, 2014, was primarily the result of a decrease of \$60,000 in stock-based compensation expense due to less options granted in the current period than prior period and a decrease of \$100,000 in outside services related to professional services fees, offset by an increase in conference fees and travel of \$100,000.

**Results of Operations for the Nine Months Ended April 30, 2015 Compared to the Nine Months Ended April 30, 2014**

The unaudited financial data for the nine-month periods ended April 30, 2015 and April 30, 2014 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	April 30, 2015 (\$)	April 30, 2014 (\$)	Increase/ (Decrease) (\$)	Increase/ (Decrease) %
<b>Revenue</b>				
<b>Operating expenses</b>				
Research and development	9,293,484	3,933,611	5,359,873	**
General and administrative	5,371,245	4,472,692	898,553	20
<b>Loss from operations</b>	(14,664,729)	(8,406,303)	6,258,426	74
<b>Other income (expense)</b>				
Interest expense non-cash and other		(20,684)	(20,684)	(100)
<b>Net loss before income taxes</b>	(14,664,729)	(8,426,987)	6,237,742	74
<b>Tax provision</b>	1,969	41,773	(39,804)	(95)

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

<b>Net loss</b>	(14,666,698)	(8,468,760)	6,197,938	73
-----------------	--------------	-------------	-----------	----

---

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

Research and Development Expenses and Operational Milestones

The \$5,400,000 increase in research and development expenses for the nine-month period ended April 30, 2015, as compared to the nine-month period ended April 30, 2014 is primarily the result of an increase of \$2,400,000 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 \$1,100,000 in other outside services to further assist in the research of next-generation devices, novel electroporation technologies and combination studies, an increase of \$900,000 in engineering and lab supplies as we prepare to undertake our internal R&D projects, an increase in clinical studies costs of \$300,000 due primarily to the progression of the clinical trials and an increase of \$700,000 in additional R&D related expenses consisting primarily of rent, conference fees and travel .

Table of Contents

We expect our research and development expenses to continue to increase and to continue to use our working capital toward activities related to our operational milestones that 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 \$3,300,000, excluding \$700,000 of personnel costs, Clinical costs of \$2,200,000, excluding \$1,200,000 of personnel costs and R&D costs of \$2,800,000, excluding of personnel costs of \$1,800,000.

General and Administrative

The \$900,000 increase in general and administrative expenses for the nine-month period ended April 30, 2015, as compared to the nine-month period ended April 30, 2014, was primarily the result of an increase of \$800,000 in salary related costs, inclusive of stock-based compensation due to hiring additional personnel to support the growth in our operations and an increase in conference fees and travel of \$500,000, offset by a decrease of \$400,000 in outside services related primarily to professional services fees.

Other Income (Expense)

The \$21,000 decrease in other expense for the nine-month period ended April 30, 2015, as compared to the comparable nine-month period ended April 30, 2014, 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.

**Liquidity and Capital Resources**

*Working Capital*

Our working capital as of April 30, 2015 and July 31, 2014 is summarized as follows:

	At April 30, 2015 (\$)	At July 31, 2014 (\$)
Current assets	26,318,633	38,319,177
Current liabilities	1,755,124	1,323,551
Working capital	24,563,509	36,995,626

Current Assets

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

Current assets as of April 30, 2015 decreased to approximately \$26,300,000, in comparison to our approximate current assets of \$38,300,000 as of July 31, 2014. This decrease in our current assets was primarily due to a decrease in cash from \$37,900,000 as of July 31, 2014, to \$25,400,000 as of April 30, 2015, which is attributable to the cash used in operations during the nine-month period ended April 30, 2015, offset by an increase of \$400,000 in prepaid assets due to contractual prepayments related to sponsored research and engineering consulting agreements.

### Current Liabilities

Current liabilities as of April 30, 2015 increased to approximately \$1,800,000, in comparison to our approximate current liabilities of \$1,300,000 as of July 31, 2014. This increase was primarily due to an increase in our accounts payables and accrued liabilities primarily related to the purchase of engineering and lab supplies for our R&D projects and costs related to our clinical programs.

### *Cash Flow*

### Cash Used in Operating Activities

Cash used in operating activities for the nine-month period ended April 30, 2015 was \$12,400,000, as compared to \$6,300,000 for the nine-month period April 30, 2014. 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.

Table of Contents

Cash Used in Investing Activities

Cash used in investing activities for the nine-month period ended April 30, 2015 was \$760,000, as compared to \$154,000 for the nine-month period ended April 30, 2014. This increase was primarily related to the purchase of property and equipment for our labs.

Cash Flow Provided by Financing Activities

Cash provided by financing activities was \$780,000 for the nine-month period ended April 30, 2015, as compared to \$25,700,000 for the comparable nine-month period ended April 30, 2014. In the current period, the activity related solely to warrant and option exercises, whereas in the prior period the activity primarily related to proceeds received from a public offering of common stock in September 2013 as well as cash received from warrant exercise activity during the period.

*Cash Requirements*

Our primary objectives for Fiscal 2015 are to continue the advancement of our operational 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 estimate our aggregate operating expenses and working capital requirements for Fiscal 2015 (inclusive of the nine-month period ended April 30, 2015) 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 April 30, 2015, we estimate the components of our operating expenses and working capital requirements for Fiscal 2015 (inclusive of the nine-month period ended April 30, 2015) to be approximately as follows:

<b>Cash Requirements</b>	<b>Amount</b>
Product development	\$ 8,300,000
Employee compensation	6,400,000
General and administration	4,100,000
Professional services fees	700,000
	\$ 19,500,000

On June 8, 2015, we closed a registered direct public offering of our equity securities whereby we issued an aggregate of 2,469,091 shares of our common stock at a purchase price of \$5.50 per share, which resulted in net proceeds to us of approximately \$12.6 million, as more fully described elsewhere in this quarterly report.

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

During the nine-month period ended April 30, 2015, our operating cash outflow was approximately \$12,400,000, which is approximately \$1.2 million less than originally projected and is primarily the result of timing of start-up of clinical trials, the deferred timing of the development and optimization of plasmid manufacturing processes in preparation of Phase III studies and revised cost estimates related to animal studies. Based on these factors, we expect our monthly cash outflows for the remainder of FY2015 to average \$2,200,000, with May anticipated as having the least cash outflow of \$1,700,000 and July anticipated as having the highest cash outflow of \$3,000,000.

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 \$14.1 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 NASDAQ 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.

Table of Contents

**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.

**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 April 30, 2015 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.





Table of Contents

**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. The business, financial condition and operating results of the Company can be affected by a number of factors, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual results of operations and financial condition to vary materially from past, or from anticipated future, results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations and common stock price.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding any statement in this Form 10-Q or elsewhere. The following information should be read in conjunction with the condensed consolidated financial statements and related notes in Part I, Item 1, Financial Statements and Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations of this Form 10-Q.

*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 April 30, 2015 we had cash and cash equivalents of approximately \$25.4 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.

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, and may not be able to generate in the future, revenue from our operations.***

We have not generated any revenue from operations since our inception. During the nine months ended April 30, 2015, we incurred a net loss of approximately \$14.7 million. From inception through April 30, 2015, we have incurred an aggregate net loss of approximately \$40.0 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.

Table of Contents

***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 successfully 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.

***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.

Table of Contents

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

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; with any of the foregoing; and
- significant and unpredictable changes in the payor landscape, coverage, and reimbursement for any products we successfully develop and commercialize.

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

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

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.

***Our failure to successfully acquire, develop and market additional product candidates or any 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.

Table of Contents

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 have also initiated an extension to the Phase 2 clinical trial in metastatic melanoma and we have announced plans to initiate a Phase 2 study in head and neck cancer and a pilot study in triple negative breast cancer. 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;

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

- 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 or curtailed.

***We may participate in clinical trials conducted under an approved investigator-sponsored investigational new drug 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 current good manufacturing practices (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.

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

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, and 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 significant expenditures on personnel and infrastructure. While we intend to market products that are aimed at a small patient population, we may not be able to create an effective sales force around even a niche market. In addition, some of our product candidates may require a large sales force to call on, educate, and support physicians and patients. We may desire in the future to enter into collaborations with one or more pharmaceutical companies to sell, market, and distribute such products, but we may not be able to enter into any such arrangement on acceptable terms, if at all. Any collaboration we do enter into may not be effective in generating meaningful product royalties or other revenues for us.

***Our success depends in large part on our ability to protect our intellectual property. Because of the difficulties of protecting our proprietary rights and technology, we may not be able to ensure their protection.***

Our commercial success will depend in large part on obtaining and maintaining patent, trademark, and trade secret protection of our product candidates and their respective components, formulations, manufacturing methods, and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell, or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The coverage claimed in a patent application typically is significantly reduced before a patent is issued, either in the United States or abroad. Consequently, any of our pending or future patent applications may not result in the issuance of patents and any patents issued may be subjected to further proceedings limiting their scope and may in any event not contain claims broad enough to provide meaningful protection. Any patents that are issued to us or our future collaborators may not provide significant proprietary protection or competitive advantage and may be circumvented or invalidated. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. Further, because development and commercialization of our potential product candidates can be subject to substantial delays, our patents may expire and provide only a short period of protection, if any, following any future commercialization of products. Moreover, obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. If any of our patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

***We may incur substantial costs as a result of litigation or other proceedings relating to protection of our patent and other intellectual property rights, and we may be unable to successfully protect our rights to our potential products and technology.***

If we choose to go to court to stop a third party from using the inventions claimed by our patents, that third party may ask the court to rule that the patents are invalid and/or should not be enforced. These lawsuits are expensive and could consume time and other resources even if we were successful in stopping the infringing activity. In addition, the court could decide that our patents are not valid and that we do not have the right to stop others from using the inventions claimed by the patents.



## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

Additionally, even if the validity of these patents is upheld, the court could refuse to stop a third party's infringing activity on the ground that such activities do not infringe our patents. The U.S. Supreme Court has recently revised certain tests regarding granting patents and assessing the validity of patents to make it more difficult to obtain patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a reexamination proceeding, or during litigation, under the revised criteria.

*Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.*

The manufacture, use, and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the biotechnology industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. Litigation may be costly and time-consuming and could divert the attention of our management and technical personnel. In addition, if we infringe on the rights of others, we could lose our right to develop, manufacture, or market products or

Table of Contents

could be required to pay monetary damages or royalties to license proprietary rights from third parties. Although the parties to patent and intellectual property disputes in the biotechnology industry have often settled their disputes through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. Furthermore, we cannot be certain that the necessary licenses would be available to us on commercially reasonable terms or at all. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, and could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

***Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing, and distribution capabilities.***

All biotechnology companies are subject to extensive, complex, costly, and evolving government regulation. For the U.S., these regulations are principally administered by the FDA and to a lesser extent by the United States Drug Enforcement Agency (the DEA) and state government agencies, as well as by various regulatory agencies in foreign countries where products or product candidates are being manufactured and/or marketed. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act, and other federal statutes and regulations, and similar foreign statutes and regulations, govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale, and distribution of our products. Under these regulations, we may become subject to periodic inspection of our facilities, procedures, and operations and/or the testing of our product candidates and products by the FDA, the DEA, and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable regulations. In addition, the FDA and foreign regulatory agencies conduct pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP and other regulations. Following such inspections, the FDA or other agency may issue observations, notices, citations, and/or warning letters that could cause us to modify certain activities identified during the inspection. To the extent that we successfully commercialize any product, we may also be subject to ongoing FDA obligations and continued regulatory review with respect to manufacturing, processing, labeling, packaging, distribution, storage, advertising, promotion, and recordkeeping for the product. Additionally, we may be required to conduct potentially costly post-approval studies and report adverse events associated with our products to the FDA and other regulatory authorities. Unexpected or serious health or safety concerns would result in labeling changes, recalls, market withdrawals, or other regulatory actions.

The range of possible sanctions includes, among others, FDA issuance of adverse publicity, product recalls or seizures, fines, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions, and civil or criminal prosecution. Any such sanctions, if imposed, could have a material adverse effect on our business, operating results, financial condition, and cash flows. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Similar sanctions as detailed above may be available to the FDA under a consent decree, depending upon the actual terms of such decree. If internal compliance programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business.

Moreover, the regulations, policies, or guidance of the FDA or other regulatory agencies may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our potential product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

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

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

Our ability to commercialize our electroporation equipment and ImmunoPulse products 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, independently and in combination with third-party products. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. A primary trend in the U.S. healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and procedures. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot assure you that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Table of Contents

In addition, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country.

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

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

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

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

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

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

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights may be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business, without limitation. The laws that may affect our ability to operate include:

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, people from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the ACA expands the government's investigative and enforcement authority and increases the penalties for fraud and abuse, including amendments to both the False Claims Act and the Anti-Kickback Statute to make it easier to bring suit under those statutes;
- 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.

Table of Contents

Additionally, the compliance environment is changing, with more states, such as California and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, Maine, and Minnesota requiring reporting to state governments of gifts, compensation, and other remuneration to physicians. Under the ACA, starting in 2012, pharmaceutical companies will be required to record any transfers of value made to doctors and teaching hospitals and to disclose such data to HHS, with initial disclosure to HHS due in 2013. These laws all provide for penalties for non-compliance. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and/or reporting requirements, increases the possibility that a company may run afoul of one or more laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

The clinical use of our product candidates exposes us to the risk of product liability claims. Any side effects, manufacturing defects, misuse, or abuse associated with our product candidates could result in injury to a patient or even death. In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies, or others coming into contact with our product candidates, among others.

Regardless of merit or potential outcome, product liability claims against us may result in, among other effects, the inability to commercialize our product candidates, impairment of our business reputation, withdrawal of clinical trial participants, and distraction of management's attention from our primary business. If we cannot successfully defend ourselves against product liability claims we could incur substantial liabilities.

***The biotechnology industry is highly competitive.***

The biotechnology industry has an intensely competitive environment that will require an ongoing, extensive search for technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety, and value of products to healthcare professionals in private practice, group practices, and payors in managed care organizations, group purchasing organizations, and Medicare & Medicaid services. We face competition from a number of sources, including large pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions. We are smaller than almost all of our competitors. Most of our competitors have been in business for a longer period of time than us, have a greater number of products on the market, and have greater financial and other resources than we do. Furthermore, recent trends in this industry are that large drug companies are consolidating into a smaller number of very large entities, which further concentrates financial, technical, and market strength and increases competitive pressure in the industry. If we directly compete with these very large entities for the same markets and/or products, their financial strength could prevent us from capturing a share of those markets. It is possible that developments by our competitors will make any products or technologies that we develop or acquire noncompetitive or obsolete.

*If our competitors market and/or develop competing product candidates that are marketed more effectively, approved more quickly, or demonstrated to be safer or more effective than our product candidates, then our commercial opportunities may be reduced or eliminated.*

The biotechnology industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary therapeutics. If we are able to obtain regulatory approval of our product candidates or any assets we may acquire in the future, we will face competition from products currently marketed by companies much larger than us that address our targeted indications.

In addition to already marketed products, we also face competition from product candidates that are or could be under development. We expect our product candidates, if approved and commercialized, to compete on the basis of, among other things, product efficacy and safety, time to market, price, patient reimbursement by third-party payors, extent of adverse side effects, and convenience of treatment procedures. We may not be able to effectively compete in one or more of these areas. We also may not be able to differentiate any products that we are able to market from those of our competitors or successfully develop or introduce new products that are less costly or offer better results than those of our competitors.

Table of Contents

Additionally, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop products that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted, or less costly than ours and may also be more successful than us in manufacturing and marketing their products. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with our potential product candidates that are approved, our business, results of operations, financial condition, and prospects may be materially adversely affected.

***We may engage in strategic transactions that could impact our liquidity, increase our expenses, and present significant distractions to our management.***

From time to time we may consider engaging in strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures, and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including, among others, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates, or technologies, difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel, and inability to retain key employees of any acquired businesses. Accordingly, although we may not choose to undertake or may not be able to successfully complete any transactions of the nature described above, any transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition, and prospects.

***Our business and operations would suffer in the event of system failures.***

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors, and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. System failures, accidents, or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercialization activities, development programs and our business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the commercialization of any potential product candidate could be delayed.

***If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results. As a result, current and potential stockholders could lose confidence in our financial reporting, which would cause the trading price of our common stock to fall.***

Effective internal controls are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our operating results could be misstated, our reputation may be harmed, and the trading price of our stock could be negatively affected. Our controls over financial processes and reporting may not continue to be effective, or we may identify additional material weaknesses or significant deficiencies in our internal controls in the future. Any failure to remediate any future material weaknesses or implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations, or result in material misstatements in our financial statements or other public disclosures. Inferior internal controls could also cause investors to lose



confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

***Maintaining compliance with our obligations as a public company may strain our resources and distract management, and if we do not remain compliant our stock price may be adversely affected.***

We are required to evaluate our internal control systems in order to allow management to report on our internal controls as required by Section 404 of the Sarbanes-Oxley Act of 2002, and our management is required to attest to the adequacy of our internal controls. Recent SEC pronouncements suggest that in the next several years we may be required to report our financial results using new International Financial Reporting Standards, replacing GAAP, which would require us to make significant investments in training, hiring, consulting, and information technology, among other investments. All of these and other reporting requirements and heightened corporate governance obligations that we face, or will face, will further increase the cost to us, perhaps substantially, of remaining compliant with our obligations under the Securities Exchange Act of 1934, as amended (the Exchange Act ) and other applicable laws, including the Sarbanes-Oxley Act and the Dodd-Frank Act of 2010. We are an accelerated filer as of July 31, 2014, and as a result we will no longer be able to avail ourselves of the scaled disclosure requirements applicable to smaller reporting companies in our filings with the SEC, which will generally increase our reporting obligations and compliance costs as a public company. Among other things, our compliance dates for the filing of our periodic reports with the SEC are accelerated and our compliance with Section 404 of the Sarbanes-Oxley Act will require that our independent registered public accounting firm issue an attestation report on management's assessment of our internal controls over financial reporting and a report on the effectiveness of our internal controls over financial reporting.

Table of Contents

**Risks Related to our Common Stock**

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

The continued operation and expansion of our business will require substantial funding. Investors seeking cash dividends in the foreseeable future should not purchase our common stock. We have paid no cash dividends on any of our capital stock to date and we currently intend to retain our available cash to fund the development and growth of our business. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law, and other factors our Board of Directors deems relevant. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

*If we issue additional shares in the future, our existing stockholders will be diluted.*

Our articles of incorporation authorize the issuance of up to 160,000,000 shares of common stock with a par value of \$0.0001 per share. In addition to capital raising activities, other possible business and financial uses for our authorized common stock include, without limitation, future stock splits, acquiring other companies, businesses, or products in exchange for shares of common stock, issuing shares of our common stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, or other transactions and corporate purposes that our Board of Directors deems are in the Company's best interest. Additionally, shares of common stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. We cannot provide assurances that any issuances of common stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our common stock. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current stockholders. Further, such issuance may result in a change of control of our Corporation.

*Sales of common stock by our stockholders, or the perception that such sales may occur, could depress our stock price.*

The market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, our existing stockholders. Since March 2011, we have completed a number of offerings of our common stock and warrants and as of June 5, 2015, we have issued an aggregate of 12,351,763 shares of our common stock, including common stock underlying warrants. Future sales of common stock by significant stockholders, including by those who acquired their shares in our prior offerings or who are affiliates, or the perception that such sales may occur, could depress the price of our common stock.

*If outstanding options and warrants to purchase shares of our common stock are exercised, the interests of our stockholders could be diluted.*

## Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

We have issued a total of 2,900,543 shares of our common stock as a result of warrant and option exercises as of April 30, 2015. No additional shares of our common stock have been issued as a result of warrant exercises between May 1, 2015 and June 5, 2015. In addition, we have as of June 5, 2015, 897,118 shares reserved for issuance under our equity compensation plan and pursuant to non-plan awards for vested and unvested stock options. The exercise of options and warrants, and the sale of shares underlying such options or warrants, could have an adverse effect on the market for our common stock, including the price that an investor could obtain for their shares. Investors may experience dilution in the net tangible book value of their investment upon the exercise of outstanding options and warrants granted under our stock option plans, and options and warrants that may be granted or issued in the future. In future periods, we may elect to reduce the exercise price of outstanding warrants as a means of providing additional financing to us.

Table of Contents

*Our common stock is illiquid and the price of our common stock may be negatively impacted by factors which are unrelated to our operations.*

Trading of our securities has in the past been highly volatile with low trading volume, and we have only very recently obtained approval to list and trade our securities on a national securities exchange. A sufficient market may never develop for our common stock, in which case it could be difficult for stockholders to sell their shares of our common stock. Additionally, if we are not able to maintain our recently obtained listing on the NASDAQ Capital Market, then our common stock will again be quoted for trading on an over-the-counter quotation system and may be subject to more significant fluctuations in stock price and trading volume. The market price of our common stock could continue to fluctuate substantially. Factors affecting the trading price of our common stock may include:

- adverse research and development or clinical trial results;
- conducting open-ended clinical trials which could lead to results (success or setbacks) being obtained by the public prior to a formal announcement by us;
- our inability to obtain additional capital;
- announcement that the U.S. Food and Drug Administration (the FDA) has denied our request to approve our products for commercialization in the United States, or similar denial by other regulatory bodies which make independent decisions outside the United States;
- potential negative market reaction to the terms or volume of any issuance of shares of our capital stock to new investors or service providers;
- sales of substantial amounts of our common stock, or the perception that substantial amounts of our common stock will be sold, by us or our stockholders in the public market;
- declining working capital to fund operations, or other signs of apparent financial uncertainty;
- significant advances made by competitors that adversely affect our potential market position; and
- the loss of key personnel and the inability to attract and retain additional highly-skilled personnel.

**Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

None.

**Item 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

**Item 4. MINE SAFETY DISCLOSURES.**

None.

**Item 5. OTHER INFORMATION.**

None.

Table of Contents

**Item 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
3.1	Certificate of Incorporation of Netventory Solutions, Inc. (incorporated by reference to our Registration Statement on Form S-1, filed on September 3, 2008)
3.2	Amended and Restated Bylaws (incorporated by reference to our Current Report on Form 8-K, filed on March 6, 2012)
3.3	Articles of Merger dated February 9, 2011 (incorporated by reference to our Current Report on Form 8-K, filed on March 3, 2011)
3.4	Certificate of Change dated February 9, 2011 (incorporated by reference to our Current Report on Form 8-K, filed on March 3, 2011)
3.5	Certificate of Correction dated March 9, 2011 (incorporated by reference to our Current Report on Form 8-K, filed on March 14, 2011)
3.6	Certificate of Change dated May 12, 2015 (incorporated by reference to our Current Report on Form 8-K, filed on May 15, 2015)
10.1	Research and Development Services Agreement, dated March 6, 2015, by and between OncoSec Medical Incorporated and Rev. 1 Engineering Inc. (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on March 11, 2015)
10.2	Research and Development Services Agreement, dated March 6, 2015, by and between OncoSec Medical Incorporated and Merlin CSI, LLC. (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed on March 11, 2015)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Financial statements from the Quarterly Report on Form 10-Q of OncoSec Medical Incorporated for the three and nine months period ended April 30, 2015, formatted in XBRL: (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statements of Cash Flows, (iv) the Notes to Condensed Financial Statements.

Table of Contents

**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.

**ONCOSEC MEDICAL INCORPORATED**

/s/ Punit Dhillon  
By: Punit Dhillon  
*(Principal Executive Officer)*

Dated: June 9, 2015

/s/ Veronica Vallejo  
By: Veronica Vallejo  
*(Principal Financial Officer)*

Dated: June 9, 2015