

ONCOSEC MEDICAL Inc  
Form 10-Q  
March 16, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**FOR THE QUARTERLY PERIOD ENDED JANUARY 31, 2017**

**OR**

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

**FOR THE TRANSITION PERIOD FROM TO**

**COMMISSION FILE NO. 000-54318**

**ONCOSEC MEDICAL INCORPORATED**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

**NEVADA** **98-0573252**  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

**5820 NANCY RIDGE DRIVE**  
**SAN DIEGO, CA** **92121**  
(Address of principal executive offices) (Zip Code)

**(855) 662-6732**

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

Non-accelerated filer

Smaller reporting company

(Do not check if a 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 20,868,194 as of March 13, 2017.

**OncoSec Medical Incorporated**

**Form 10-Q**

**for the Quarterly Period Ended January 31, 2017**

**PART I—FINANCIAL INFORMATION**

Item		
1.	<u>Financial Statements:</u>	
	a) <u>Condensed Consolidated Balance Sheet as of January 31, 2017 (unaudited) and Condensed Balance Sheet as of July 31, 2016</u>	3
	b) <u>Condensed Consolidated Statements of Operations and Condensed Statements of Operations for the three and six months ended January 31, 2017 and 2016 (unaudited)</u>	4
	c) <u>Condensed Consolidated Statements of Comprehensive Loss and Condensed Statements of Comprehensive Loss for the three and six months ended January 31, 2017 and 2016 (unaudited)</u>	5
	d) <u>Condensed Consolidated Statement of Cash Flows and Condensed Statement of Cash Flows for the six months ended January 31, 2017 and 2016 (unaudited)</u>	6
	e) <u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
Item		
2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	17
Item		
3.	<u>Quantitative and Qualitative Disclosure about Market Risk</u>	24
Item		
4.	<u>Controls and Procedures</u>	24

**PART II—OTHER INFORMATION**

Item		
1.	<u>Legal Proceedings</u>	25
Item		
1A.	<u>Risk Factors</u>	25
Item		
2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	42
Item		
3.	<u>Defaults Upon Senior Securities</u>	42
Item		
4.	<u>Mine Safety Disclosures</u>	42
Item		
5.	<u>Other Information</u>	42
Item		
6.	<u>Exhibits</u>	42



**PART I—FINANCIAL INFORMATION****Item 1. Financial Statements:****OncoSec Medical Incorporated****Condensed Consolidated Balance Sheet and Condensed Balance Sheet**

	January 31, 2017 (unaudited)	July 31, 2016
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$20,541,455	\$28,746,224
Prepaid expenses and other current assets	793,612	671,184
<b>Total Current Assets</b>	<b>21,335,067</b>	<b>29,417,408</b>
Property and equipment, net	2,589,063	2,799,930
Other long-term assets	383,780	189,309
<b>Total Assets</b>	<b>\$24,307,910</b>	<b>\$32,406,647</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Liabilities</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$3,296,824	\$3,223,327
Accrued compensation	116,930	242,924
<b>Total Current Liabilities</b>	<b>3,413,754</b>	<b>3,466,251</b>
Other long-term liabilities	1,193,230	887,292
<b>Total Liabilities</b>	<b>4,606,984</b>	<b>4,353,543</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Common stock authorized - 160,000,000 common shares with a par value of \$0.0001, common stock issued and outstanding — 19,734,645 and 18,036,263 common shares as of January 31, 2017 and July 31, 2016, respectively	25,439	25,269
Additional paid-in capital	91,196,781	88,233,965
Warrants issued and outstanding — 11,286,995 and 12,859,286 warrants as of January 31, 2017 and July 31, 2016, respectively	12,964,244	13,288,527
Accumulated other comprehensive income	14	-
Accumulated deficit	(84,485,552)	(73,494,657)

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

Total Stockholders' Equity	19,700,926	28,053,104
Total Liabilities and Stockholders' Equity	\$24,307,910	\$32,406,647

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

**OncoSec Medical Incorporated****Condensed Consolidated Statements of Operations and Condensed Statements of Operations (unaudited)**

	Three Months Ended		Six Months Ended	
	January 31, 2017	January 31, 2016	January 31, 2017	January 31, 2016
Revenue	\$-	\$-	\$-	\$-
Expenses:				
Research and development	2,882,611	4,113,582	5,982,351	7,772,895
General and administrative	2,504,700	2,924,138	5,007,152	6,300,044
Loss before income taxes	(5,387,311 )	(7,037,720 )	(10,989,503 )	(14,072,939 )
Provision for income taxes	-	-	1,391	2,172
Net loss	\$(5,387,311 )	\$(7,037,720 )	\$(10,990,894 )	\$(14,075,111 )
Basic and diluted net loss per common share	\$(0.27 )	\$(0.42 )	\$(0.57 )	\$(0.89 )
Weighted average shares used in computing basic and diluted net loss per common share	19,733,015	16,761,586	19,376,998	15,794,970

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



**OncoSec Medical Incorporated**

**Condensed Consolidated Statements of Comprehensive Loss and Condensed Statements of Comprehensive Loss (unaudited)**

	Three Months Ended		Six Months Ended	
	January 31,	January 31,	January 31,	January 31,
	2017	2016	2017	2016
Net Loss	\$(5,387,311)	\$(7,037,720)	\$(10,990,894)	\$(14,075,111)
Foreign currency translation adjustments	23	-	14	-
Comprehensive Loss	\$(5,387,288)	\$(7,037,720)	\$(10,990,880)	\$(14,075,111)

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

**OncoSec Medical Incorporated****Condensed Consolidated Statement of Cash Flows and Condensed Statement of Cash Flows (unaudited)**

	Six Months Ended	
	January 31, 2017	January 31, 2016
Operating activities		
Net loss	\$(10,990,894)	\$(14,075,111)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	189,039	151,601
Loss on disposal of property and equipment	-	41,989
Stock-based compensation	2,596,280	3,030,225
Changes in operating assets and liabilities:		
(Increase) in prepaid expenses and other current assets	(122,428 )	313,499
(Increase) in other long-term assets	(163,064 )	25,751
Increase in accounts payable and accrued liabilities	73,497	1,100,097
Increase (decrease) in accrued compensation	(125,994 )	104,237
Increase in other long-term liabilities	305,936	292,534
Net cash used in operating activities	(8,235,628 )	(9,015,178 )
Investing activities		
Purchases of property and equipment	(9,578 )	(1,060,910 )
Net cash used in investing activities	(9,578 )	(1,060,910 )
Financing activities		
Proceeds from issuance of common stock and warrants	-	7,500,010
Payment of financing and offering costs	-	(613,915 )
Proceeds from exercise of warrants (Sabby)	16,808	-
Proceeds from issuance of common stock (ESPP)	25,615	-
Net cash provided by financing activities	42,423	6,886,095
Effect of exchange rate changes on cash	14	-
Net (decrease) in cash	(8,204,769 )	(3,189,993 )
Cash and cash equivalents, at beginning of period	28,746,224	32,035,264
Cash and cash equivalents, at end of period	\$20,541,455	\$28,845,271
Supplemental disclosure for cash flow information:		
Cash paid during the period for:		
Interest	\$-	\$-
Income taxes	\$1,391	\$2,172
Noncash investing and financing transaction:		
Fair value of placement agent warrants issued in the public offering	\$-	\$242,143
Issuance of common stock in connection with a contractual agreement	\$-	\$55,500
Noncash expiration of warrants	309,477	-

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



## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

### Note 1—Nature of Operations and Basis of Presentation

OncoSec Medical Incorporated (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 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 immunologically active agents, to deliver the therapeutic directly into the tumor and promote an inflammatory response against the cancer. The Company was incorporated in the State of Nevada on February 8, 2008 under the name of Netventory Solutions, Inc. and changed its name in March 2011 when it began operating as a biotechnology company.

The Company’s core technology, the ImmunoPulse® platform, is a unique therapeutic modality 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. The Company’s lead product candidate, ImmunoPulse® IL-12, consists of a proprietary electroporation delivery device (an electrical pulse generator and disposable applicators) and DNA-encoded interleukin-12 (“IL-12”). ImmunoPulse® IL-12 is clinically and preclinically validated to drive tumor infiltrating lymphocytes and stimulate anti-cancer immune activity. The Company believes the therapy may be used to treat multiple tumor types and can be used in combination with other therapies.

During the quarter ended January 31, 2017, the investigator continued to enroll patients in an investigator-sponsored combination trial of ImmunoPulse® IL-12 with pembrolizumab in patients with advanced, metastatic melanoma. The Company also amended the clinical protocol for its biomarker-focused pilot study of ImmunoPulse® IL-12 in triple negative breast cancer, in order to improve the enrollment rate for that study. The Company’s Phase II clinical trials of ImmunoPulse® IL-12 as a monotherapy in Merkel Cell carcinoma, melanoma, cutaneous T-cell lymphoma, and head and neck squamous cell carcinoma are now closed for enrollment and database-locked.

In addition, the Company made further advancements toward prototypes of its next generation electroporation devices and performed an internal assessment of its efforts in discovery research to identify new gene combinations for use with the ImmunoPulse® platform. The Company’s efforts are focused on moving ImmunoPulse® IL-12 toward a

potential registration pathway for metastatic melanoma and to pursue clinically relevant data in breast cancer and additional combination trials.

On October 7, 2016, OncoSec Medical Australia Pty, Ltd. (“OncoSec Australia”) was created as a wholly-owned subsidiary of OncoSec Medical Incorporated to facilitate the operation of clinical trials principally in Australia where there is a high rate of melanoma cases. OncoSec Australia issued 100 shares (AU\$1.00 par value) to the Company for AU\$100. OncoSec Australia’s functional currency, the Australian dollar, is also its reporting currency. Its financial statements are translated to US dollars, the reporting currency of the Company, prior to consolidation. All intercompany accounts and transactions have been eliminated in consolidation.

The accompanying unaudited condensed consolidated 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 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The condensed consolidated balance sheet as of January 31, 2017, condensed consolidated statements of operations and condensed statements of operations, condensed consolidated statements of comprehensive loss and condensed statements of comprehensive loss for the three and six months ended January 31, 2017 and 2016, respectively, and the condensed consolidated statement of cash flows and the condensed statement of cash flows for the six months ended January 31, 2017 and 2016, respectively, 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 condensed consolidated statements of operations and condensed statements of operations for the three and six months ended January 31, 2017 shown herein are not necessarily indicative of the consolidated results that may be expected for the year ending July 31, 2017, 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, 2016, included in the Company’s Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) on October 13, 2016. The balance sheet at July 31, 2016 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.

*Reclassifications*

Certain amounts in the condensed balance sheet for the year ended July 31, 2016 and the condensed consolidated statement of cash flows for the six-month period ended January 31, 2017 have been reclassified to conform to the interim presentation of prepaid expenses, other current assets and property and equipment.

**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.

*Concentrations and Credit Risk*

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

*Use of Estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts in the financial statements and disclosures made in the accompanying notes to the consolidated financial statements. The Company's significant estimates pertain to stock-based compensation expense—see Note 7. Actual results could differ materially from the estimates.

*Recent Accounting Pronouncements*

Recent pronouncements during the quarter 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 this Quarterly Report on Form 10-Q. See the Company's Annual Report on Form 10-K for discussion of recent pronouncements not yet adopted by 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 January 31, 2017 and July 31, 2016, cash and cash equivalents were primarily comprised of cash in checking, savings and money market accounts.

The Company's activities to date have been primarily supported by equity financings. It has sustained losses in previous reporting periods with an inception to date loss of \$84.5 million as of January 31, 2017.

As of January 31, 2017, the Company had cash and cash equivalents of approximately \$20.5 million. The Company believes based on its projected fiscal year 2017 cash requirements 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, clinical trials and commercialization of its potential product candidates. In addition, the Company will require additional financing in order to license or acquire new assets, research and develop compounds and new technology and pursue related patent protection, 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 possibly debt financings. If the Company secures additional financing by issuing equity securities, its existing stockholders' ownership will be diluted. Obtaining loans, assuming those loans would be available, would increase the Company's liabilities and future cash commitments. The Company may also pursue non-dilutive financing sources. However, 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 for the six months ended January 31, 2017 and 2016 is provided below:

	January 31, 2017	January 31, 2016
Stockholders' equity at beginning of period	\$28,053,104	\$32,695,621
Net loss	(10,990,894)	(14,075,111)
Public Offering on November 9, 2015, net of issuance costs of \$613,915	-	6,886,095
Stock-based compensation	2,596,280	3,030,225
Accumulated other comprehensive income	14	-
Issuance of common stock through employee stock purchase plan	25,615	-
Exercise of common stock warrants	16,808	-
Common stock issued in connection with a contractual agreement	-	55,500
Stockholders' equity at end of period	\$19,700,926	\$28,592,330



**Note 5—Balance Sheet Details***Property and Equipment*

Property and equipment, net, is comprised of the following:

	January 31, 2017	July 31, 2016
Equipment and Furniture	\$3,072,706	\$2,851,900
Computer Software	14,979	226,207
Leasehold Improvements	80,102	80,102
Construction In Progress	53,996	85,402
Property and Equipment, gross	3,221,783	3,243,611
Accumulated Depreciation and Amortization	(632,720 )	(443,681 )
	\$2,589,063	\$2,799,930

Depreciation and amortization expense recorded for the three- and six-month periods ended January 31, 2017 and 2016, was approximately \$94,000 and \$189,000 and approximately \$86,000 and \$152,000, respectively.

*Accounts Payable and Accrued Liabilities*

Accounts payable and accrued liabilities are comprised of the following:

	January 31, 2017	July 31, 2016
Research & Development Costs	\$2,157,856	\$2,389,711
Professional Services Fees	832,626	707,070
Other	306,342	126,546
	\$3,296,824	\$3,223,327

On September 8, 2016, the Company entered into a \$50,000 credit card facility with Banc of California, which collateralized the Company's visa business card from Elan Financial Services. At November 30, 2016, the Banc of California discontinued utilization of Elan Financial Services and replaced the visa business card with their own debit

MasterCard, which acts similar to a credit card.

*Accrued Compensation*

Accrued compensation is comprised of the following:

	January 31, 2017	July 31, 2016
Separation Costs	\$ -	\$ 134,993
Payroll Accrual	116,192	93,021
401K Payable	-	14,365
Other	738	545
	\$ 116,930	\$ 242,924

*Other Long-Term Liabilities*

Other long-term liabilities are comprised of the following:

	January 31, 2017	July 31, 2016
Deferred rent	\$1,193,230	\$887,292

**Note 6—Common Stock Transactions***May 2016 Registered Direct Offering*

On May 26, 2016, the Company closed a registered direct offering (the “May 2016 Offering”) with a single healthcare-dedicated institutional fund for the purchase of: (i) 665,049 shares of common stock; (ii) Series A Warrants to purchase up to an aggregate of 5,509,642 shares of common stock at an exercise price of \$1.69 per share with a term of nine (9) years; and (iii) Series B Warrants to purchase 4,844,593 shares of common stock at an exercise price of \$0.01. The investor paid a purchase price of \$1.815 per unit of one share of common stock and an accompanying Series A Warrant, and \$1.805 per unit of one Series B Warrant and accompanying Series A warrant. The Series B warrants have an exercise price of \$0.01 per share and were issued to prevent the beneficial ownership of the purchaser (together with its affiliates and certain related parties) of the Company’s common stock from exceeding 4.99%. The Series B warrants expire upon their exercise in full. Both the Series A and Series B warrants are immediately exercisable on the date of issuance. The fair value of the Series A and Series B warrants issued to the purchaser in connection with the May 2016 Offering, based on their fair value relative to the common stock issued, was \$4.4 million (based on the Black-Scholes Option Pricing Model assuming no dividend yield, a nine (9) year life for the Series A, volatility of 100.03%, and a risk-free interest rate of 1.74%), \$48,446 of which was ascribed to the Series B warrants. The Company completed an evaluation of the Series A and Series B warrants issued to the purchaser and determined that the Series A and Series B warrants should be classified as equity within the balance sheet.

The Company agreed to pay an aggregate cash fee for placement agent and financial advisory services equal to five percent (5%) of the gross proceeds of the May 2016 Offering, as well as expense reimbursement of thirty-five thousand dollars (\$35,000) for legal and clearing firm fees. At the closing of the May 2016 Offering, the placement agents were also issued warrants to purchase an aggregate of up to 5% of the aggregate number of shares of common stock and Series B warrants sold in this offering, or 275,482 shares. The placement agent warrants have an exercise price of \$2.26875, are immediately exercisable and expire on May 24, 2021. The fair value of the placement agent warrants was \$0.3 million (based on the Black-Scholes Option Pricing Model assuming no dividend yield, a five-year life, volatility of 94.36%, and a risk-free interest rate of 1.38%). The Company completed an evaluation of these

warrants and determined the warrants should be classified as equity within the condensed balance sheet.

The gross proceeds of the offering were \$9.9 million. Net proceeds, after deducting the placement agent's fee, financial advisory fees, and other estimated offering expenses payable by the Company, were approximately \$9.2 million. The Company intends to use proceeds from the offering for general corporate purposes, including clinical trial expenses and research and development expenses.

#### *November 2015 Public Offering*

On November 9, 2015, the Company closed a public offering of an aggregate of 2,142,860 shares of common stock and warrants to purchase an aggregate of 1,071,430 shares of common stock at a purchase price of \$3.50 per unit (the "November 2015 Offering"). Each purchaser was issued a warrant to purchase up to that number of shares of the Company's common stock equal to 50% of the shares issued to such purchaser. The warrants issued to the purchasers have an exercise price of \$4.50 per share, became exercisable six months after issuance, and expire on May 9, 2021. The fair value of the warrants issued to the purchasers, based on their fair value relative to the common stock issued, was approximately \$1.6 million (based on the Black-Scholes Option Pricing Model assuming no dividend yield, a 5.05 year life, volatility of 88.63%, and a risk-free interest rate of 1.75%). The Company completed an evaluation of these warrants and determined the warrants should be classified as equity within the condensed balance sheet.

The Company agreed to pay an aggregate cash fee for placement agent and financial advisory services equal to six percent (6%) of the gross proceeds of the November 2015 public offering, as well as a non-accountable expense allowance equal to one percent (1%) of the gross proceeds of the offering and certain other expense reimbursements. In addition, the placement agents were issued warrants to purchase an aggregate of up to five percent (5%) of the aggregate number of shares of common stock sold in the offering, or 107,143 shares. The placement agent warrants have substantially the same terms as the warrants issued to investors in the offering, except that they have an exercise price of \$4.375 and expire on November 9, 2020. The fair value of the placement agent warrants was \$0.2 million (based on the Black-Scholes Option Pricing Model assuming no dividend yield, a five-year life, volatility of 89.08%, and a risk-free interest rate of 1.75%). The Company completed an evaluation of these warrants and determined the warrants should be classified as equity within the balance sheet.

The gross proceeds of the November 2015 Offering were \$7.5 million. Net proceeds, after deducting the placement agent's fee, financial advisory fees, and other offering expenses payable by the Company, were approximately \$6.9 million. The Company intends to use proceeds from the offering for general corporate purposes, including clinical trial expenses and research and development expenses.

#### *Outstanding Warrants*

At January 31, 2017, the Company had outstanding warrants to purchase 11,328,693 shares of common stock, with exercise prices ranging from \$0.01 to \$20.00, all of which were classified as equity instruments. These warrants expire at various times between March 2017 and May 2025, with the exception of the aforementioned Series B Warrants, which expire upon their exercise in full. At January 31, 2017, 2,764,000 Series B Warrants were available to exercise.

#### *Dividends*

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

#### **Note 7—Stock-Based Compensation**

##### *Stock Options*

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 awards granted during the three and six-month periods ended January 31, 2017 and 2016, 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 generally re-valued each month. The Company's expected volatility is derived from the historical daily change in the market price of its common stock, 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 consolidated 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.

On November 11, 2016, the Company filed a Tender Offer Statement on Schedule TO relating to an offer (the “Exchange Offer”) by the Company to exchange certain stock options to purchase up to an aggregate of 2,479,671 shares of its common stock that had been granted to eligible participants with an exercise price significantly above current market value for a lesser number of new stock options with a lower exercise price. Stock options with an exercise price greater than or equal to \$3.00, and held by employees, directors, and consultants in continuous service through the termination of the Exchange Offer, were eligible for exchange in the Exchange Offer. An exchange rate of 2 for 1 applied to options priced from \$3.00 to \$9.99, and an exchange rate of 3 for 1 applied to options priced at \$10 or greater. Each new stock option was granted pursuant to OncoSec’s 2011 Stock Incentive Plan, as amended and restated, on the date the Exchange Offer closed and was priced at the market price on that date. As of the closing of the Exchange Offer on December 14, 2016, 29 eligible participants had exchanged 2,214,500 options for 1,070,536 new options and the Company treated those new options as a modification. After analysis of the modification, the Company determined that there was no incremental expense.

During the three and six months ended January 31, 2017, the Company granted options to purchase 1,124,536 and 1,511,036 shares of the Company’s common stock under the 2011 Plan, respectively (including those granted under the Exchange Offer), of which options to purchase 695,037 and 771,537 shares, respectively, were granted to employees and options to purchase 164,083 and 474,083 shares, respectively, were granted to consultants, and options to purchase 265,416 and 265,416 shares, respectively, were granted to non-employee directors. The options issued to employees have a ten-year term, vest over three years and have exercise prices ranging from \$1.29–\$1.78. The options issued to consultants have three- to ten-year terms, generally vest in accordance with the terms of the applicable agreement, and have exercise prices ranging from \$1.29–\$2.00 per share. The options issued to non-employee directors have a ten-year term, vest over one year and have exercise prices of \$1.29.

During the three and six months ended January 31, 2016, the Company granted options to purchase 8,750 and 2,052,250 shares, respectively, of the Company’s common stock under the 2011 Plan, of which options to purchase 8,750 and 1,984,250 shares, respectively, were granted to employees and non-employee directors, and options to purchase 0 and 68,000 shares, respectively, were granted to consultants. The options issued to employees have a ten-year term, vest over a range of three years, and have exercise prices ranging from \$3.44–\$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 and six months ended January 31, 2017, the Company granted options to purchase 0 and 270,000 shares, respectively, of the Company’s common stock to employees outside of the 2011 Plan. These options were issued as inducement stock options. They have a term of 10 years, vest over a period of three years, and have an exercise price of \$1.71. No options were issued to directors or consultants outside of the 2011 Plan during these periods. No options were issued to employees, directors, or consultants outside of the 2011 Plan during the corresponding periods ended January 31, 2016.

The following assumptions were used to calculate the fair value of stock-based compensation during the three-month periods ended January 31, 2017 and 2016:

Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

	January 31, 2017	January 31, 2016
Expected volatility	96.13% - 124.47 %	88.31% - 88.37 %
Risk-free interest rate	1.24% - 2.52 %	1.58% - 2.01 %
Expected forfeiture rate	0 %	0 %
Expected dividend yield	—	—
Expected term	2.92 - 10 years	5 - 6.5 years



The following assumptions were used to calculate the fair value of stock-based compensation during the six-month periods ended January 31, 2017 and 2016:

	January 31, 2017	January 31, 2016
Expected volatility	91.73% - 124.47 %	83.57% - 89.70 %
Risk-free interest rate	0.82% - 2.54 %	0.86% - 2.01 %
Expected forfeiture rate	0 %	0 %
Expected dividend yield	—	—
Expected term	2.59 - 10 years	2.6 - 6.5 years

Stock-based compensation expense recorded in the Company's condensed consolidated statement of operations for the three- and six-month periods ended January 31, 2017 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$1.4 million and \$2.6 million, respectively. Of this balance, \$0.5 million and \$0.8 million, respectively, was recorded to research and development and \$0.9 million and \$1.8 million, respectively, was recorded in general and administrative in the Company's condensed consolidated statement of operations for the three- and six-month periods ended January 31, 2017.

Stock-based compensation expense recorded in the Company's condensed statement of operations for the three and six-month periods ended January 31, 2016 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$1.5 million and \$3.0 million, respectively. Of this balance, \$0.2 million and \$0.5 million, respectively, was recorded to research and development, and \$1.3 million and \$2.5 million, respectively, was recorded in general and administrative in the Company's condensed statement of operations for the period ended January 31, 2016.

The weighted-average grant date fair value of stock options granted during the three- and six-month periods ended January 31, 2017 were \$1.12 and \$1.13, respectively. The weighted-average grant date fair value of stock options granted during the three- and six-month periods ended January 31, 2016 were \$2.81 and \$4.14, respectively.

#### *Restricted Stock Units*

In March 2016, the Company granted 555,000, 100,000 and 25,000 restricted stock unit awards (or, RSUs) to motivate and retain certain employees, directors and consultants, respectively, under the 2011 Plan. All RSUs vest in full three (3) years following the date of grant. The Company's closing common stock price on the date of issue was \$2.02 per share, which is the RSUs fair market value per unit. Stock-based compensation expense related to RSUs for the three and six-month periods ended January 31, 2017 was approximately \$110,000 and \$184,000, respectively, of which approximately \$24,000 and \$36,000, respectively, was recorded to research and development and \$86,000 and \$148,000, respectively, was recorded to general and administrative. During the three-month period ended January 31,

2017, 65,000 RSUs were forfeited, and prior to this period, 25,000 RSUs were forfeited. As of January 31, 2017, 590,000 RSUs were outstanding.

*Employee Stock Purchase Program*

Under the Company's 2015 Employee Stock Purchase Plan ("ESPP"), the Company is authorized to issue 500,000 shares of the Company's common stock. The first offering period ended on July 31, 2016, with 17,789 shares purchased and distributed to employees. The second offering period ended on January 31, 2017, with 18,631 shares purchased and distributed to employees. At January 31, 2017, 463,580 shares are available for issuance under the ESPP.

The ESPP is considered a Type B plan. The fair value of the awards were calculated at the beginning of the offering period as the sum of:

15% of the share price of a unvested share at the beginning of the offering period,

85% of the fair market value of a six (6)-month call on the unvested share aforementioned, and

15% of the fair market value of a six (6)-month put on the unvested share aforementioned.

The fair market value of the 6-month call and 6-month put are based on the Black-Scholes option pricing model, using the following assumptions: six (6) month maturity, 0.40% risk free interest, 96.91% volatility, 0% forfeitures and \$0 dividends.

Stock-based compensation expense related to the ESPP and recorded in the Company's condensed consolidated statement of operations for the three- and six-month periods ended January 31, 2017 was approximately (\$6,000) and \$18,000, respectively, (with the three-month figure representing an adjustment to the original estimate for withdrawals, terminations, and final purchase price determination), of which (\$3,000) and \$9,000, respectively, was recorded to research and development and (\$3,000) and \$9,000, respectively, was recorded to general and administrative.

**Note 8—Net Loss Per Share**

The Company computes basic net loss per share using the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Common share equivalents outstanding, determined using the treasury stock method, are comprised of shares that may be issued under the Company's stock option agreements and warrants. Common share equivalents are excluded from the diluted net loss per share calculation if their effect is anti-dilutive.

The following potentially dilutive outstanding securities were excluded from diluted net loss per common share because of their anti-dilutive effect:

	January 31, 2017	January 31, 2016
Stock Options	2,590,543	2,970,224
Warrants	11,286,995	3,073,675
Total	13,877,538	6,043,899

**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.

The Company has entered employment agreements with each of its executive level officers. Generally, the terms of each agreement are such that if the officer is terminated other than for cause, death or disability, or if the case of termination of employment with the Company is for good cause, the officer shall be entitled to receive severance payments equal to either six or 12 months of his/her then-current annual base salary plus any accrued bonus and six or 12 months of benefits coverage.

On April 15, 2016, the Company and the Company's former Chief Scientific Officer ("CSO") entered into a separation, release and consulting agreement, in which the CSO would voluntarily resign from the Company on June 18, 2016 and become a consultant of the Company. The terms of the agreement afforded no severance pay related to the termination of employment; however, the terms of the agreement provide for a fee of \$30,000 per month for consulting services. The consulting agreement will terminate automatically on June 18, 2017, unless renewed by a written agreement of both parties or earlier terminated as provided within the agreement. On the date of termination of employment, the Company recorded a liability of \$360,000 in its balance sheet as the consulting services to be performed are not substantive and the offsetting charge was recorded in research and development as other outside service fees. As of January 31, 2017, the Company has paid \$180,000 against the liability.

On December 27, 2015, the Company and the Company's former Chief Medical Officer ("CMO") entered into a separation and release agreement pursuant to which the Company agreed to pay the former CMO \$286,000, less applicable withholdings, in the form of salary continuation in accordance with the Company's customary payroll practices. At the separation date, the Company recorded a liability of \$286,000 on its condensed balance sheet and the offsetting charge was recorded in research and development as salary expense. As of January 31, 2017, the Company has paid the entire liability in full.

On December 31, 2014, the Company entered into a lease agreement for approximately 34,000 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 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. 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 disclosed in Note 1, and the amendments thereto, while performing his duties as Executive Chairman of Inovio.

#### **Note 11—Subsequent Events**

On February 27, 2017, the Company announced that it received Fast Track designation from the U.S. Food and Drug Administration ("FDA") for its lead product candidate ImmunoPulse® IL-12. This could qualify ImmunoPulse® IL-12 for expedited FDA review, a rolling Biologics License Application review, and other benefits.

## 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, 2016, our subsequent quarterly reports on Form 10-Q and our subsequent reports on Form 8-K, which discuss our business in greater detail.*

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

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

### Company Overview

Our mission is to pioneer new intratumoral immunotherapy treatments to benefit cancer patients. Our core platform technology, the ImmunoPulse® platform, is a unique drug-device therapeutic modality comprised of a proprietary electroporation delivery device consisting of an electrical pulse generator and disposable applicators. The ImmunoPulse® platform is designed to deliver DNA-encoded drugs and treat different tumor types. Our lead product candidate, ImmunoPulse® IL-12, uses our electroporation device to deliver a DNA-encoded interleukin-12 (“IL-12”) to reverse the immunosuppressive microenvironment in the tumor and engender a systemic anti-tumor response against untreated tumors in other parts of the body. We are currently focused on developing ImmunoPulse® IL-12 in combination with an approved anti-PD-1 therapy for melanoma in patients who have previously failed an anti-PD-1 therapy. On February 27, 2017, we announced that we received Fast Track designation from the U.S. Food and Drug Administration (“FDA”) for ImmunoPulse® IL-12. This could qualify ImmunoPulse® IL-12 for expedited FDA review, a rolling Biologics License Application review, and other benefits.

We are in collaboration with University of California, San Francisco, the sponsor of a Phase II clinical trial evaluating ImmunoPulse® IL-12 in combination with pembrolizumab (KEYTRUDA®) for the treatment of advanced, metastatic melanoma in patients who are predicted to not respond to anti-PD-1 therapy alone. During the quarter ended January 31, 2017, the investigator continued to enroll patients in this combination trial. In addition to this investigator-initiated study, during 2017 we expect to initiate a Phase II registration-directed study of ImmunoPulse® IL-12 in combination with an approved anti-PD-1 therapy in patients with advanced, metastatic (stage 3-4) melanoma who previously failed anti-PD-1 therapy.

We have amended the clinical protocol for our biomarker-focused pilot study of ImmunoPulse® IL-12 in triple negative breast cancer in order to improve the enrollment rate for that study, which has been slow to enroll. This study is ongoing and is focused on evaluating the ability of ImmunoPulse® IL-12 to alter the tumor microenvironment and promote a pro-inflammatory response. In addition, our Phase II clinical trials of ImmunoPulse® IL-12 as a monotherapy in Merkel Cell carcinoma, melanoma, cutaneous T-cell lymphoma, and head and neck squamous cell carcinoma are now closed for enrollment and database-locked.

Concurrently, we are continuing development of our next-generation electroporation devices and a proprietary multi-gene immune-modulating therapeutic candidate. We have made further advancements toward prototypes of our next generation electroporation devices and performed an internal assessment of our efforts in discovery research to identify new gene combinations for use with the ImmunoPulse® platform.

We expect to use our working capital primarily for the advancement of our existing and planned clinical programs, including the conclusion of our Phase II clinical trials in Merkel Cell Carcinoma, melanoma, and cutaneous T-cell lymphoma, the completion of enrollment in our Phase II clinical trial in triple negative breast cancer, and the initiation of our proposed registration-directed study in melanoma.

### *Exchange Offer*

On November 11, 2016, we filed a Tender Offer Statement on Schedule TO relating to our offer (the “Exchange Offer”) to exchange certain stock options to purchase up to an aggregate of 2,479,671 shares of our common stock that had been granted to eligible participants for a lesser number of new stock options with a lower exercise price. Stock options with an exercise price greater than or equal to \$3.00, and held by employees, directors, and consultants in continuous service through the termination of the Exchange Offer, were eligible for exchange in the Exchange Offer. An exchange rate of 2 for 1 applied to options priced from \$3.00 to \$9.99, and an exchange rate of 3 for 1 applied to options priced at \$10 or greater. Each new stock option was granted pursuant to OncoSec’s 2011 Stock Incentive Plan, as amended and restated, on the date the Exchange Offer closed and was priced at the market price on that date. As of the closing of the Exchange Offer on December 14, 2016, 29 eligible participants had exchanged 2,214,500 options for 1,070,536 new options.

### **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

### *Stock Options*

We primarily 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.

### *Restricted Stock Units*

We grant restricted stock units under our stock-based compensation plan. The fair value of restricted stock units is based on our closing stock price on the date of grant. The vesting of all outstanding restricted stock units is three-year cliff vesting. Stock-based compensation expense is based on awards ultimately expected to vest, and therefore is reduced by forfeitures.

### *Employee Stock Purchase Plan*

Employees may elect to participate in our shareholder approved employee stock purchase plan. Our employee stock purchase plan generally provides for two six-month offering periods per year, contains a look-back option and offers the purchase of our stock at a 15% discount. We estimate the fair value of the awards using the Black-Scholes option valuation model. 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 the offering period. This fair value is then amortized at the onset of the offering period. Stock-based compensation expense is based on awards expected to be purchased at the onset of the offering period, and therefore is reduced when participants withdraw during the offering period.

## **Results of Operations for the Three Months Ended January 31, 2017 Compared to the Three Months Ended January 31, 2016**

The unaudited financial data for the three-month periods ended January 31, 2017 and January 31, 2016 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	January 31, 2017	January 31, 2016	Increase/(Decrease)	Increase/(Decrease) %
Revenue	\$-	\$-	\$ -	-
Operating expenses				
Research and development	2,882,611	4,113,582	(1,230,971 )	(30 )
General and administrative	2,504,700	2,924,138	(419,438 )	(14 )
Loss before income taxes	(5,387,311)	(7,037,720)	1,650,409	(23 )
Tax provision	-	-	-	-
Net loss	\$(5,387,311)	\$(7,037,720)	\$ 1,650,409	(23 )

### 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, employee 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 decrease in research and development expenses for the three-month period ended January 31, 2017, as compared to the three-month period ended January 31, 2016, is primarily the result of an decrease of \$1.2 million related to our clinical trial costs that were lower due to a lower number of patient enrollments in a smaller number of actively enrolling trials as well as lower trial management costs, a decrease of \$0.4 million related to lower salary costs, and a small decrease in rent and utilities related to our vivarium of \$0.1 million, offset by \$0.2 million related to stock compensation expense as a result of our tender offer to exchange stock options, \$0.2 million related to engineering and laboratory supplies, and \$0.1 million in costs related to establishing our clinical presence in Australia.

We expect our clinical study expenses and plasmid costs to increase as we advance toward initiation of our multi-center, multi-country, Phase II, adaptive, parallel trial of ImmunoPulse® IL-12 in combination with an anti-PD-1 therapy in patients with stage 3/4 melanoma who are progressing on an anti-PD-1 therapy.

### 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 \$0.4 million decrease in general and administrative expenses for the three-month period ended January 31, 2017, as compared to the three-month period ended January 31, 2016, was primarily the result of a decrease of \$0.3 million in stock compensation expense and a decrease of \$0.1 million in salary costs.

**Results of Operations for the Six Months Ended January 31, 2017 Compared to the Six Months Ended January 31, 2016**

The unaudited financial data for the six-month periods ended January 31, 2017 and January 31, 2016 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	January 31, 2017	January 31, 2016	Increase/(Decrease)	Increase/(Decrease) %
Revenue	\$-	\$-	\$ -	-
Operating expenses				
Research and development	5,982,351	7,772,895	(1,790,544)	(23)
General and administrative	5,007,152	6,300,044	(1,292,892)	(21)
Net loss before income taxes	(10,989,503)	(14,072,939)	3,083,436	(22)
Tax provision	1,391	2,172	(781)	(36)
Net loss	\$(10,990,894)	\$(14,075,111)	\$ 3,084,217	(22)

We expect our cash-based general and administrative expenses to remain relatively flat as we continue to leverage internal resources and automate processes to decrease our outside services expenses.

Research and Development Expenses and Operational Milestones

The \$1.8 million decrease in research and development expenses for the six-month period ended January 31, 2017, as compared to the six-month period ended January 31, 2016 is primarily the result of a decrease of \$1.4 million related to clinical trial costs that were lower due to a lower number of patient enrollments in a smaller number of actively enrolling trials as well as lower trial management costs, a decrease of \$0.5 million related to lower salary costs, lower consulting fees of \$0.3 million, and a small decrease in travel cost of \$0.1 million, offset by an increase of \$0.2 million related to stock compensation expense as a result of our tender offer to exchange stock options, an increase of \$0.2 million in rent due to our new facility and an increase of \$0.1 million in lab supplies and depreciation.

General and Administrative

The \$1.3 million decrease in general and administrative expenses for the six-month period ended January 31, 2017, as compared to the six-month period ended January 31, 2016, was primarily the result of a decrease of \$0.7 million in stock compensation expense, a decrease of \$0.2 million in salaries, a decrease of \$0.2 million related to lower accounting fees, a decrease in supplies of \$0.1 million, and a small decrease in outside services of \$0.1 million.

We expect our general and administrative expenses to remain essentially flat in the near term.

**Liquidity and Capital Resources**

*Working Capital*

Our working capital as of January 31, 2017 and July 31, 2016 is summarized as follows:

	At January 31, 2017	At July 31, 2016
Current assets	\$ 21,335,067	\$ 29,417,408
Current liabilities	3,413,754	3,466,251
Working capital	\$ 17,921,313	\$ 25,951,157

Current Assets

Current assets as of January 31, 2017 decreased to approximately \$21.3 million, in comparison to current assets of approximately \$29.4 million as of July 31, 2016. This decrease in our current assets was primarily due to a decrease in cash from \$28.7 million as of July 31, 2016, to \$20.5 million as of January 31, 2017, which is attributable to the cash used in operating and investing activities during the six-month period ended January 31, 2017.

Current Liabilities

Current liabilities as of January 31, 2017 decreased to approximately \$3.4 million, in comparison to our approximate current liabilities of \$3.5 million as of July 31, 2016. This slight decrease was primarily due to lower spending on clinical trials, related to a lower number of patient enrollments, a smaller number of actively enrolling trials, and lower trial management costs.

*Cash Flow*

Cash Used in Operating Activities

Cash used in operating activities for the six-month period ended January 31, 2017 was \$8.2 million, as compared to \$9.0 million for the six-month period ended January 31, 2016. This decrease was primarily related to lower patient costs related to our Phase II clinical trials in Merkel Cell Carcinoma, melanoma, and cutaneous T-cell lymphoma.

### Cash Used in Investing Activities

Cash used in investing activities for the six-month period ended January 31, 2017 was \$9,578, as compared to \$1.1 million for the six-month period ended January 31, 2016. During the six-month period ended January 31, 2016, we purchased laboratory equipment during the move to our new facility. No new equipment was purchased during the same period of 2017.

### Cash Flow Provided by Financing Activities

Cash provided by financing activities was \$42,423 for the six-month period ended January 31, 2017, as compared to \$6.9 million for the comparable six-month period ended January 31, 2016. We did not raise additional capital during the six-month period ending January 31, 2017. During the comparable period in 2016, we raised \$6.9 million in the registered direct offering described below.

### *Recent Equity Financings*

#### *May 2016 Offering*

On May 26, 2016, the Company closed a registered direct offering (the “May 2016 Offering”) with a single healthcare-dedicated institutional fund for the purchase of: (i) 665,049 shares of common stock; (ii) Series A Warrants to purchase up to an aggregate of 5,509,642 shares of common stock at an exercise price of \$1.69 per share with a term of nine (9) years; and (iii) Series B Warrants to purchase 4,844,593 shares of common stock at an exercise price of \$0.01. The investor paid a purchase price of \$1.815 per unit of one share of common stock and an accompanying Series A Warrant, and \$1.805 per unit of one Series B Warrant and accompanying Series A warrant. The Series B warrants have an exercise price of \$0.01 per share and were issued to prevent the beneficial ownership of the purchaser (together with its affiliates and certain related parties) of the Company’s common stock from exceeding 4.99%. The Series B warrants expire upon their exercise in full. Both the Series A and Series B warrants are immediately exercisable on the date of issuance. At the closing, the placement agents were also issued warrants to purchase an aggregate of up to five percent (5%) of the aggregate number of shares of common stock sold in this offering, or 275,482 shares. The placement agent warrants have an exercise price of \$2.26875, are immediately exercisable, and expire on May 24, 2021. The gross proceeds of the offering were \$9.9 million. Net proceeds, after deducting the placement agent’s fee, financial advisory fees, and other estimated offering expenses payable by us, were approximately \$9.1 million. We are using the proceeds from the offering for general corporate purposes, including clinical trial expenses and research and development expenses.



*November 2015 Offering*

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 warrants have an exercise price of \$4.50 per share, are exercisable on May 9, 2016 and expire on May 9, 2021. The warrants were classified as equity at a relative fair market value to common stock of approximately \$1.6 million recorded in our balance sheet. The gross proceeds to us from the offering were approximately \$7.5 million. After deducting for fees and expenses, the aggregate net proceeds from the sale of the common stock in the offering were approximately \$6.9 million. In connection with the 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, have a term of 5 years are exercisable on May 9, 2016 and expire on November 9, 2020. The warrants were classified as equity with a fair market value of approximately \$0.2 million in our balance sheet. We are using the net proceeds from the offering for general corporate purposes, including clinical trials and research and development expenses.

*Cash Requirements*

Our primary objective for the next twelve-month period is to focus on advancing our ImmunoPulse® platform through the initiation of a new combination trial of ImmunoPulse® IL-12 and an approved anti-PD-1 therapy. In addition, we expect to pursue raising sufficient capital to fund our operations and to acquire and develop additional assets or technologies consistent with our focus on innovative gene therapies, therapeutics and proprietary medical approaches to stimulate anti-tumor immune responses for the treatment of cancer.

We expect to continue to focus on reducing expenses through leveraging our in-house capabilities and reducing reliance on consultants and outside service providers and pursue ImmunoPulse® 1L-12 as a combination therapy. We currently estimate our cash-based operating expenses and working capital requirements for the remainder of the fiscal year ending July 31, 2017 (“Fiscal 2017”) to be approximately \$10.4 million as set forth in the table. However, 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.

Cash Requirements	Amount
Product development	\$6,200,000
Employee compensation	2,700,000
General and administration	1,100,000
Professional services fees	400,000
	\$10,400,000

During the six-month period ended January 31, 2017, our operating cash outflow was approximately \$8.2 million. Based on our current operating costs and our operational goals, we expect our monthly cash outflows for the remainder of Fiscal 2017 to average approximately \$1.7 million per month. In general, our cash outflows for future periods will be dependent on the progress of our proposed combination trial. We expect our current funds 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 six-month period ended January 31, 2017, we received \$16,808 related to the exercise of Series B Warrants. At January 31, 2017, 2,764,000 Series B warrants were outstanding and exercisable at a price of \$0.01 per share, and 8,522,995 other warrants were outstanding and exercisable at prices ranging from \$1.69 to \$20.00 per share. At January 31, 2017, if the holders of our outstanding warrants were to exercise all of the warrants outstanding in full on a cash basis, we would receive approximately \$4.4 million in proceeds. If the holders of all of our other outstanding 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 \$8.6 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, would 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**

Our primary exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investments. The primary objective of our investment activities is to preserve principal. Our risk associated with fluctuating interest rates is limited to our investments in interest rate sensitive financial instruments and we do not use interest rate derivative instruments to manage exposure to interest rate changes. We mitigate default risk by investing in investment grade securities. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments due to their relatively short term nature.

Cash and cash equivalents as of January 31, 2017 were \$20.5 million and were primarily invested in interest bearing money market, checking and savings accounts. A hypothetical 10% adverse change in the average interest rate on our cash and cash equivalents would not have had a material effect on net loss for the three or six months ended January 31, 2017.

### **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 three or six month periods ended January 31, 2017 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

## **PART II—OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

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

### **ITEM 1A. RISK FACTORS**

You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q. If any of the following events, 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 \$20.2 million. As of January 31, 2017, we had cash and cash equivalents of approximately \$20.5 million.

We have a history of raising funds through offerings of our common stock and warrants to purchase our common stock. Although we are exploring non-dilutive or less-dilutive ways of funding our operations, including but not limited to technology licensing and partnership arrangements, we may need to continue to fund our operations through more dilutive public or private equity financings in the near future, and we may also raise funds through debt financings or grants.

We will require additional financing to fund our planned operations, including our proposed registration-directed combination study of ImmunoPulse IL-12 as combination therapy with an anti-PD-1 therapy for the treatment of advanced metastatic melanoma, which is expected to begin in the first half of 2017, 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 other clinical trials and seeking regulatory approval relating to our assets and any assets we may develop or 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 further 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 and uncertain conditions in the capital and financial markets, and more particularly the market for early-development-stage biotechnology and life science 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 technology licensing and partnership arrangements or 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 may be unable to continue our operations, and our stockholders could lose their entire investment in our Company.

***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, such as the development of our ImmunoPulse® IL-2 platform through our proposed registration-directed trial in melanoma. 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:

obtaining requisite regulatory approvals for such products in a timely manner or at all;

conducting or completing clinical trials, including receiving incomplete, unconvincing, or equivocal clinical trials data;

successfully identifying new potential product candidates;

developing potential product candidates;

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;

being dependent upon third parties to conduct certain aspects of clinical and preclinical studies;

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.



***If the commencement or completion of clinical testing for product candidates based on our technology is delayed or prevented, that 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 we are able to complete our proposed clinical trials and the results 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, including but not limited to our proposed registration-directed study in melanoma, could significantly affect our product development costs and business plan. We do not know whether our triple negative breast cancer Phase II clinical trial, our melanoma combination investigator-initiated Phase II clinical trial, or our proposed registration-directed clinical trial in melanoma will be completed on schedule, if at all. Currently, our Phase II clinical trials in Merkel Cell carcinoma, melanoma, head and neck squamous cell carcinoma, and cutaneous T-Cell lymphoma are closed to enrollment and have database lock, and they are proceeding to clinical study report writing. Our proposed registration-directed clinical trial in melanoma is currently projected to be begin in calendar year 2017 and to complete enrollment in calendar year 2018. We do not know whether any other pre-clinical or clinical trials, including Phase III clinical trials, will begin for this combination therapy as it will be dependent on the phase II trial results. An investigator-initiated trial is a research effort in which the investigator designs and implements the study and the investigator or the institution acts as the study sponsor. The trial sponsor has control over the design, conduct and timing of such trials, and we have limited or no control over the commencement and completion of such trials.

The commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including delays or issues related to:

obtaining clearance from the Food and Drug Administration, or 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;

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; and

identifying and maintaining a sufficient supply of necessary products or product candidates, including those produced by third parties, on commercially reasonable terms.

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 and put a clinical hold on the proposed trial. This could delay the commencement of the trial and would be a setback for the commercialization strategy for ImmunoPulse® IL-12, and it could have a material adverse impact on our business and our stockholders' investment in our Company.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend our 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.

***To the extent we conduct clinical trials of our product candidates in combination with third parties' products, we will face additional risks relating to supply of those products.***

To the extent that our strategy focuses on the combination of our product candidates with third parties' products or product candidates, such as anti-PD-1/PD-L1 products or product candidates, certain of our clinical studies may involve the combination of our product candidates with the products or product candidates of third parties. This is true of our melanoma combination investigator-sponsored Phase II clinical trial led by the University of California San Francisco to assess the combination of ImmunoPulse® IL-12 and Merck's PD-1 antibody KEYTRUDA®, as well as our proposed registration-directed study in melanoma to assess the combination of ImmunoPulse® IL-12 with an approved anti-PD-1 therapy in patients who have previously failed an anti-PD-1 therapy, which we plan to begin in the first half of 2017. These studies involve additional risks due to their reliance on factors outside our control, such as those relating to the availability and marketability of an approved anti-PD-1 therapy. If the marketability of third-party products is impacted, or we are unable to secure and maintain a sufficient supply of such third-party products or candidates on commercially reasonable terms, our clinical studies could be delayed or we could be forced to terminate these studies. Such a delay or termination would have a material impact on our development strategy, business, results of operations, financial conditions, and prospects.

***Regulatory authorities may not approve our product candidates or the approvals we secure may be too limited or too late 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.

Although we have seen no systemic drug related adverse events to date, 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 could be delayed or prevented, which could impair our reputation, increase our costs and prevent us from earning revenues. Success in preclinical testing and early clinical studies does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including many with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. 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 could have an adverse effect on our business, reputation and results of operations.

Because of the substantial competition we face, even if we are able to secure regulatory approval of our product candidates, delays in such regulatory approval could delay or even prevent our ability to commercialize our product candidates. Even a failure to secure accelerated regulatory approval under the FDA Accelerated Approval Program, or similar foreign programs, could lead us to reconsider our development strategies and delay or prevent us from commercializing our product candidates.

***If we are unable to successfully recruit and retain qualified personnel, we may not successfully maintain or grow 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, scientists and other employees having relevant experience in life sciences and the biotechnology industry. Competition for qualified individuals is intense, particularly in our geographical location where there are several larger, more established life science and

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, clinical, and regulatory 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 retain existing personnel and find, attract, and retain new qualified personnel on acceptable terms and in a timely manner to coincide with our growth, we may not be able to successfully maintain or grow 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, including recent changes within our 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, and perceptions of prospective employees, partners and investors, regarding our business and prospects, (iii) cause us to incur substantial costs in connection with managing transitions and recruiting suitable replacements, and (iv) 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.

***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.***

We recently established a subsidiary corporation in Australia, and our business plan includes the continued growth of our operations, including, but not limited to, the growth of our workforce and the expansion of our clinical studies beyond the U.S. Such growth could place an additional 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. International growth, such as the expansion of our clinical trials to overseas clinical sites, will expose us to more complexity in our regulatory and accounting compliance and will expose us to new risks and challenges inherent in international operations with which we may not be familiar, such as changing taxes or duties, fluctuations in currency exchange rates, changes in applicable laws or policies, and potential for war or civil unrest. In addition, we must continue to improve our operational, financial, and management controls and our reporting systems and procedures, which can be made even more challenging while our operations are growing. If we fail to successfully manage our growth, we may be unable to execute on our business plan.

***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, 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. As we describe elsewhere in this Quarterly Report, we have patent protection for components of our ImmunoPulse® product candidates. Our current device portfolio includes 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. To the extent that pending or planned patent applications do not provide sufficient protection, 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 January 31, 2017, we incurred a net loss of approximately \$5.4 million. From inception through January 31, 2017, we have incurred an aggregate net loss of approximately \$84.5 million. We expect to tightly manage our monthly operating expenses; however, we expect our cumulative operating expenses will continue to increase as we further our development activities and 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.

***We 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 help us manage critical aspects of the clinical trials we sponsor. We currently rely on these third parties for the execution of certain of our clinical and pre-clinical studies, and we only control 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, and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guidelines. The FDA and similar foreign regulators enforce these Good Clinical Practice 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 Good Clinical Practice regulations, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA and similar foreign regulators may determine that our clinical trials are not compliant with Good Clinical Practice regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would increase costs and 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 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 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 application, including our melanoma combination investigator-sponsored Phase II clinical trial led by the University of California San Francisco to assess the combination of ImmunoPulse® IL-12 and Merck's PD-1 antibody KEYTRUDA®. Regulations and guidelines imposed by the FDA with respect to IND applications include a requirement that the sponsor of a clinical trial provide ongoing communication with the agency as it pertains to safety of the treatment. This communication can be relayed to the agency in the form of safety reports, annual reports, or verbal communication at the request of the FDA. Accordingly, it is the responsibility of each investigator (as the sponsor of the trial) to be the point of contact with the FDA. The communication and information provided by the investigator may not be appropriate and accurate, and the investigator has the ultimate responsibility and final decision-making authority with respect to submissions to the FDA. This may result in reviews, audits, delays, or clinical holds by the FDA ultimately affecting the timelines for these studies and potentially risking the completion of these trials.

***We 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 are investigating licensing and partnering opportunities with respect to raising additional capital, we are not currently planning on generating any significant near term revenue from those potential opportunities; therefore, the revenue generating potential from 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.

***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.

In addition to the risks and uncertainties described in this section of this Quarterly 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 or other securities to new investors or service providers or to employees or directors;

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.

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

In addition, as of January 31, 2017 we have outstanding (i) options to purchase 2,590,543 shares of common stock, (ii) warrants to purchase 11,286,995 shares of our common stock, including Series B Warrants to purchase 2,764,000 shares of common stock at an exercise price of \$0.01 per share, and (iii) 590,000 restricted stock units. In addition, we have as of January 31, 2017, 2,089,457 shares reserved for future issuance under our 2011 Stock Incentive Plan and 463,580 shares reserved for future issuance under our 2015 Employee Stock Purchase Plan. The exercise of options and warrants, the vesting and settlement of restricted stock units, the issuance of additional shares of common stock or other awards under our 2011 Stock Incentive Plan and the sale of any resulting shares of our common stock in connection with the foregoing, 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 or the vesting of restricted stock units granted under our stock option plans, and options, restricted stock units and warrants that may be granted or issued in the future. In addition, 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 with Nasdaq regulations, 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 of NASDAQ’s 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 or prevented.

***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 many of our competitors. Many 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.

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.

***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 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.

***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 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 Européenne*) approvals, and late-stage clinical studies in the United States. This strategy includes seeking approval from the FDA and similar foreign regulators to initiate pivotal registration studies in the United States and abroad, including studies in select rare cancers that have limited, adverse, or no therapeutic alternatives. This strategy also includes expanding the addressable markets for our therapies through the addition of relevant indications. Our commercialization plan also includes partnering and/or co-developing our technology in developing regions, such as Eastern Europe and Asia, where local resources are best leveraged and appropriate collaborators can be secured.

Our commercialization strategy may include the establishment of our own sales, marketing, and distribution capabilities to market products to our target markets. Developing these capabilities would require significant expenditures on personnel and infrastructure. While we intend to market products that are aimed at a small patient population, we might not be able to create an effective sales force around even a niche market. In addition, some of our product candidates could require a large sales force to call on, educate, and support physicians and patients. We could 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.

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 or other regulator-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.

Certain characteristics of our ImmunoPulse® platform, including its reliance on electroporation technology, intratumoral delivery, and surface-accessible tumors, may impact market acceptance of the platform.

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. In addition, recent trends in U.S. politics suggest that we may see changes to the U.S. healthcare insurance framework. For all of these reasons and more, we cannot guarantee 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.

Physicians, patients, and third-party payors may be less accepting of our product candidates due to certain characteristics of our product candidates. They may have concerns, for example, about the complexity inherent in a combination therapy approach, or about the clinical application of electroporation technology which is less prevalent in the United States. A lack of acceptance of our product candidates could prevent us from successfully commercializing product candidates for which we secure regulatory approval.

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.

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

All biotechnology companies are subject to extensive, complex, costly, and evolving government regulation. For the U.S., these regulations are principally administered by the FDA and to a lesser extent by the United States Drug Enforcement Agency 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 Drug Enforcement Agency, 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.***

Although our staff and internal/external legal teams strive to comply with all applicable healthcare laws and regulations, the regulatory environment is constantly changing and certain federal and state healthcare laws and regulations may affect our business, including:

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

the Federal Food, Drug and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by Health Insurance Portability and Accountability Act, 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 Affordable Care Act, 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. These laws all provide for penalties for non-compliance. The shifting regulatory environment, including proposed revisions to or replacement of the Affordable Care Act, 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 we operate in a foreign country or 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.

***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. The pursuit of such transactions could also create a distraction for management and entail increased expenses in connection with the pursuit, evaluation, and negotiation of such transactions. 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, the pursuit of such transactions, and 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 could 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 or prevented.

***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 could 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.

***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 and other applicable laws, including the Sarbanes-Oxley Act and the Dodd-Frank Act of 2010.

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

Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of net operating loss carryforwards and other tax attributes. In the event that we undergo such an ownership change, our net operating loss 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 net operating loss carryforwards may include estimates and judgments by our management, and the Internal Revenue Service has not audited or otherwise validated the amount of our net operating loss carryforwards. Additionally, legislative changes could negatively impact our ability to use any tax benefits associated

with our net operating loss 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 net operating loss carryforwards, this could deter potential buyers of our common stock and adversely impact the trading price of our common stock.

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

We have exclusively licensed certain technology and related assets that cover our current therapeutic methods. Patents for technology we have licensed are still in force in certain jurisdictions, and the technology patent family will expire between 2017 and 2018. Method-of-use patents are granted in certain jurisdictions and applications are pending in others, with an expiry between 2025 and 2027. These 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 Pharmaceuticals, Inc., or 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 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.

The foregoing risks of third parties' infringement of our intellectual property rights may be increased as we continue to engage in discussions, collaborations, and other arrangements with third parties. New challenges also arise as we engage with third parties located outside the United States. These factors could increase the risks and costs associated with building and protecting our intellectual property portfolio.

***Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some or all 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. These risks may be amplified by our size relative to many of our competitors. 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.

***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. Future sales of common stock by significant stockholders, including by those who acquired their shares in our prior offerings, or through the exercise of outstanding warrants, or who are affiliates, or the perception that such sales may occur, could depress the price of our common stock.

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

None.

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

None.

**Item 4. MINE SAFETY DISCLOSURES.**

None.

**Item 5. OTHER INFORMATION.**

None.

**Item 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
3.1	Certificate of Incorporation of Netventory Solutions, Inc. (incorporated by reference to our Registration Statement on Form S-1, filed on September 3, 2008)
3.2	Amended and Restated Bylaws (incorporated by reference to our Current Report on Form 8-K, filed on March 6, 2012)
3.3	Articles of Merger dated February 9, 2011 (incorporated by reference to our Current Report on Form 8-K, filed on March 3, 2011)



Edgar Filing: ONCOSEC MEDICAL Inc - Form 10-Q

- 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 OncoSec Medical Incorporated 2011 Stock Incentive Plan (as amended and restated on December 6, 2016) (incorporated by reference to our Current Report on Form 8-K, filed on December 6, 2016)
- 31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
- 31.2 Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101 Financial statements from the Quarterly Report on Form 10-Q of OncoSec Medical Incorporated for the three- and six- months period ended January 31, 2017, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, (iv) the Notes to Condensed Consolidated Financial Statements.

**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: March 16, 2017

*/s/ Richard B. Slansky*

By: Richard B. Slansky  
*(Principal Financial Officer)*

Dated: March 16, 2017

