

ONCOSEC MEDICAL INCORPORATED

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

NEVADA

(State or other jurisdiction of incorporation or organization)

98-0573252

(I.R.S. Employer Identification No.)

5820 NANCY RIDGE DRIVE

SAN DIEGO, CA

(Address of principal executive offices)

92121

(Zip Code)

9810 Summers Ridge Road, Suite 110

SAN DIEGO, CA

(Former Address of principal executive offices)

92121

(Former Zip Code)

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

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

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

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

The number of shares outstanding of the Registrant's Common Stock, \$0.0001 par value, was 16,971,214 as of December 1, 2015.

Table of Contents

OncoSec Medical Incorporated

Form 10-Q

for the Quarterly Period Ended October 31, 2015

PART I FINANCIAL INFORMATION

Item 1.	Financial Statements:	
	<u>a) Condensed Balance Sheets as of October 31, 2015 (unaudited) and July 31, 2015</u>	3
	<u>b) Condensed Statements of Operations for the three months ended October 31, 2015 and 2014 (unaudited)</u>	4
	<u>c) Condensed Statements of Cash Flows for the three months ended October 31, 2015 and 2014 (unaudited)</u>	5
	<u>d) 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>	12
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosure about Market Risk</u>	16
<u>Item 4.</u>	<u>Controls and Procedures</u>	17

PART II OTHER INFORMATION

<u>Item 1.</u>	<u>Legal Proceedings</u>	18
<u>Item 1A.</u>	<u>Risk Factors</u>	18
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	30
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	30
<u>Item 5.</u>	<u>Other Information</u>	31
<u>Item 6.</u>	<u>Exhibits</u>	31

Table of Contents**OncoSec Medical Incorporated****Condensed Balance Sheets**

	(unaudited) October 31, 2015	July 31, 2015
Assets		
Current assets		
Cash and cash equivalents	\$ 26,896,369	\$ 32,035,264
Prepaid expenses and other current assets	1,091,048	1,532,717
Total Current Assets	27,987,417	33,567,981
Property and equipment, net	2,223,391	1,807,982
Other long-term assets	187,442	214,127
Total Assets	\$ 30,398,250	\$ 35,590,090
Liabilities and Stockholders Equity		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	\$ 2,909,725	\$ 2,360,505
Accrued other	268,229	533,964
Total Liabilities	3,177,954	2,894,469
Commitments and Contingencies		
Stockholders Equity		
Common stock authorized - 160,000,000 common shares with a par value of \$0.0001, common stock issued and outstanding 14,828,354 and 14,820,854 common shares as of October 31, 2015 and July 31, 2015, respectively	24,948	24,947
Additional paid-in capital	73,134,779	71,572,714
Warrants issued and outstanding 1,895,102 warrants as of October 31, 2015 and July 31, 2015	7,704,103	7,704,103
Accumulated deficit	(53,643,534)	(46,606,143)
Total Stockholders Equity	27,220,296	32,695,621
Total Liabilities and Stockholders Equity	\$ 30,398,250	\$ 35,590,090

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

Table of Contents

OncoSec Medical Incorporated
Condensed Statements of Operations (unaudited)

	Three Months Ended October 31, 2015	Three Months Ended October 31, 2014
Revenue	\$	\$
Expenses:		
Research and development	3,659,313	2,501,268
General and administrative	3,375,906	1,558,938
Net loss before income taxes	(7,035,219)	(4,060,206)
Provision for income taxes	2,172	910
Net loss, net of tax	\$ (7,037,391)	\$ (4,061,116)
Basic and diluted net loss per common share (1)	\$ (0.47)	\$ (0.33)
Weighted average shares used in computing basic and diluted net loss per common share (1)	14,826,887	12,231,554

(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 Statements of Cash Flows (unaudited)**

	Three Months Ended October 31, 2015	Three Months Ended October 31, 2014
<i>Operating activities</i>		
Net loss	\$ (7,037,391)	\$ (4,061,116)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	65,125	211,347
Loss on disposal of fixed assets	572	2,635
Stock-based compensation	1,562,066	611,240
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other current assets	441,669	30,324
Decrease in long-term assets	26,685	
Increase (decrease) in accounts payable and accrued liabilities	549,221	(188,667)
Decrease in accrued other and taxes	(265,735)	(35,445)
Net cash used in operating activities	(4,657,788)	(3,429,682)
<i>Investing activities</i>		
Purchases of property and equipment	(481,107)	(433,415)
Net cash used in investing activities	(481,107)	(433,415)
Net decrease in cash and cash equivalents	(5,138,895)	(3,863,097)
Cash and cash equivalents, at beginning of period	32,035,264	37,852,694
Cash and cash equivalents, at end of period	\$ 26,896,369	\$ 33,989,597
Supplemental disclosure for cash flow information:		
Cash paid during the period for:		
Interest	\$	\$
Income taxes	\$ 2,172	\$ 910
Noncash investing and financing transaction:		
Issuance of common stock in connection with a contractual agreement	\$ 55,500	\$

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 in the State of Nevada on February 8, 2008 under the name of Netventory Solutions Inc. The Company began its operations as a biotechnology company in March 2011, following its completion of 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 Company has not produced any revenues, nor has it commenced planned principal operations. The Company's technology includes intellectual property relating to certain delivery technologies including ImmunoPulse, an electroporation delivery device that is used in combination with the Company's therapeutic product candidates, including DNA plasmids that encode for immunologically active agents, to deliver the therapeutic directly into the tumor and promote an inflammatory response against the cancer. The Company has no subsidiaries.

During the quarter, the Company continued to enroll patients in its clinical programs: ImmunoPulse IL-12 monotherapy in patients with metastatic melanoma; ImmunoPulse IL-12 with pembrolizumab combination trial in patients with advanced, metastatic melanoma; head and neck squamous cell carcinoma; and, a triple negative breast cancer pilot study. In addition, the Company made further advancements toward prototypes of its next generation electroporation devices and continued its efforts in discovery research related to identifying and developing new immune-targeting agents for use with the ImmunoPulse platform. The Company is planning to continue these program but focus its current and future efforts on developing clinically relevant data in breast cancer and additional combination trials. 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.

The accompanying unaudited condensed financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The condensed balance sheet as of October 31, 2015, condensed statements of operations for the three months ended October 31, 2015 and 2014 and the condensed statements of cash flow for the three months ended October 31, 2015 and 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 flows for the periods presented. The results of operations for the three months ended October 31, 2015 shown herein are not necessarily indicative of the results that may be expected for the year ending July 31, 2016, or for any other period. These financial statements, and notes thereto, should be read in conjunction with the audited financial statements for the year ended July 31, 2015, included in the Company's Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on October 14, 2015. The balance sheet at July 31, 2015 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.

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

Effective May 18, 2015, the Company implemented a reverse stock split pursuant to which each 20 shares of issued and outstanding common stock held by each stockholder were combined into and became one share of common stock, with such resulting shares rounded up to the next whole share. No fractional shares were issued. All options, warrants and other convertible securities outstanding immediately prior to the reverse split were adjusted by dividing the number of shares of common stock into which the options, warrants and other convertible securities are exercisable or convertible by 20 and multiplying the exercise or conversion price by 20, all in accordance with the terms of the agreements governing such options, warrants and other convertible securities. The accompanying financial statements and related disclosures give retroactive effect to the reverse stock split for all periods presented.

Note 2 Significant Accounting Policies

Segment Reporting

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

Table of Contents

Concentrations and Credit Risk

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

Use of Estimates

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

Recent Accounting Pronouncements

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

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

Note 3 Cash and Cash Equivalents and Liquidity

The Company considers all liquid investments with maturities of ninety days or less when purchased to be cash equivalents. As of October 31, 2015 and July 31, 2014, cash and cash equivalents were primarily comprised of cash in checking accounts.

The Company's activities to date have been supported by equity financing. It has sustained losses in previous reporting periods with an inception to date loss of \$53.6 million as of October 31, 2015.

As of October 31, 2015, the Company had cash and cash equivalents of approximately \$26.9 million. The Company believes based on its projected fiscal year 2016 cash requirements and the funds raised in the November 2015 Public Offering (see footnote 11 below for further information) that its cash resources are sufficient to meet its anticipated needs at least through the next twelve months from the date of this filing. 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.

Note 4 Stockholders' Equity

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

	October 31, 2015	October 31, 2014
Stockholders' equity at beginning of period	\$ 32,695,621	\$ 38,068,058
Net loss	(7,037,391)	(4,061,116)
Stock-based compensation	1,562,066	611,240
Stockholders' equity at end of period	\$ 27,220,296	\$ 34,618,182

Table of Contents

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 1.5%; 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.

As of July 31, 2015, the patents are fully amortized. Amortization expense for the three-month period ended October 31, 2015 and 2014 were approximately \$0 and \$174,000, respectively. In addition, during the three-month period ended October 31, 2015 and 2014, no impairment was recorded.

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

Table of Contents

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.

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

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

The Company has made all scheduled payments under this arrangement.

Note 7 Recent Other Equity and Common Stock Transactions

At October 31, 2015, the Company had outstanding warrants to purchase 1,895,102 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.

The Company has not adopted any policy regarding payment of dividends. No dividends have been declared or 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. Stock-based compensation expense for

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

awards granted during the three-month periods ended October 31, 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 generally 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 and became available for trading, as well as the historical daily changes in the market price for the peer group as determined by the Company. The Company uses the simplified method to calculate the expected term of options issued to employees and directors. The Company's estimation of the expected term for stock options granted to parties other than employees or directors is the contractual term of the option award. The risk-free interest rate used in the Black-Scholes calculation is based on the prevailing U.S. Treasury yield in effect at the time of grant, commensurate with the expected term. Stock-based compensation expense recognized in the Company's condensed statements of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. Authoritative guidance requires forfeitures to be estimated at the time of grant, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Because the Company records stock-based compensation monthly and utilizes cliff vesting and/or monthly vesting, the Company has estimated the forfeiture rate of its outstanding stock options as zero since the Company can adjust stock-based compensation due to terminations in the month of termination. The Company has never paid any dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future.

During the three months ended October 31, 2015, the Company granted options to purchase 1,982,500, and 61,000 shares of the Company's common stock to employees and directors, and consultants under the Company's 2011 Stock Incentive Plan (as

Table of Contents

amended, the 2011 Plan), respectively. The options issued to employees and directors have a ten-year term, vest over a range of one to three years, and have exercise prices ranging from \$4.15 to \$6.21. The options issued to consultants have three-year terms, vest in accordance with the terms of the applicable agreement, and have an exercise price of \$5.76 per share.

During the three months ended October 31, 2014, the Company granted options to purchase 107,500 and 25,000 shares of the Company's common stock to employees and consultants under the 2011 Plan, respectively. The options issued to employees have a ten-year term, vest over a range of two to three years, and have exercise prices ranging from \$8.80 to \$10.40. 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 \$7.80 to \$8.60.

The following assumptions were used to calculate the fair value of stock-based compensation during the three months ended October 31, 2015 and 2014:

	October 31, 2015	October 31, 2014
Expected volatility	88.96% - 89.70%	88.82%-92.83%
Risk-free interest rate	0.86% - 1.74%	0.36%-2.13%
Expected forfeiture rate	0.00%	0.00%
Expected dividend yield		
Expected term	2.8 - 6.5 years	2 - 7 years

Stock-based compensation expense recorded in the Company's condensed statement of operations for the three months ended October 31, 2015 resulting from stock-based compensation awarded to the Company's employees, directors and consultants was approximately \$1.5 million. Of this balance, \$0.3 million was recorded to research and development, and \$1.2 million was recorded in general and administrative in the Company's condensed statement of operations for the period ended October 31, 2015.

Stock-based compensation expense recorded in the Company's condensed statement of operations for the three months ended October 31, 2014 resulting from stock-based compensation awarded to the Company's employees, directors and consultants was approximately \$0.6 million. Of this balance, \$0.3 million was recorded to research and development, and \$0.3 million was recorded in general and administrative in the Company's condensed statement of operations for the period ended October 31, 2014.

The weighted-average grant date fair value of stock options granted during the three months ended October 31, 2015 and 2014 were \$4.15 and \$7.20, 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 for approximately 33,928 rentable square feet located at 5820 Nancy Ridge Drive, San Diego, California to serve as the Company's new corporate headquarters and research and development laboratory. The lease term commenced on October 19, 2015 and expires 120 months after commencement. The Company has an option to extend the lease for an additional 5 years, if notice is given within 12 months prior to the expiration of the lease term. The Company also has the right to terminate the lease after the expiration of the 84th month after the lease commencement 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. The lease agreement provides for base rent at \$2.65 per rentable square foot, 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. Upon commencement of the lease, 12 months of rent abatement is provided. The lease also provides for a tenant improvement (TI) fund of \$6,107,040, which the landlord is solely responsible for and covers base building improvements. An additional TI allowance up to \$508,920 was available to the Company, in the form of TI rent; however, the Company did not use it. The Company's corporate relocation completed in October 2015 and its research and development lab relocation was completed in November 2015. 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.

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

Table of Contents

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

November 2015 Public Offering

On November 3, 2015, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain accredited investors (collectively, the "Purchasers") pursuant to which the Company has agreed to issue and sell to the Purchasers in a registered public offering (the "November 2015 Public Offering") an aggregate of 2,142,860 shares of the Company's Common Stock (collectively, the "Shares") and warrants to purchase an aggregate of 1,071,430 shares of the Company's Common Stock (collectively, the "Warrants" and the shares issuable upon exercise of the Warrants, collectively, the "Warrant Shares") at a purchase price of \$3.50 per unit, for aggregate expected gross proceeds of approximately \$7.5 million. Net proceeds, after deducting the Placement Agent Fee (described below) and other estimated offering expenses payable by the Company, are expected to be approximately \$6.9 million. The November 2015 Public Offering closed on November 9, 2015. The Company intends to use the net proceeds from the November 2015 Public Offering for general corporate purposes, including clinical trial expenses and research and development expenses.

Pursuant to the terms of the Securities Purchase Agreement, at the closing each Purchaser will be issued a Warrant to purchase up to a number of shares of the Company's Common Stock equal to 50% of the shares issued to such Purchaser. The Warrants have an exercise price of \$4.50 per share, are exercisable six months after issuance and have a term of exercise equal to five and one-half years from the date of issuance of the Warrants.

Pursuant to a Placement Agent Agreement (the "Placement Agent Agreement"), dated November 3, 2015, by and between the Company and Wainwright, Wainwright agreed to act as the Company's placement agent in connection with the November 2015 Public Offering. Pursuant to the Placement Agent Agreement, the Company agreed to pay an aggregate cash fee for placement agent and financial advisory services equal to 6.0% of the gross proceeds of the November 2015 Public Offering (the "Placement Agent Fee"), as well as a non-accountable expense allowance equal to 1% of the gross proceeds of the November 2015 Financing and certain other expense reimbursements. In addition, the Company agreed to issue warrants to purchase an aggregate of up to 5% of the aggregate number of shares of Common Stock sold in the November 2015 Public Offering to the placement agent or its designees (the "Placement Agent Warrants"). Placement Agent Warrants shall have substantially the same terms as the Warrants to be issued to the Purchasers in the November 2015 Financing, except that such warrants shall have an exercise price of \$4.375 and shall expire on the fifth anniversary of the closing date of the November 2015 Public Offering.

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, 2015, 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 1A of this Quarterly Report on Form 10-Q, and similar discussions in our other SEC filings. Risks that could cause actual results to differ from those contained in the forward-looking statements include but are not limited to risks related to: our ability to continue as a going concern; our need to raise additional capital and our ability to obtain financing; uncertainties inherent in pre-clinical studies and clinical trials and our ability to commercialize our products; our expected reliance on third parties; general economic and business conditions; our limited operating history; our ability to recruit and retain qualified personnel; competition we face within our industry; our ability to manage future growth; our ability to develop our planned products; our ability to protect our intellectual property; and various risks related to our common stock. These forward-looking statements speak only as of the date of this Form 10-Q, except as required by applicable law, we do not intend to update any of these forward-looking statements.*

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

Company Overview

As a biotechnology company, our mission is to focus on the advancement of immune system-stimulating treatments, with a focus on discovering and developing novel immuno-oncology therapies. Our portfolio includes biologic immunology therapeutic product candidates intended to treat a wide range of tumor types. Our technology also includes intellectual property relating to our ImmunoPulse delivery technology. ImmunoPulse is an electroporation delivery device that we use in combination with our therapeutic product candidates, including DNA plasmids that encode for immunologically active agents, to deliver the therapeutic directly into the tumor and promote an inflammatory response against the cancer. This unique therapeutic modality is intended to reverse the immunosuppressive microenvironment in the tumor and engender a systemic anti-tumor response against untreated tumors in other parts of the body. Our electroporation devices consist of an electrical pulse generator and disposable applicators, which can be adapted to treat different tumor types.

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

In August 2015, we enrolled the first patient into the Phase II investigator sponsored clinical trial led by the University of California, San Francisco to assess the anti-tumor activity, safety, and tolerability of the combination of ImmunoPulse IL-12, and Merck's approved anti-PD-1 agent, KEYTRUDA® (pembrolizumab), in patients with unresectable metastatic melanoma. The primary endpoint is the best Overall Response Rate (bORR) of the combination regimen in patients whose tumors are characterized by low numbers of tumor-infiltrating lymphocytes. In September 2015, we announced the results from a Phase II clinical trial of ImmunoPulse IL-12 in patients with Merkel cell carcinoma (MCC). In the MCC study led by the University of Washington, 79% of patients (11/14) showed an increase in IL-12 protein levels in tumor biopsy samples obtained approximately 22 days after treatment compared to baseline, indicating that ImmunoPulse IL-12 leads to successful DNA transfection and sustained protein expression within the tumor microenvironment. ImmunoPulse IL-12 was well-tolerated, with no treatment-related adverse events above Grade 2 and no treatment-related serious adverse events. The most common adverse event was Grade 1 transient pain associated with the treatment procedure. Toward the end of October 2015, we enrolled the first patient in our biomarker-focused pilot study of ImmunoPulse IL-12 in patients with triple negative breast cancer (TNBC). We anticipate enrolling approximately 10 patients in

Table of Contents

the TNBC pilot study, led by Stanford University, with the primary objective of the study to evaluate the potential of ImmunoPulse IL-12 to promote a pro-inflammatory molecular and histological signature in tumor samples and the secondary objectives include the evaluation of safety and tolerability; evaluation of local ablation effect (% of necrosis) and description of other evidence of anti-tumor activity. In addition to ImmunoPulse IL-12, we continue our research programs to identify and develop new immune-targeting agents for use with the ImmunoPulse platform.

Recent Events

November 2015 Public Offering

On November 9, 2015, we closed a registered direct offering with two healthcare focused funds for the purchase of 2,142,860 shares of our common stock at a price of \$3.50 and warrants to purchase up to an aggregate of 1,071,430 shares of common stock. The warrants have an exercise price of \$4.50 per share, a term of 5.5 years and become exercisable after 6 months. The gross proceeds of the offering were approximately \$7.5 million. Net proceeds, after deducting the placement agent's fee and other estimated offering expenses payable by us, were approximately \$6.9 million. On November 9, the placement agents were also issued warrants to purchase an aggregate of up to 5% of the aggregate number of shares of common stock sold in this offering. The placement agent warrants have an exercise price of \$4.375, are exercisable after 6 months of issuance and expire on November 9, 2020. We intend to use proceeds from the offering for general corporate purposes, including clinical trial expenses and research and development expenses.

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, 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 generally each month. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Results of Operations for the Three Months Ended October 31, 2015 Compared to the Three Months Ended October 31, 2014

The unaudited financial data for the three-month periods ended October 31, 2015 and October 31, 2014 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	October 31, 2015 (\$)	October 31, 2014 (\$)	Increase/ (Decrease) (\$)	Increase/ (Decrease) %
Revenue				
Operating expenses				
Research and development	3,659,313	2,501,268	1,158,045	46
General and administrative	3,375,906	1,558,938	1,816,968	**
Net loss before income taxes	(7,035,219)	(4,060,206)	2,975,013	73
Tax provision	2,172	910	1,262	**
Net loss	(7,037,391)	(4,061,116)	2,976,275	73

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

Table of Contents

Operational Milestones and Research and Development Expenses

Our research and development expenses primarily include expenses related to the development of our therapeutic product candidates and electroporation technologies. These expenses also include certain clinical study expenses, intellectual property prosecution and maintenance costs, and quality assurance expenses. The expenses primarily consisted of salaries, benefits, stock-based compensation costs, outside design and consulting services, laboratory supplies, contract research organization expenses and clinical study supplies. We expense all research and development costs in the periods in which they are incurred.

The \$1.2 million increase in research and development expenses for the three-month period ended October 31, 2015, as compared to the three-month period ended October 31, 2014, is primarily the result of an increase of \$0.7 million in other outside services to assist with the development of next-generation electroporation device prototypes, novel electroporation technologies and combination studies, an increase of \$0.1 million in engineering and lab supplies primarily for discovery research, an increase of \$0.1 million in salary related costs and an increase of \$0.3 million in additional R&D related expenses consisting primarily of rent, conference fees and travel.

We expect to use our working capital for the advancement of our operational milestones. Our significant milestones currently include generating clinically relevant data in triple negative breast cancer and our current combination trial, designing additional combination trials, continuing our discovery research, but, on a more focused scale and continuing the advancement of our novel electroporation technologies by leveraging internal capabilities to analyze and test our next generation electroporation device prototypes.

Activities related to the above milestones are primarily conducted by our Engineering, Clinical and R&D departments. We estimate we may incur engineering costs of \$3.3 million, clinical costs of \$3.1 million and R&D costs of \$5.1 million, in each case exclusive of personnel costs, stock-based compensation and depreciation, during our current fiscal year ending July 31, 2016 (Fiscal 2016).

General and Administrative

Our general and administrative expenses include expenses related to our executive, accounting and finance, compliance, information technology, legal, facilities, human resources, administrative and corporate communications activities. These expenses consist primarily of salaries, benefits, stock-based compensation costs, independent auditor costs, legal fees, consultants, travel, insurance, and public company expenses, such as stock transfer agent fees and listing fees in connection with listing on a national exchange.

The \$1.8 million increase in general and administrative expenses for the three-month period ended October 31, 2015, as compared to the three-month period ended October 31, 2014, was primarily the result of an increase of \$1.5 million in salary related costs, inclusive of stock-based compensation, an increase of \$0.2 million in audit and legal fees primarily related to internal controls attestation and an increase of \$0.1 million in outside services primarily related to corporate communications.

We expect our general and administrative expenses related to outside services to decrease in the near-term, as we leverage internal capabilities and increase productivity.

Liquidity and Capital Resources*Working Capital*

Our working capital as of October 31, 2015 and July 31, 2015 is summarized as follows:

	At October 31, 2015 (\$)	At July 31, 2015 (\$)
Current assets	27,987,417	33,567,981
Current liabilities	3,177,954	2,894,469
Working capital	24,809,463	30,673,512

Current Assets

Current assets as of October 31, 2015 decreased to approximately \$28.0 million, in comparison to current assets of approximately \$33.6 million as of July 31, 2015. This decrease in our current assets was primarily due to a decrease in cash from \$32.0 million as of July 31, 2015, to \$26.9 million as of October 31, 2015, which is attributable to the cash used in operations during the three-month period ended October 31, 2015.

Table of Contents

Current Liabilities

Current liabilities as of October 31, 2015 increased to approximately \$3.2 million, in comparison to our approximate current liabilities of \$2.9 million as of July 31, 2015. This increase was primarily due to an increase in audit fees related to our fiscal year-end 2015 internal controls attestation and an increase in accrued expenses related to patient treatment costs for our on-going clinical studies.

Cash Flow

Cash Used in Operating Activities

Cash used in operating activities for the three-month period ended October 31, 2015 was \$4.7 million, as compared to \$3.4 million for the three-month period ended October 31, 2014. This increase was primarily related to research and development efforts related to next-generation electroporation 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 and our corporate infrastructure.

Cash Used in Investing Activities

Cash used in investing activities for the three-month period ended October 31, 2015 was \$0.5 million, as compared to \$0.4 million for the three-month period ended October 31, 2014. Investing activities in the current quarter relate to the purchase of property and equipment for our new corporate headquarters.

Cash Flow Provided by Financing Activities

There were no exercises of stock options, exercise of warrants or financings completed during the three-month period ended October 31, 2015.

Recent Equity Financings

November 2015 Public Offering

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

On November 9, 2015, we closed a registered direct offering of an aggregate of 2,142,860 shares of our common stock at a purchase price of \$3.50 per share and warrants to purchase an aggregate of 1,071,430 shares of our common stock (the November 2015 Public Offering). The warrants have an exercise price of \$4.50 per share, a term of 5.5 years and become exercisable after 6 months. The gross proceeds to us from the November 2015 Public Offering was approximately \$7.5 million. After deducting for fees and expenses, the aggregate net proceeds from the sale of the common stock in the November 2015 Public Offering were approximately \$6.9 million. In connection with the November 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 107,143 shares of our common stock. The warrants issued to the placement agent are exercisable at an exercise price of \$4.375 per share, have a term of 5 years and become exercisable after 6 months. We intend to use the net proceeds from the November 2015 Public Offering for general corporate purposes, including clinical trials and research and development expenses.

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 \$12.5 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 warrants issued to the placement agent are exercisable at an exercise price of \$6.88 per share, are exercisable beginning December 8, 2015 and will expire on May 12, 2019. These warrants were classified as equity with a fair market value of \$571,868 recorded in our balance sheet. We intend to use the net proceeds from the June 2015 Public Offering for general corporate purposes, including clinical trials and research and development expenses.

Table of Contents*Cash Requirements*

Our primary objectives for the next twelve-month period are to continue the advancement of our ImmunoPulse platform, while fine-tuning our focus on discovery research of new, novel immune-oncology products and optimizing our clinical programs. 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 focus on innovative gene therapies, therapeutics and proprietary medical approaches to stimulate and guide an anti-tumor immune response for the treatment of cancer.

As we continue to focus on reducing expenses through leveraging our in-house capabilities and increasing productivity to reduce reliance on consultants and outside service providers, we currently estimate our operating expenses and working capital requirements for Fiscal 2016 to be approximately \$22.6 million, although we may modify or deviate from our estimates and it is likely that our actual results for certain categories of operating expenses and working capital requirements will vary from the estimates as set forth in the table below (in millions).

Cash Requirements	Amount
Product development	\$ 11.5
Employee compensation	7.7
General and administration	2.5
Professional services fees	0.9
	\$ 22.6

During the three-month period ended October 31, 2015, our operating cash outflow was approximately \$4.7 million. Based on our current operating costs and our operational goals, we expect our monthly cash outflows for the remainder of Fiscal 2016 to range from approximately \$1.8 million to \$2.2 million per month. In general, our cash outflows for future periods may increase as we expand our business, increase our headcount and further our development activities. We expect our current funds, coupled with the cash raised in the November 2015 Public Offering, to be sufficient to allow us to continue to operate our business for at least the next twelve months from the date of filing these financial statements.

During the first quarter of Fiscal 2016, there were no exercises of warrants previously issued to investors of our equity securities. If the holders of warrants to purchase our common stock were to exercise their remaining outstanding warrants in full on a cash basis, we would receive an aggregate of approximately \$21.7 million in proceeds. However, the warrant holders may choose not to exercise any of the warrants they hold, may choose to net exercise their warrants as provided in such warrants under certain limited circumstances, or may choose to exercise only a portion of the warrants issued. As a result, we may never receive proceeds from the exercise of such warrants.

Since the inception of our current business in March 2011, we have funded our operations primarily through equity financings and we expect to continue to pursue capital-raising transactions in future periods. 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 and may subject us to financial covenants and other restrictions applicable to our business. We may be unable to maintain operations at a level sufficient for investors to obtain a return on their investments in our common stock. Further, we may continue to be unprofitable.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

Table of Contents

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Our Controls

There were no changes in our internal controls over financial reporting during our fiscal quarter ended October 31, 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. If any of the following events, risks or uncertainties actually occur, either alone or taken together, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. 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 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 any cash from operations and will need to raise additional funds in future periods in order to continue operating our business. We estimate our cash requirements for the next 12 months to be approximately \$22.6 million. As of October 31, 2015, we had cash and cash equivalents of approximately \$26.9 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, or corporate collaborations and licensing arrangements. We expect to continue to fund our operations primarily through equity and debt financings in the near future. If additional capital is not available, we may not be able to continue to operate our business or we may have to significantly change our business plan or 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 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.

Our success depends in large part on our ability to protect our intellectual property using a combination of patents, trade secrets, and confidentiality agreements. Certain of our patents will expire in the near future, and we may have difficulties protecting our proprietary rights and technology and 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, including devices, 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,

Table of Contents

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. We have patent protection for components of our ImmunoPulse product candidates. Our current device portfolio includes US6,014,584, US6,055,453, US6,068,050, US6,181,964, US6,216,034, US6,233,482, US6,241,701, US6,516,233, US7,412,284, and EP999867, which cover our current clinical device. These patents will expire between 2017 and 2018, at which point we can no longer enforce these against third parties to prevent them from making, using, selling, offering to sell, or importing our current clinical device. This could expose us to substantially more competition and have a material adverse impact on our business and our ability to commercialize or license our technology and products.

In addition, 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 or 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 products.

We have never generated, and may never generate, profit from our operations.

We have not generated any revenue from operations since our inception. During the quarter ended October 31, 2015, we incurred a net loss of approximately \$7.0 million. From inception through October 31, 2015, we have incurred an aggregate net loss of approximately \$53.6 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.

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.

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 five clinical trials to assess our ImmunoPulse IL-12 single-agent therapy in patients with metastatic melanoma, Merkel cell carcinoma, cutaneous T-cell lymphoma, squamous cell carcinoma of the head and neck, and triple negative breast cancer. In addition, a Phase 2 clinical trial has been initiated by researchers at the University of California San Francisco to assess the combination of ImmunoPulse IL-12 and Merck's anti-PD-1 antibody, KEYTRUDA. 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 effect on our business, reputation and results of operations.

Table of Contents

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 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 body equivalents to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, clinical investigators, and trial sites;
- obtaining institutional review board, or IRB, approval to initiate and conduct a clinical trial at a prospective site;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for similar indications; and
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy, personal issues, death 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.

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

Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize our product candidates, including the assets we acquired from Inovio, encompassing 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;
- 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;
- significant and unpredictable changes in the payor landscape, coverage, and reimbursement for any products we successfully develop and commercialize; and
- delays or unanticipated costs, including those related to the foregoing.

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.

Table of Contents

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

We are an early-stage, pre-commercial 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. Although we plan to investigate licensing and partnering opportunities, we are not currently planning on generating any significant near term revenue; therefore, the 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. 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.

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

Our business plan includes the expansion of our clinical pipeline and our product portfolio through the acquisition, in-license, development and/or marketing of additional products and product candidates. The success of our efforts to expand our clinical pipeline and to build our product portfolio will depend in significant part on our ability to successfully identify, select and acquire promising product candidates and products.

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

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

- exposure to unknown liabilities;

- disruption of our business and diversion of our management's time and attention to manage the acquisition and 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 have entered into or 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

Table of Contents

standards and other important factors. Thereafter, such products face continued risk and uncertainty related to manufacturing and supply until 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, or the terms of such 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, who would likely 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 party has final decision-making authority. Collaborations with third parties often are terminated or allowed to expire by the third party, which would adversely affect us financially and could harm our business reputation.

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, which could 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.

If we are unable to successfully recruit and retain qualified personnel, we may not successfully grow or maintain our business.

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 support 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, especially to the extent that we are not able to recruit suitable replacements in a timely manner.

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 have entered into, and expect to continue to enter into, agreements with third-party clinical research organizations, or CROs, to conduct our clinical trials. 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 Good Clinical Practice, or GCP, and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or 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

Table of Contents

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, on a timely basis, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate additional revenues could be delayed.

We may 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, which is our delivery mechanism for our biologic to a patient's cell. We 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.

In addition, all manufacturers of our products must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance, and the generation and maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state, and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product is compromised due to our or our manufacturers' failure to

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

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.

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

We intend to advance a commercialization strategy that leverages previous in-depth clinical experiences, previous CE (Conformité Européene) approvals, 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

Table of Contents

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 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.

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

Cost containment is a primary trend in the U.S. healthcare industry. 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.

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.

Our efforts to educate the medical community and third-party payors on the benefits of any of our potential product candidates 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, physicians may not choose to utilize our product and we may not generate sufficient revenue from these products to become or remain profitable.

In order to market our proprietary products, we may choose to establish our own sales, marketing, and distribution capabilities, 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. 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.

Table of Contents

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.

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 Food and Drug Administration, or FDA, and to a lesser extent by the United States Drug Enforcement Agency, or 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.

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

Certain federal and state healthcare laws and regulations may be applicable to our business, including:

- 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 Patient Protection and Affordable Care Act, or 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

Table of Contents

- 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 Health Insurance Portability and Accountability Act, or HIPAA, thus complicating compliance efforts.

Additionally, the compliance environment is changing, with more states, such as California and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, Maine, and Minnesota requiring reporting to state governments of gifts, compensation, and other remuneration to physicians. Under the ACA, pharmaceutical companies must record any transfers of value made to doctors and teaching hospitals and to disclose such data to the U.S. Department of Health and Human Services, or HHS. 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. It also 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.

Further, even though we do not and will not control referrals of healthcare services or bill directly to third-party payors, 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. To the extent that any product we make is sold in a foreign country, we also may be subject to foreign laws and regulations.

If we or 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 and have a significant adverse effect on us.

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

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 and our competitors tend to be larger and have been in business longer than us.

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.

Table of Contents

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. 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 larger competitors that address our targeted indications. 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. 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.

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.

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, 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. Further, such transactions could result in substantial dilution of our stockholders. 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 cyber-attacks or 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 harm our business.

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 significant deficiencies or material weaknesses in our internal controls in the future. Any failure to remediate any significant deficiencies or material weaknesses or to 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.

Table of Contents

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. The U.S. Financial Accounting Standards Board and International Accounting Standards Board have been working together since 2002 to achieve convergence of and U.S. generally accepted accounting principles, or GAAP, and International Financial Reporting Standards, or IFRS. As GAAP and IFRS converge into a single set of high quality standards, implementing the new standards could require us to make adjustments to our previously reported financial statements and could 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. In addition, we are an accelerated filer , which generally increases our reporting obligations and compliance costs as a public company.

We may not be able to realize value from, or otherwise preserve and utilize, our net operating loss (NOL) carryforwards.

Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of net operating loss (NOL) carryforwards and other tax attributes. In the event that we undergo such an ownership change, our NOL carryforwards generated prior to the ownership change would be subject to annual limitations, which could reduce, eliminate, or defer the utilization of these losses. Further, the recognition and measurement of our NOL carryforwards may include estimates and judgments by our management, and the Internal Revenue Service has not audited or otherwise validated the amount of our NOL carryforwards. Additionally, legislative changes could negatively impact our ability to use any tax benefits associated with our NOL carryforwards. If we put in place limitations on ownership of our common stock or adopt a shareholder rights plan to preserve our ability to use NOL carryforwards, this could deter potential buyers of our common stock and adversely impact the trading price of our common stock.

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

We have participated in, and continue to 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.

Our licensed intellectual property may not provide us with sufficient rights and may not prevent competitors from pursuing similar technology.

We have acquired the use of certain technology and related assets from the University of South Florida, or USF, pursuant to an exclusive milestone and royalty bearing license. US8,026,223 covers our current therapeutic method. Patents have also been granted in Australia, and applications are pending in Canada, China, Japan, and Korea. This patent family will expire between 2025 and 2027. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

We have entered into a cross-license agreement for certain electroporation technology with Inovio. Under the terms of the cross-license agreement, Inovio granted to us a non-exclusive, worldwide license to certain electroporation patents held by Inovio. In exchange, we granted to Inovio an exclusive license to our acquired technology in a limited field of use. While we do not currently substantially rely on the intellectual property we have non-exclusively licensed from Inovio, our product candidates may, in the future, utilize this intellectual property. This license is non-exclusive and Inovio may use its technology to compete with us. As there are no restrictions on Inovio's ability to license their technology to others, Inovio could license to others, including our competitors, the

Table of Contents

intellectual property rights covered by their license to us, including any of our improvements to the licensed intellectual property. Either party may terminate the cross-license agreement with 30 days' notice; and, if either party were to terminate the cross-license agreement, they would no longer have the right to use intellectual property that is subject to the cross license.

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. Even if we were successful in stopping the infringing activity, these lawsuits are expensive and could consume time and other resources. In addition, the court could decide that our patents are not valid and that we do not have the right to stop others from making, using, or selling the inventions claimed by the patents.

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, making 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 relating 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 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.

Our common stock has low trading volume and the price of our common stock has been, and will likely continue to be, highly volatile.

Trading of our common stock is frequently highly volatile, with low trading volume. We have experienced, and are likely to continue experiencing, significant fluctuations in the stock price and trading volume. There is no assurance that a sufficient market will develop in our stock, in which case it could be difficult for stockholders to sell their stock. Furthermore, the volatility of our stock price could negatively impact our ability to raise capital or acquire businesses or technologies.

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

In addition to the risks and uncertainties described in this section of this Annual Report, other factors affecting the trading price and trading volume 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 FDA 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 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 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.

Table of Contents

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 company.

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 December 1, 2015, we have issued an aggregate of 16,971,214 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.

As of the date of this Report, we have outstanding (i) options to purchase 3,160,158 shares of common stock and (ii) warrants to purchase 3,073,675 shares of our common stock. We have not issued any shares of our common stock as a result of warrant and option exercises during the first quarter of Fiscal 2016. In addition, we have as of December 1, 2015, 638,710 shares reserved for future issuance under our 2011 compensation plan. 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.

If our common stock is delisted from The Nasdaq Capital Market or we are found noncompliant, our stock's market price and liquidity could be negatively impacted.

Our listing on The Nasdaq Capital Market (NASDAQ) is contingent upon our meeting all the continued listing requirements. If we are found noncompliant by NASDAQ, or if our common stock is delisted from NASDAQ, our stock price could be negatively impacted, our stock's liquidity could be reduced, and our ability to raise capital in the future may be limited.

Item 2.
AND USE OF PROCEEDS.

UNREGISTERED SALES OF EQUITY SECURITIES

None.

Item 3.

DEFAULTS UPON SENIOR SECURITIES.

None.

Item 4.

MINE SAFETY DISCLOSURES.

None.

Table of Contents

Item 5. OTHER INFORMATION.

None.

Item 6. EXHIBITS

Exhibit Number	Description of Exhibit
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	Executive Employment Agreement, effective July 6, 2015, by and between the Company and Richard B. Slansky
10.2	Executive Employment Agreement, effective November 1, 2015, by and between the Company and Sheela Mohan-Peterson
10.3	Form of Indemnification Agreement (incorporated by reference to our Current Report on Form 8-K, filed on October 29, 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 quarter ended October 31, 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: December 8, 2015

/s/ Richard B. Slansky
By: Richard B. Slansky
(Principal Financial Officer)

Dated: December 8, 2015