

ONCOSEC MEDICAL Inc  
Form 10-Q  
December 07, 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 OCTOBER 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**

(State or other jurisdiction of  
incorporation or organization)

**98-0573252**

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

**5820 NANCY RIDGE DRIVE**

**SAN DIEGO, CA**

(Address of principal executive offices)

**92121**

(Zip Code)

**(855) 662-6732**

(Registrant's telephone number, including area code)

**Not applicable**

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Emerging growth company

If an emerging growth company, indicated by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The number of outstanding shares of the registrant's common stock, \$0.0001 par value per share, was 35,517,727 as of December 5, 2017.

**OncoSec Medical Incorporated**

**Form 10-Q**

**For the Quarterly Period Ended October 31, 2017**

	<b>Page</b>
<b><u>PART I—FINANCIAL INFORMATION</u></b>	<b>3</b>
Item 1. <b><u>Financial Statements:</u></b>	<b>3</b>
a) <b><u>Condensed Consolidated Balance Sheets as of October 31, 2017 (Unaudited) and July 31, 2017</u></b>	<b>3</b>
b) <b><u>Condensed Consolidated Statements of Operations for the three months ended October 31, 2017 and 2016 (Unaudited)</u></b>	<b>4</b>
c) <b><u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended October 31, 2017 and 2016 (Unaudited)</u></b>	<b>5</b>
d) <b><u>Condensed Consolidated Statements of Cash Flows for the three months ended October 31, 2017 and 2016 (Unaudited)</u></b>	<b>6</b>
e) <b><u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u></b>	<b>7</b>
Item 2. <b><u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b>17</b>
Item 3. <b><u>Quantitative and Qualitative Disclosure about Market Risk</u></b>	<b>24</b>
Item 4. <b><u>Controls and Procedures</u></b>	<b>24</b>
<b><u>PART II—OTHER INFORMATION</u></b>	<b>25</b>
Item 1. <b><u>Legal Proceedings</u></b>	<b>25</b>
Item 1A. <b><u>Risk Factors</u></b>	<b>25</b>
Item 2. <b><u>Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	<b>45</b>
Item 3. <b><u>Defaults Upon Senior Securities</u></b>	<b>46</b>
Item 4. <b><u>Mine Safety Disclosures</u></b>	<b>46</b>
Item 5. <b><u>Other Information</u></b>	<b>46</b>
Item 6. <b><u>Exhibits</u></b>	<b>46</b>
<b><u>SIGNATURES</u></b>	<b>47</b>

**PART I—FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS.****OncoSec Medical Incorporated****Condensed Consolidated Balance Sheets**

	October 31, 2017 <b>(Unaudited)</b>	July 31, 2017
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 14,661,418	\$ 11,444,676
Prepaid expenses and other current assets	1,419,226	1,068,947
<b>Total Current Assets</b>	<b>16,080,644</b>	<b>12,513,623</b>
Property and equipment, net	2,314,095	2,410,099
Other long-term assets	301,804	309,187
<b>Total Assets</b>	<b>\$ 18,696,543</b>	<b>\$ 15,232,909</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Liabilities</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 3,803,908	\$ 3,281,133
Accrued compensation	208,373	114,841
<b>Total Current Liabilities</b>	<b>4,012,281</b>	<b>3,395,974</b>
Other long-term liabilities	1,145,120	1,140,953
<b>Total Liabilities</b>	<b>5,157,401</b>	<b>4,536,927</b>
<b>Commitments and Contingencies (Note 9)</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 — 29,608,085 and 21,618,194 common shares as of October 31, 2017 and July 31, 2017, respectively	2,961	2,162
Additional paid-in capital	99,688,473	93,866,088
Warrants issued and outstanding — 12,526,340 and 9,044,740 warrants as of October 31, 2017 and July 31, 2017, respectively	14,702,980	11,775,807
Accumulated other comprehensive loss	(10,365 )	(3,620 )
Accumulated deficit	(100,844,907)	(94,944,455)

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Total Stockholders' Equity	13,539,142	10,695,982
Total Liabilities and Stockholders' Equity	\$ 18,696,543	\$ 15,232,909

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

**OncoSec Medical Incorporated****Condensed Consolidated Statements of Operations  
(Unaudited)**

	Three Months Ended October 31, 2017	Three Months Ended October 31, 2016
Revenue	\$—	\$—
Expenses:		
Research and development	3,413,151	3,099,739
General and administrative	2,514,037	2,548,573
Loss from operations	(5,927,188 )	(5,648,312 )
Other income (expense), net	26,736	46,118
Loss before income tax	(5,900,452 )	(5,602,194 )
Provision for income taxes	-	1,391
Net loss	\$(5,900,452 )	\$(5,603,585 )
Basic and diluted net loss per common share	\$(0.26 )	\$(0.29 )
Weighted average shares used in computing basic and diluted net loss per common share	22,318,117	19,020,982

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

**OncoSec Medical Incorporated**

**Condensed Consolidated Statements of Comprehensive Loss  
(Unaudited)**

	Three Months Ended October 31, 2017	Three Months Ended October 31, 2016
Net loss	\$(5,900,452)	\$(5,603,585)
Foreign currency translation adjustments	(10,365 )	(9 )
Comprehensive loss	\$(5,910,817)	\$(5,603,594)

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



**OncoSec Medical Incorporated****Condensed Consolidated Statements of Cash Flows  
(Unaudited)**

	Three Months Ended October 31, 2017	Three Months Ended October 31, 2016
Operating activities		
Net loss	\$(5,900,452 )	\$(5,603,585 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	96,004	94,784
Stock-based compensation	554,575	1,148,209
Common stock issued for services	109,000	—
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other current assets	200,980	(189,886 )
(Increase) decrease in other long-term assets	7,383	(476 )
(Decrease) increase in accounts payable and accrued liabilities	(245,050 )	(183,121 )
Increase in accrued compensation	93,531	66,539
Increase (decrease) in other long-term liabilities	4,167	242,874
Net cash used in operating activities	(5,079,862 )	(4,424,662 )
Investing activities		
Purchases of property and equipment	—	(9,578 )
Net cash used in investing activities	—	(9,578 )
Financing activities		
Proceeds from issuance of common stock through employee stock purchase plan	19,048	25,617
Proceeds from issuance of common stock and warrants	9,283,443	—
Payment of financing and offering costs	(1,008,143 )	—
Proceeds from exercise of warrants	9,000	13,306
Net cash provided by financing activities	8,303,348	38,923
Effect of exchange rate changes on cash	(6,744 )	(9 )
Net increase (decrease) in cash	3,216,742	(4,395,326 )
Cash and cash equivalents, at beginning of period	11,444,676	28,746,224
Cash and cash equivalents, at end of period	\$14,661,418	\$24,350,898
Supplemental disclosure for cash flow information:		
Cash paid during the period for:		
Interest	\$—	\$—
Income taxes	\$—	\$1,391
Noncash investing and financing transactions:		
Accrued offering costs	\$201,068	\$—
Noncash expiration of warrants	\$535,857	\$228,509

Noncash activity related to the issuance of warrants in-transit	\$—	\$2,000
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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 (together with its subsidiaries, unless the context indicates otherwise, being collectively referred to as 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”). The Company has not produced any revenues since its inception. 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 is a biotechnology company focused on designing, developing and commercializing innovative therapies and proprietary medical approaches to stimulate and guide an anti-tumor immune response for the treatment of cancer. Its core platform technology, ImmunoPulse®, is a drug-device therapeutic modality comprised of a proprietary intratumoral electroporation delivery device. The ImmunoPulse® platform is designed to deliver DNA-encoded drugs directly into a solid tumor and promote an inflammatory response against cancer. The ImmunoPulse® device can be adapted to treat different tumor and tissue types, and consists of an electrical pulse generator, a reusable handle and disposable applicators. The Company’s lead product candidate, ImmunoPulse® IL-12, uses its electroporation device to deliver a DNA-encoded interleukin-12 (“IL-12”), called tavokinogene telseplasmid (“tavo”), with the aim of reversing the immunosuppressive microenvironment in the treated tumor and engendering a systemic anti-tumor response against both the treated tumor and untreated distal tumors. In February 2017, the Company received Fast Track designation from the U.S. Food and Drug Administration (“FDA”) for ImmunoPulse® IL-12, which could qualify ImmunoPulse® IL-12 for expedited FDA review, a rolling Biologics License Application review and certain other benefits.

The Company’s current focus is to pursue its registration-directed study of ImmunoPulse® IL-12 in combination with an approved therapy for melanoma in patients who have shown refractory or relapse from certain other cancer therapies, which is referred to as the PISCES/KEYNOTE-695 study. Most of the Company’s present activities are, and it expects most of its near-term expenditures will be, directed toward advancing the PISCES/KEYNOTE-695 study. To this end, in May 2017, the Company entered into a clinical trial collaboration and supply agreement with a subsidiary of Merck & Co., Inc. (“Merck”) in connection with the PISCES/KEYNOTE-695 study, in which the Company has agreed to sponsor and fund the study and Merck has agreed to manufacture and supply its anti-PD-1 therapy KEYTRUDA® for use in the study. The PISCES/KEYNOTE-695 study opened for enrollment in October 2017.

The Company also intends to continue to pursue other ongoing or potential new trials and studies related to ImmunoPulse® IL-12, all with the goal of obtaining requisite regulatory approvals from the FDA and comparable regulators in certain other jurisdictions to market and sell this product candidate. For instance, the Company is in collaboration with the University of California, San Francisco (“UCSF”), the sponsor of a multi-center Phase II clinical trial evaluating ImmunoPulse® IL-12 in combination with Merck’s KEYTRUDA® for the treatment of advanced, metastatic melanoma in patients who are predicted to not respond to anti-PD-1 therapy alone. Merck is manufacturing and supplying its drug KEYTRUDA® to UCSF to support this trial. In addition, the Company is pursuing a biomarker-focused pilot study of ImmunoPulse® IL-12 in triple negative breast cancer, which is focused on evaluating the ability of ImmunoPulse® IL-12 to alter the tumor microenvironment and promote a pro-inflammatory response. In January 2017, the Company amended the clinical protocol for this study to improve the enrollment rate, as it had been slow to enroll, and in September 2017, the Company enrolled half the patients needed for the study, which is now open for enrollment and is ongoing. Additionally, the Company’s Phase II clinical trials of ImmunoPulse® IL-12 as a monotherapy in Merkel Cell carcinoma, melanoma, and head and neck squamous cell carcinoma are now closed and clinical study reports are filed. The Company is no longer pursuing its Phase II clinical trial of ImmunoPulse® IL-12 as a monotherapy in cutaneous T-cell lymphoma, which has been closed.

In addition, the Company is developing its next-generation electroporation devices, including advancements toward prototypes and pursuing discovery research to identify other product candidates that, like IL-12, can be encoded into DNA and delivered intratumorally or into other tissues using electroporation to augment anti-tumor immune function by reversing the immunosuppressive mechanisms and/or enhancing effector function, all with the aim of expanding the Company’s ImmunoPulse® pipeline beyond the delivery of plasmid-DNA encoding for cytokines.

*Basis of Presentation*

In October 2016, the Company created an Australian corporation as its wholly-owned subsidiary. This corporation's functional currency, the Australian dollar, is also its reporting currency, and its financial statements are translated to U.S. dollars, the Company's reporting currency, prior to consolidation. The accompanying consolidated financial statements include the accounts of the Company and its subsidiary, and all intercompany accounts and transactions have been eliminated in consolidation.

*Unaudited Interim Financial Information*

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 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The condensed consolidated balance sheet as of October 31, 2017, and condensed consolidated statements of operations, condensed consolidated statements of comprehensive loss, and condensed consolidated statements of cash flows for the three months ended October 31, 2017 and 2016, are unaudited, but include all adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of the Company's financial position, results of operations and cash flows for the periods presented. The condensed consolidated results of operations for the three months ended October 31, 2017 shown herein are not necessarily indicative of the consolidated results that may be expected for the year ending July 31, 2018, or for any other period. These condensed consolidated financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements for the fiscal year ended July 31, 2017, included in the Company's Annual Report on Form 10-K (the "Annual Report") filed with the U.S. Securities and Exchange Commission ("SEC") on October 25, 2017. The consolidated balance sheet at July 31, 2017 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 accompanying condensed consolidated balance sheet for the year ended July 31, 2017 have been reclassified to conform to an interim presentation, but there was no effect on net loss at July 31, 2017.

**Note 2—Significant Accounting Policies**

The Company's significant accounting policies are described in Note 2 to the consolidated financial statements included in the Annual Report. Since the date of those financial statements, there have been no material changes to the Company's significant accounting policies.

*Use of Estimates*

The accompanying condensed consolidated financial statements have been prepared in conformity with U.S. GAAP, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Such estimates include stock-based compensation, accounting for long-lived assets and accounting for income taxes, including the related valuation allowance on the deferred tax asset and uncertain tax positions. The Company bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. On an ongoing basis, the Company reviews its estimates to ensure that they appropriately reflect changes in the business or as new information becomes available. Actual results could differ materially from these estimates.

### *Segment Reporting*

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

### *Concentrations and Credit Risk*

The Company maintains cash balances at a small number of financial institutions, where 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 its cash and cash equivalents.

### *Recent Accounting Pronouncements*

There were no accounting pronouncements during the three months ended October 31, 2017 that the Company anticipates will have a material impact on the Company's financial condition, results of operations or related disclosures. See Note 2 to the Annual Report for a discussion of certain recent accounting pronouncements not yet adopted by the Company.

### **Note 3—Cash and Cash Equivalents and Liquidity**

The Company considers all liquid investments with maturities of three months or less when purchased to be cash equivalents. As of October 31, 2017 and July 31, 2017, cash and cash equivalents were primarily comprised of cash in savings and checking accounts.

As of October 31, 2017, the Company had cash and cash equivalents of \$14.7 million. Additionally, subsequent to October 31, 2017, the Company received additional net proceeds of approximately \$9.1 million from the exercise of certain warrants (see Note 11). As of November 30, 2017, the Company had cash and cash equivalents of \$21.4 million. The Company currently estimates its operating expenses and working capital requirements for the current fiscal year ending July 31, 2018 to be approximately \$21.0 million, although the Company may modify or deviate from this estimate and it is likely that actual operating expenses and working capital requirements will vary from this

estimate. Based on these expectations regarding future expenses, as well as the current cash levels and rate of cash consumption, the Company believes that current cash resources are sufficient to meet the Company's anticipated needs for the 12 months following the issuance of this report. The Company will continue to assess its cash resources and anticipated needs on a quarterly basis.

The Company has sustained losses in all reporting periods since inception, with an inception-to date-loss of \$100.8 million as of October 31, 2017. Further, the Company has never generated any cash from its operations, does not expect to generate such cash in the near term, and does not presently have any firm commitments for future capital. Consequently, the Company will need significant additional capital to continue operating its business and fund its planned operations, including research and development, clinical trials and, if regulatory approval is obtained, commercialization of its product candidates. In addition, the Company will require additional financing if it desires to in-license or acquire new assets, research and develop new compounds or new technologies and pursue related patent protection, or obtain any other intellectual property rights or other assets.

Historically, the Company has raised the majority of the funding for its business through offerings of its common stock and warrants to purchase its common stock. Although the Company is exploring other ways of funding its operations that involve less dilution to its existing stockholders', including, among others, technology licensing or other collaboration arrangements, debt financings or grants, the Company has not successfully established or raised any funds through any of these types of arrangements, and it may need to continue to seek funding for its operations through additional dilutive public or private equity financings. If the Company issues equity or convertible debt securities to raise additional funds, its existing stockholders would experience further dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of its existing stockholders. If the Company incurs debt, its fixed payment obligations, liabilities and leverage relative to our equity capitalization would increase, which could increase the cost of future capital. Further, the terms of any debt securities the Company issues or borrowings it incurs, if available, could impose significant restrictions on its operations, such as limitations on its ability to incur additional debt or issue additional equity or other operating restrictions that could adversely affect its ability to conduct its business, and any such debt could be secured by any or all of the Company's assets pledged as collateral. Additionally, the Company may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other costs.



Moreover, equity or debt financings or any other source of capital may not be available when needed or at all, or, if available, may not be available on commercially reasonable terms. Weak economic and capital market conditions generally or uncertain conditions in the Company's industry could increase the challenges it faces in raising capital for its operations. In recent periods, the capital and financial markets for early and development-stage biotechnology and life science company stocks have been volatile and uncertain. If the Company cannot raise the funds that it needs, it could be forced to delay or scale down some or all of its development activities or cease all operations, and its stockholders could lose all of their investment in the Company.

#### Note 4—Stockholders' Equity

A summary of the changes in the Company's stockholders' equity for the three months ended October 31, 2017 and 2016 is provided below:

	October 31, 2017	October 31, 2016
Stockholders' equity at beginning of period	\$10,695,982	\$28,053,104
Net loss	(5,900,452 )	(5,603,585 )
Stock-based compensation	554,575	1,148,208
Common stock issued for services	109,000	—
Issuance of common stock through employee stock purchase plan	19,048	25,617
Equity offerings (see Note 6), net of costs	8,058,733	—
Accumulated other comprehensive income (loss)	(6,744 )	(9 )
Exercise of common stock warrants (net)	9,000	15,306
Stockholders' equity at end of period	\$13,539,142	\$23,638,641

#### Note 5—Balance Sheet Details

##### *Property and Equipment*

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

	October 31, 2017	July 31, 2017
Equipment and furniture	\$2,861,632	\$2,861,632

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Computer software	292,034	292,034
Leasehold improvements	80,102	80,102
Property and equipment, gross	3,233,768	3,233,768
Accumulated depreciation and amortization	(919,673 )	(823,669 )
	\$2,314,095	\$2,410,099

Depreciation and amortization expense recorded for the three months ended October 31, 2017 and 2016, was approximately \$96,000 and \$95,000, respectively.

*Accounts Payable and Accrued Liabilities*

Accounts payable and accrued liabilities are comprised of the following:

	October 31, 2017	July 31, 2017
Research and development costs	\$2,438,653	\$1,537,892
Professional and other outside service fees	1,202,834	1,584,899
Rent	5,000	—
Other	157,421	158,342
	\$3,803,908	\$3,281,133

*Accrued Compensation*

Accrued compensation is comprised of the following:

	October 31, 2017	July 31, 2017
Separation costs	\$—	\$100,295
Accrued payroll	194,271	14,222
401(k) plan payable	13,778	—
Other	324	324
	\$208,373	\$114,841

Separation costs relate to agreements with certain of the Company's former executive officers. See Note 9 for more information.

*Other Long-Term Liabilities*

Other long-term liabilities are comprised of the following:

	October 31, 2017	July 31, 2017
Deferred rent	\$1,145,120	\$1,140,953
	\$1,145,120	\$1,140,953

As of October 31, 2017, the deferred rent liability is related to the Company's straight-line expense recognition of rent for its corporate headquarters. See Note 9 for more information.

**Note 6—Equity Offerings***November 2017 Warrant Exercise Inducement Offering*

In November 2017, the Company entered into a warrant exercise agreement with the holders of certain of the Company's outstanding warrants in connection with its offer and sale to such holders of additional warrants to purchase shares of its common stock as an inducement to exercise such holders' outstanding warrants. See Note 11 for more information about this offering.

*First October 2017 Offerings*

On October 25, 2017, the Company completed an offer and sale to certain accredited investors of, in a registered public offering, 5,270,934 shares of its common stock and, in a concurrent private placement offering, warrants to purchase an aggregate of up to 3,953,200 shares of its common stock, all at a purchase price of \$1.34375 per share. The warrants have an initial exercise price of \$1.25 per share, became exercisable on October 25, 2017 and expire on April 25, 2022. The gross proceeds of the offering were \$7.1 million and the net proceeds, after deducting the placement agent's fee and other offering fees and expenses paid or payable by the Company (and excluding the proceeds, if any, from any cash exercise of the warrants), were approximately \$6.2 million. In connection with the offering, the Company paid the placement agent (i) a cash fee equal to 5.5% of the gross proceeds of the offering, as well as offering expenses in a non-accountable sum of \$60,000, and (ii) warrants to purchase up to an aggregate of 316,256 shares of its common stock. The warrants issued to the placement agent are exercisable at an exercise price of \$1.68 per share, became exercisable on their original issuance date and expire on October 21, 2022.

The fair value of the warrants issued to the purchasers in the offerings, based on their fair value relative to the common stock issued, was approximately \$2.4 million (based on the Black-Scholes option valuation model assuming no dividend yield, a 5.5-year life, volatility of 75.55% and a risk-free interest rate of 2.12%). The fair value of the warrants issued to the placement agent in the offerings was \$0.2 million (based on the Black-Scholes option valuation model assuming no dividend yield, a 5.0-year life, volatility of 73.25% and a risk-free interest rate of 2.06%). The Company completed an evaluation of these warrants and determined they should be classified as equity within the accompanying condensed consolidated balance sheets.

*Second October 2017 Offering*

On October 25, 2017, the Company completed an offer and sale to one accredited investor of 800,000 shares of its common stock and warrants to purchase up to 600,000 shares of its common stock, all at a purchase price of \$1.34375 per share and associated warrant. The warrants have an initial exercise price of \$1.25 per share, become exercisable on April 27, 2018 and expire on April 27, 2022. The gross proceeds of the offering were \$1.1 million and the net proceeds, after deducting the placement agent's fee and other offering fees and expenses paid or payable by the Company (and excluding the proceeds, if any, from any cash exercise of the warrants), were approximately \$1.0 million. In connection with the offering, the Company paid the placement agent (i) a cash fee equal to 5.5% of the gross proceeds of the offering, as well as offering expenses in a non-accountable sum of \$15,000, and (ii) warrants to purchase up to an aggregate of 48,000 shares of its common stock. The warrants issued to the placement agent are exercisable at an exercise price of \$1.68 per share, became exercisable on their original issuance date and expire on October 25, 2022.

The fair value of the warrants issued to the purchasers in the offering, based on their fair value relative to the common stock issued, was approximately \$0.4 million (based on the Black-Scholes option valuation model assuming no dividend yield, a 5.5-year life, volatility of 75.51% and a risk-free interest rate of 2.12%). The fair value of the warrants issued to the placement agent in the offering was \$31,000 (based on the Black-Scholes option valuation model assuming no dividend yield, a 5.0-year life, volatility of 73.22% and a risk-free interest rate of 2.06%). The Company completed an evaluation of these warrants and determined they should be classified as equity within the accompanying condensed consolidated balance sheets.

*ATM Program*

On July 25, 2017, the Company entered into an equity distribution agreement with Oppenheimer & Co. Inc. ("Oppenheimer") to commence an "at the market" offering program (the "ATM Program"), under which the Company was permitted to offer and sell, from time to time through or to Oppenheimer, acting as sales agent or principal, shares of the Company's common stock having an aggregate gross sales price of up to \$8.4 million. An aggregate of 897,311 shares of the Company's common stock were sold in the ATM Program during the three months ended October 31, 2017, for net proceeds to the Company, after deducting Oppenheimer's commissions and other expenses paid or payable by the Company, of \$1.1 million. Effective as of October 22, 2017, the Company terminated the ATM Program. As a result of such termination, no further offers or sales of the Company's common stock will be made in the ATM Program. Upon such termination, \$0.2 million in costs related to the ATM Program, previously recorded as a prepaid asset, were expensed.

*Outstanding Warrants*

At October 31, 2017, the Company had outstanding warrants to purchase 12,526,340 shares of its common stock, with exercise prices ranging from \$1.25 to \$18.00, all of which were classified as equity instruments. These warrants expire at various dates between December 2017 and May 2025. Subsequent to October 31, 2017, certain of these warrants, consisting of warrants to purchase up to an aggregate of 5,509,642 shares of the Company's common stock, were exercised in full (see Note 11).

### *Dividends*

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

## Note 7—Stock-Based Compensation

### *2011 Plan*

The OncoSec Medical Incorporated 2011 Stock Incentive Plan (as amended and approved by the Company's stockholders (the "2011 Plan")), authorizes the Company's Board of Directors to grant equity awards, including stock options and restricted stock units, to employees, directors and consultants. The 2011 Plan includes an automatic increase of the number of shares of common stock reserved thereunder on the first business day of each calendar year by the lesser of: (i) 3% of the shares of the Company's common stock outstanding as of the last day of the immediately preceding calendar year; (ii) 500,000 shares; or (iii) such lesser number of shares as determined by the Company's Board of Directors. As of October 31, 2017, there were an aggregate of 5,000,000 shares of the Company's common stock authorized for issuance pursuant to awards granted under the 2011 Plan. The 2011 Plan allows for an annual fiscal year per-individual grant of up to 500,000 shares of its common stock. Under the 2011 Plan, incentive stock options are to be granted at a price that is no less than 100% of the fair value of the Company's common stock at the date of grant. Stock options vest over a period specified in the individual option agreements entered into with grantees, and are exercisable for a maximum period of 10 years after the date of grant. Stock options granted to stockholders who own more than 10% of the outstanding stock of the Company at the time of grant must be issued at an exercise price of no less than 110% of the fair value of the Company's common stock on the date of grant.

### Stock Options

During the three months ended October 31, 2017, the Company granted options to purchase 163,500, 200,000 and 50,000 shares of its common stock to employees, directors and consultants under the 2011 Plan, respectively. The stock options issued to employees have a 10-year term, vest over three years and have exercise prices ranging from \$0.92 and \$0.96. The stock options issued to directors have a 10-year term, vest over one year and have exercise prices ranging from \$0.979 and \$1.08. The stock options issued to consultants have a 10-year term, vest in accordance with the terms of the applicable consulting agreement and have an exercise price of \$1.00 per share.

During the three months ended October 31, 2016, the Company granted options to purchase 346,500 and 310,000 shares of its common stock to employees and consultants under the 2011 Plan, respectively. The stock options issued to employees have a 10-year term, vest over three years and have exercise prices ranging from \$1.71 and \$1.94. The stock options issued to consultants have a 10-year term, vest in accordance with the terms of the applicable consulting agreement and have exercise prices ranging from \$1.74 and \$2.00 per share.

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 stock options granted pursuant to a consulting agreement, in which case the stock 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 months ended October 31, 2017 and 2016 were based on the grant date fair value estimated using the Black-Scholes option valuation model. Stock-based compensation expense related to stock options granted to consultants in which the options are not entirely vested at the grant date are generally re-measured each month.

The following assumptions were used for the Black-Scholes calculation of the fair value of stock-based compensation related to stock options granted during the periods presented:

	<b>Three Months Ended October 31, 2017</b>	<b>Three Months Ended October 31, 2016</b>
Expected volatility	74.87% - 91.80 %	91.73% - 97.10 %
Risk-free interest rate	1.66% - 1.99 %	0.82% - 1.54 %
Expected forfeiture rate	0.00 %	0.00 %
Expected dividend yield	—	—
Expected term	5.0 – 6.5 years	2.9 – 6.5 years

The Company's expected volatility is derived from the historical daily change in the market price of its common stock since its stock became available for trading, as well as the historical daily changes in the market price of its peer group, based on weighting, as determined by the Company. The Company uses the simplified method to calculate the expected term of options issued to employees and directors, and 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. For the expected dividend yield used in the Black-Scholes calculation, 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.



Stock-based compensation expense recognized in the accompanying 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 annual vesting and/or monthly vesting, the Company has estimated the forfeiture rate of its outstanding stock options as zero, as the Company can adjust stock-based compensation due to terminations in the month of termination.

Stock-based compensation expense recorded in the accompanying condensed consolidated statements of operations for the three months ended October 31, 2017 and 2016 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$0.6 million and \$1.0 million, respectively. Of this amount, \$0.2 million and \$0.3 million, respectively, was recorded to research and development and \$0.4 million and \$0.7 million, respectively, was recorded in general and administrative in the accompanying condensed consolidated statements of operations for the three months ended October 31, 2017 and 2016.

The weighted-average grant date fair value of stock options granted during the three months ended October 31, 2017 and 2016 was \$0.67 and \$1.16, respectively.

#### *Employee Stock Purchase Plan*

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 three offering periods completed under the ESPP as of October 31, 2017 have resulted in an aggregate of 58,066 shares purchased and distributed to employees. The fourth offering period commenced on August 1, 2017 and will end on January 31, 2018, and the Company estimates 18,862 shares will be purchased in this fourth offering period (assuming an \$0.88 purchase price per share, based on a 15% discount from the closing price of the Company's common stock on August 1, 2017). At October 31, 2017, taking into account the anticipated purchases in the fourth offering period, there were 423,072 shares remaining available for issuance under the ESPP.

The ESPP is considered a Type B plan under the Financial Accounting Standards Board Accounting Standards Codification Topic 718 because the number of shares a participant is permitted to purchase is not fixed based on the stock price at the beginning of the offering period and the expected withholdings. The ESPP enables the participant to "buy-up" to the plan's share limit, if the stock price is lower on the purchase date. As a result, the fair value of the awards granted under the ESPP is calculated at the beginning of each offering period as the sum of:

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

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

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

The fair market value of the six-month call and six-month put are based on the Black-Scholes option valuation model. For the fourth offering period, the following assumptions were used: six-month maturity, 0.40% risk free interest, 96.91% volatility, 0% forfeitures and \$0 dividends.

Stock-based compensation expense recorded in the accompanying condensed consolidated statements of operations for the three months ended October 31, 2017 and 2016 resulting from purchases under the ESPP was approximately \$7,000 and \$24,000, respectively, after adjusting for withdrawals and terminations.

**Note 8—Net Loss Per Share**

The Company computes basic net loss per common share by dividing the applicable net loss by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing the applicable net loss by the weighted-average number of common shares outstanding during the period plus additional shares to account for the dilutive effect of potential future issuances of common stock relating to stock options and other potentially dilutive securities using the treasury stock method. There was a net loss per share of \$0.26 and \$0.29 for the three months ended October 31, 2017 and 2016, respectively. The weighted average shares used in computing basic and diluted net loss per common share for the three months ended October 31, 2017 and 2016 were 22,318,117 and 19,020,982, respectively. There were no dividends declared.

The Company did not include shares underlying stock options, restricted stock units and warrants issued and outstanding during any of the periods presented in the computation of net loss per share, as the effect would have been anti-dilutive. The following potentially dilutive outstanding securities were excluded from diluted net loss per share because of their anti-dilutive effect:

	October 31, 2017	October 31, 2016
Stock options	3,947,709	3,840,860
Restricted stock units	1,100,000	655,000
Warrants	12,526,340	11,478,693
Total	17,574,049	15,974,553

**Note 9—Commitments and Contingencies***Contingencies*

In the ordinary course of business, the Company may become a party to lawsuits involving various matters. The Company is not currently a party, and its properties are not currently subject, to any legal proceedings that, in the opinion of management, are expected to have a material adverse effect on the Company's business, financial condition or results of operations.

*Employment Agreements*

The Company has entered into employment agreements with each of its executive officers and certain other key employees. Generally, the terms of these agreements provide that, if the Company terminates the officer or employee other than for cause, death or disability, or if the officer terminates his or her employment with the Company for good cause, the officer shall be entitled to receive certain severance compensation and benefits as described in each such agreement.

#### *Lease Agreements*

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, which serves as the Company's corporate headquarters and research and development laboratory. The term of the lease commenced on October 19, 2015 and expires on October 19, 2025, subject to certain options to extend and termination rights granted to the Company as described in the lease agreement. Base rent under the lease agreement is approximately \$90,000 per month and increases by 3% annually. The lease agreement also requires the Company to share in certain operating expenses of the premises, and required the Company to pay a security deposit of approximately \$90,000 in December 2014 upon entering into the lease agreement.

#### **Note 10—Related Party Transactions**

The Company has subleased a portion of its office space to another company. The Company's President and Chief Executive Officer and two other members of the Company's Board of Directors hold positions as directors and/or officers of the sublessee. The Company had received payments totaling \$10,500 related to the sublease for the three months ended October 31, 2017.

## Note 11—Subsequent Events

### *Leadership Restructuring*

On November 7, 2017, the Board of Directors of the Company approved (i) the appointment of Mr. Daniel J. O'Connor as the Company's new Chief Executive Officer, upon Mr. Punit Dhillon's voluntary resignation from such position, (ii) the confirmation of Mr. Dhillon to continue to serve in his current position as the Company's President, and (iii) entry into an executive employment agreement with each of Mr. O'Connor and Mr. Dhillon in connection with such appointments and confirmations. Such resignations, appointments and confirmations became effective on November 7, 2017. Mr. O'Connor and Mr. Dhillon both also serve as directors on the Board.

As a one-time grant in connection with his appointment as Chief Executive Officer, Mr. O'Connor received an option award to purchase up to 2,000,000 shares of the Company's common stock, contingent upon obtaining the approval of the Company's stockholders at its next annual meeting, at an exercise price of \$1.25 per share. In addition, Mr. O'Connor received a performance stock option award to purchase up to 500,000 shares of the Company's common stock, which is contingent upon obtaining the approval of the Company's stockholders at its next annual meeting, has an exercise price of \$1.25 per share, and is subject to vesting as to 250,000 of such shares on the date of the Company's achievement of 100% enrollment in its PISCES study and as to the remaining 250,000 of such shares in one installment on the one-year anniversary of the date of achievement of such enrollment.

### *November 2017 Warrant Exercise Inducement Offering*

On November 13, 2017, the Company entered into a Warrant Exercise Agreement (the "Exercise Agreement") with certain holders (the "Exercising Holders") of outstanding warrants (the "Original Warrants") to purchase up to an aggregate of 5,509,642 shares of the Company's common stock at an exercise price of \$1.69 per share. Pursuant to the terms of the Exercise Agreement, each Exercising Holder agreed to exercise, from time to time and in accordance with the terms of the Original Warrants, including certain beneficial ownership limitations set forth therein, all Original Warrants held by it for cash. As a result of the exercise of all of the Original Warrants, the Company received gross proceeds of approximately \$9.3 million and net proceeds, after deducting estimated expenses paid or payable by the Company, of approximately \$9.1 million.

Pursuant to the terms of the Exercise Agreement, and in order to induce each Exercising Holder to exercise its Original Warrants, the Company offered and sold to each Exercising Holder new warrants (the "New Warrants") to purchase a number of shares of its common stock equal to 25% of the number of shares of common stock received by such Exercising Holder upon the cash exercise of its Original Warrants. The terms of the New Warrants are

substantially similar to the terms of the Original Warrants, except that the New Warrants (i) have an initial exercise price of \$2.26 per share; (ii) become exercisable on May 13, 2018 and expire November 13, 2019, and (iii) contain certain additional transfer restrictions and limitations due to their offer and sale in a private placement offering.

Also on November 13, 2017, and in connection with its entry into the Exercise Agreement, the Company agreed to issue warrants (the "October 2017 Investor Warrants") to purchase up to an aggregate of 1,138,300 shares of its common stock to the accredited investors that participated in the Company's offerings completed in October 2017 (see Note 6) (such investors, the "October 2017 Investors"), in consideration for such investors' agreement to waive certain covenants made by the Company to such investors and as an inducement to such investors to exercise certain other warrants to purchase the Company's common stock. The terms of the October 2017 Investor Warrants are substantially similar to the terms of the New Warrants, except that the October 2017 Investor Warrants will become exercisable only if and when each October 2017 Investor exercises in full and for cash the warrants to purchase the Company's common stock that were sold to such investors in the Company's offerings completed in October 2017.

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

*Unless the context indicates otherwise, all references to "OncoSec," "our company," "we," "us" and "our" in this report refer to OncoSec Medical Incorporated and its consolidated subsidiary. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes included in this report.*

*This discussion and analysis of our financial condition and results of operations is not a complete description of our business or the risks associated with an investment in our common stock. As a result, this discussion and analysis should be read together with our condensed consolidated financial statements and related notes included in this report, as well as the other disclosures in this report and in the other documents we file from time to time with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for our fiscal year ended July 31, 2017 filed with the SEC on October 25, 2017, or the Annual Report. Pursuant to Instruction 2 to paragraph (b) of Item 303 of Regulation S-K promulgated by the SEC, in preparing this discussion and analysis, we have presumed that readers have access to and have read the discussion and analysis of our financial condition and results of operations included in the Annual Report.*

*This discussion and analysis and the other disclosures in this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. Forward-looking statements relate to future events or circumstances or our future performance and are based on our current assumptions, expectations and beliefs about future developments and their potential effect on our business. All statements in this report that are not statements of historical fact could be forward-looking statements. The forward-looking statements in this discussion and analysis include statements about, among other things, the status, progress and results of our clinical programs and our expectations regarding our liquidity and performance, including our expense levels, sources of capital and ability to maintain our operations as a going concern. Forward-looking statements are only predictions and are not guarantees of future performance, and they are subject to known and unknown risks, uncertainties and other factors, including the risks described under "Risk Factors" in Part II, Item IA of this report and similar discussions contained in the other documents we file from time to time with the SEC. In light of these risks, uncertainties and other factors, the forward-looking events and circumstances described in this report may not occur and our results, levels of activity, performance or achievements could differ materially from those expressed in or implied by any forward-looking statements we make. As a result, you should not place undue reliance on any of our forward-looking statements. Forward-looking statements speak only as of the date they are made, and unless required to by law, we undertake no obligation to update or revise any forward-looking statement for any reason, including to reflect new information, future developments, actual results or changes in our expectations.*

### **Overview**

***Our Company***

We are a biotechnology company focused on designing, developing and commercializing innovative therapies and proprietary medical approaches to stimulate and guide an anti-tumor immune response for the treatment of cancer. Our core platform technology, ImmunoPulse®, is a drug-device therapeutic modality comprised of a proprietary intratumoral electroporation delivery device. The ImmunoPulse® platform is designed to deliver DNA-encoded drugs directly into a solid tumor and promote an inflammatory response against cancer. The ImmunoPulse® device can be adapted to treat different tumor and tissue types, and consists of an electrical pulse generator, a reusable handle and disposable applicators. Our lead product candidate, ImmunoPulse® IL-12, uses our electroporation device to deliver a DNA-encoded interleukin-12, or IL-12, called tavokinogene telseplasmid, or tavo, with the aim of reversing the immunosuppressive microenvironment in the treated tumor and engendering a systemic anti-tumor response against both the treated tumor and untreated distal tumors. In February 2017, we received Fast Track designation from the U.S. Food and Drug Administration, or FDA, for ImmunoPulse® IL-12, which could qualify ImmunoPulse® IL-12 for expedited FDA review, a rolling Biologics License Application review and certain other benefits.



Our current focus is to pursue our registration-directed study of ImmunoPulse® IL-12 in combination with an approved therapy for melanoma in patients who have shown refractory or relapse from certain other cancer therapies, which we refer to as the PISCES/KEYNOTE-695 study. Most of our present activities are, and we expect most of our near-term expenditures will be, directed toward advancing the PISCES/KEYNOTE-695 study. To this end, in May 2017, we entered into a clinical trial collaboration and supply agreement with a subsidiary of Merck & Co., Inc., or Merck, in connection with the PISCES/KEYNOTE-695 study, in which we have agreed to sponsor and fund the study and Merck has agreed to manufacture and supply its anti-PD-1 therapy KEYTRUDA® for use in the study. The PISCES/KEYNOTE-695 study opened for enrollment in October 2017.

We also intend to continue to pursue other ongoing or potential new trials and studies related to ImmunoPulse® IL-12, all with the goal of obtaining requisite regulatory approvals from the FDA and comparable regulators in certain other jurisdictions to market and sell this product candidate. For instance, we are in collaboration with the University of California, San Francisco, or UCSF, the sponsor of a multi-center Phase II clinical trial evaluating ImmunoPulse® IL-12 in combination with Merck's KEYTRUDA® for the treatment of advanced, metastatic melanoma in patients who are predicted to not respond to anti-PD-1 therapy alone. Merck is manufacturing and supplying its drug KEYTRUDA® to UCSF to support this trial. Recent data presented at the October 2017 Society for Melanoma Research indicated that 50% of the patients treated had an overall response to the combination therapy and that the therapy was well tolerated. Further clinical and biomarker data, presented at the SITC meeting in November 2017, demonstrated that the response rate was durable and the progression free survival was 57% at 15 months. Mechanistically, this was due to a re-stimulation of anti-tumor immunity in the tumor microenvironment. Data suggest that IT-tavo-EP monotherapy triggers key immunologic events that are then enhanced with the addition of an anti-PD-1 antibody; combined, we believe this enables a coordinated innate and adaptive immune response. In addition, we are pursuing a biomarker-focused pilot study of ImmunoPulse® IL-12 in triple negative breast cancer, which is focused on evaluating the ability of ImmunoPulse® IL-12 to alter the tumor microenvironment and promote a pro-inflammatory response. In January 2017, we amended the clinical protocol for this study to improve the enrollment rate, as it had been slow to enroll, and in September 2017, we enrolled half the patients needed for the study and is ongoing. Additionally, our Phase II clinical trials of ImmunoPulse® IL-12 as a monotherapy in Merkel Cell carcinoma, melanoma, and head and neck squamous cell carcinoma are now closed and clinical study reports are filed. The Company is no longer pursuing its Phase II clinical trial of ImmunoPulse® IL-12 as a monotherapy in cutaneous T-cell lymphoma, which has been closed.

In addition, we are developing our next-generation electroporation devices, including advancements toward prototypes and pursuing discovery research to identify other product candidates that, like IL-12, can be encoded into DNA and delivered intratumorally or into other tissues using electroporation to augment anti-tumor immune response by reversing immunosuppressive mechanisms and/or enhancing effector function, all with the aim of expanding our ImmunoPulse® pipeline beyond the delivery of plasmid-DNA encoding for cytokines.

### ***Performance Outlook***

We expect to use our available working capital in the near term primarily for the advancement of our existing and planned clinical programs, including primarily the initiation of the PISCES/KEYNOTE-695 study and, to a lesser extent, the continuation of our other clinical trials and studies described above. We anticipate our spending on clinical programs and the development of our next-generation electroporation device for our ImmunoPulse® IL-12 platform will increase throughout our current fiscal year, primarily in support of the PISCES/KEYNOTE-695 study, while our spending on research and development programs will decrease due to our focus on the PISCES/KEYNOTE-695 study. We expect our cash-based general and administrative expenses to remain relatively flat in the near term, as we seek to continue to leverage internal resources and automate processes to decrease our outside services expenses. See “Results of Operations” below for more information.

### *Liquidity*

As of October 31, 2017, we had cash and cash equivalents of approximately \$14.7 million and, subsequent to October 31, 2017, we received additional net proceeds of approximately \$9.1 million from the exercise of certain warrants. As of November 30, 2017, we had cash and cash equivalents of \$21.4 million. However, we have sustained losses in all reporting periods since inception, including a net loss of \$5.9 million and \$5.6 million for the three months ended October 31, 2017 and 2016, respectively, and an inception-to date-loss of \$100.8 million as of October 31, 2017. Further, we have never generated any cash from our operations, we do not expect to generate such cash in the near term, and we do not presently have any firm commitments for future capital. Consequently, we will need significant additional capital to continue operating our business. See “Liquidity and Capital Resources” below for more information.

## Results of Operations

The following table and subsequent discussion summarize our results of operations for each of the periods presented:

	<b>October 31, 2017 (\$)</b>	October 31, 2016 (\$)	Increase/ (Decrease) (\$)	Increase/ (Decrease) %
Revenue	—	—	—	—
Operating expenses				
Research and development	3,413,151	3,099,739	313,412	10
General and administrative	2,514,037	2,548,573	(34,536)	(1)
Loss from operations	(5,927,188)	(5,648,312)	278,876	5
Other income (expense), net	26,736	46,118	(19,382)	(42)
Loss before income tax	(5,900,452)	(5,602,194)	298,258	5
Provision for income taxes	—	1,391	(1,391)	(100)
Net loss	(5,900,452)	(5,603,585)	296,867	5

### *Revenue*

We have not generated any revenue since our inception, and we do not anticipate generating meaningful, or any, revenue in the near term.

### *Research and Development Expenses*

Our research and development expenses primarily include expenses related to the development of our therapeutic product candidates, including ImmunoPulse® IL-12, the advancement of electroporation technologies and research and development related to identification and discovery of potential new product candidates. These expenses also include certain clinical study costs, intellectual property prosecution and maintenance costs and quality assurance expenses. These expenses primarily consist of costs for salaries, benefits, stock-based compensation, outside design and consulting services, engineering and laboratory supplies, contract research organization services and clinical study supplies. We expense all research and development costs in the periods in which they are incurred, except for certain costs of materials to be used in future clinical trials, which are expensed when used in a clinical trial. As of October 31, 2017, \$0.7 million of costs related to clinical trial materials for our PISCES/KEYNOTE-695 study were recorded as a prepaid asset, and we anticipate these costs will be expensed when used in the PISCES/KEYNOTE-695 study.

Our research and development expenses increased by \$0.3 million, from \$3.1 million in the three months ended October 31, 2016 to \$3.4 million in the three months ended October 31, 2017. This increase was primarily due to increases of (i) \$0.4 million in engineering and product development costs related to development of our next-generation electroporation device and (ii) \$0.5 million in pharmaceutical material costs related to our PISCES/KEYNOTE-695 study, partially offset by decreases of (iii) \$0.2 million in payroll-related expenses related to decreased headcount, (iv) \$0.2 million in clinical study expenses related to completion of or reduced activity for certain of our clinical studies as we prepare to commence the PISCES/KEYNOTE-695 study (costs for which have not yet increased significantly, as we do not expect enrollment to commence until the second quarter of our current fiscal year), and (v) \$0.2 million in stock-based compensation expense related to a reduction in headcount.

### ***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 primarily consist of costs for salaries, benefits, stock-based compensation, independent auditor services, legal services, outside consulting services, travel, insurance, and public company compliance, such as stock transfer agent services and the listing of our common stock on a national securities exchange.

Our general and administrative expenses remained relatively flat between periods, decreasing by \$30,000 from \$2.5 million in the three months ended October 31, 2016 to \$2.5 million in the three months ended October 31, 2017. This small decrease was primarily due to a decrease of \$0.4 million in stock-based compensation expense related to a reduction in headcount, mainly offset by an increase of \$0.4 million in fees for outside consulting services related to business development, investor relation and product commercialization activities.

### ***Other Income (Expense), Net***

Other income (expense), net, was not significant in the three months ended October 31, 2017 or 2016. The primary component of other income (expense), net, in the three months ended October 31, 2017 and 2016 was interest income.

### ***Provision for Income Taxes***

We did not record an income tax provision in the three months ended October 31, 2017 and \$1,391 in the three months ended October 31, 2016 comprised solely of minimum state taxes because we have calculated a net tax loss in both periods.

### **Liquidity and Capital Resources**

#### ***Working Capital***

The following table and subsequent discussion summarize our working capital as of each of the periods presented:

	At October 31, 2017 (\$)	At July 31, 2017 (\$)
Current assets	16,080,644	12,513,623
Current liabilities	4,012,281	3,395,974
Working capital	12,086,363	9,117,649

#### *Current Assets*

Current assets as of October 31, 2017 increased to \$16.1 million, from \$12.5 million as of July 31, 2017. This increase was primarily due to an increase in cash from \$11.4 million as of July 31, 2017 to \$14.7 million as of October 31, 2017, which is attributable to the net proceeds received from our equity offerings completed in the three months ended October 31, 2017 (see “—Sources of Capital” below).

#### *Current Liabilities*

Current liabilities as of October 31, 2017 increased to \$4.0 million, from \$3.4 million as of July 31, 2017. This increase was primarily due to an increase in accrued expenses for research-related manufacturing activities to support the PISCES/KEYNOTE-695 study.

## ***Cash Flow***

### ***Cash Used in Operating Activities***

Net cash used in operating activities for the three months ended October 31, 2017 was \$5.1 million, as compared to \$4.4 million for the three months ended October 31, 2016. The \$0.7 million increase was primarily attributable to increased cash used for research-related manufacturing activities to support the PISCES/KEYNOTE-695 study, as well as increased facility rent as a result of the expiration of a rent abatement under the terms of the lease agreement for our corporate headquarters and laboratory space.

### ***Cash Used in Investing Activities***

Net cash used in investing activities for the three months ended October 31, 2017 was \$0, as compared to \$10,000 for the three months ended October 31, 2016. The decrease was primarily attributable to decreased property and equipment acquisition costs because our laboratory space is now being fully equipped.

### ***Cash Provided by Financing Activities***

Net cash provided by financing activities was \$8.3 million for the three months ended October 31, 2017, as compared to \$39,000 for the three months ended October 31, 2016. The increase was primarily attributable to the net proceeds received from our equity offerings completed in the three months ended October 31, 2017 (see “—Sources of Capital” below).

### ***Uses of Cash and Cash Requirements***

Our primary uses of cash have been to finance clinical and research and development activities focused on the identification and discovery new potential product candidates, the development of innovative and proprietary medical approaches for the treatment of cancer, and the design and advancement of pre-clinical and clinical trials and studies related to our pipeline of product candidates. We have also used our capital resources on general and administrative activities, including building and strengthening our corporate infrastructure, programs and procedures to enable compliance with applicable federal, state and local laws and regulations.

Our primary objectives for the next 12 months are to continue the advancement of our PISCES study and, to a lesser extent, our other ongoing clinical trials and studies, and to continue our research and development activities for our next-generation electroporation device and drug discovery efforts. In addition, we expect to pursue capital-raising transactions, which could include equity or debt financings, in the near term to fund our existing and planned operations and acquire and develop additional assets and technology consistent with our business objectives as opportunities arise.

We currently estimate our operating expenses and working capital requirements for our current fiscal year ending July 31, 2018 to be approximately \$21.0 million, although we may modify or deviate from this estimate and it is likely that our actual operating expenses and working capital requirements will vary from our estimate. Based on these expectations regarding future expenses, as well as our current cash levels and rate of cash consumption, we believe our cash resources are sufficient to meet our anticipated needs for the 12 months following the issuance of this report. We will continue to assess our cash resources and anticipated needs on a quarterly basis.



### *Sources of Capital*

We have not generated any revenue since our inception, and we do not anticipate generating meaningful, or any, revenue in the near term. Historically, we have raised the majority of the funding for our business through offerings of our common stock and warrants to purchase our common stock. Although we are exploring other ways of funding our operations that involve less dilution to our existing stockholders, including, among others, technology licensing or other collaboration arrangements, debt financings or grants, we have not successfully established or raised any funds through any of these types of arrangements, and we may need to continue to seek funding for our operations through additional dilutive public or private equity financings. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders would 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, our fixed payment obligations, liabilities and leverage relative to our equity capitalization would increase, which could increase the cost of future capital. Further, the terms of any debt securities we issue or borrowings we incur, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity or other operating restrictions that could adversely affect our ability to conduct our business, and any such debt could be secured by any or all of our assets pledged as collateral. Additionally, we may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other costs.

Moreover, equity or debt financings or any other source of capital may not be available to us when needed or at all, or, if available, may not be available on commercially reasonable terms. Weak economic and capital market conditions generally or uncertain conditions in our industry could increase the challenges we face in raising capital for our operations. In recent periods, the capital and financial markets for early and development-stage biotechnology and life science company stocks have been volatile and uncertain. If we cannot raise the funds that we need, we could be forced to delay or scale down some or all of our development activities or cease all operations, and our stockholders could lose all of their investment in our Company.

### *November 2017 Warrant Exercise Inducement Offering*

On November 13, 2017, we entered into a warrant exercise agreement with certain holders of outstanding warrants to purchase up to an aggregate of 5,509,642 shares of our common stock at an exercise price of \$1.69 per share, pursuant to which such holders agreed to exercise all such warrants held by them for cash, in exchange for our offer and sale to such holders, as an inducement to such exercise, of new warrants to purchase an aggregate of up to 1,377,411 shares of our common stock. The new warrants have an initial exercise price of \$2.26 per share, become exercisable on May 13, 2018 and expire on November 13, 2019. As a result of the exercise of all of the outstanding warrants, we received gross proceeds of approximately \$9.3 million and net proceeds, after deducting estimated expenses paid or payable by us, of approximately \$9.1 million. Also on November 13, 2017, and in connection with the warrant exercise agreement, we issued warrants to purchase up to an aggregate of 1,138,300 shares of our common stock to the investors that participated in our October 2017 offerings (described below), in consideration for such investors'

agreement to waive certain covenants we made to such investors. These warrants are substantially similar to the exercise inducement warrants described above, except that they will become exercisable only if and when the warrants we issued and sold in the October 2017 offerings are exercised in full and for cash.

#### *October 2017 Offerings*

On October 25, 2017, we completed our offer and sale to certain accredited investors of, in a registered public offering, 5,270,934 shares of our common stock and, in a concurrent private placement, warrants to purchase an aggregate of up to 3,953,200 shares of our common stock, all at a purchase price of \$1.34375 per share. The warrants have an initial exercise price of \$1.25 per share, became exercisable on October 25, 2017 and expire on April 25, 2022. The gross proceeds of the offering were \$7.1 million and the net proceeds, after deducting the placement agent's fees and other estimated offering expenses paid or payable by us (and excluding the proceeds, if any, from any cash exercise of the warrants), were \$6.2 million. At the closing of the offerings, we also issued warrants to purchase up to an aggregate of 316,256 shares of our common stock to the placement agent for the offerings, which have an exercise price of \$1.68, are immediately exercisable and expire on October 21, 2022.

On October 27, 2017, we completed our offer and sale to one accredited investor of our offer and sale, in a registered public offering, of 800,000 shares of our common stock and warrants to purchase up to 600,000 shares of our common stock, all at a purchase price of \$1.34375 per share. The warrants have an initial exercise price of \$1.25 per share, become exercisable on April 27, 2018 and expire on April 27, 2022. The gross proceeds of the offering were \$1.1 million and the net proceeds, after deducting the placement agent's fees and other estimated offering expenses paid or payable by us (and excluding the proceeds, if any, from any cash exercise of the warrants), were approximately \$1.0 million. At the closing of the offering, we also issued warrants to purchase up to an aggregate of 48,000 shares of our common stock to the placement agent for the offerings, which have an exercise price of \$1.68, are immediately exercisable and expire on October 25, 2022.

### *ATM Program*

On July 25, 2017, we entered into an equity distribution agreement with Oppenheimer & Co. Inc., or Oppenheimer, to commence an “at the market” offering program, or the ATM Program, under which we were permitted to offer and sell, from time to time through or to Oppenheimer, acting as sales agent or principal, shares of our common stock having an aggregate gross sales price of up to \$8.4 million. An aggregate of 897,311 shares of our common stock were sold in the ATM Program during the three months ended October 31, 2017, for net proceeds to us, after deducting Oppenheimer’s commissions and other expenses paid or payable by us, of \$1.1 million. Effective as of October 22, 2017, we terminated the ATM Program. As a result of such termination, no further offers or sales of our common stock will be made in the ATM Program.

### *Warrant Exercises*

During the three months ended October 31, 2017, we received an immaterial amount of cash related to the exercise of outstanding warrants, and subsequent to October 31, 2017, we received gross proceeds of \$9.3 million from the exercise of outstanding warrants (see “—November 2017 Warrant Exercise Inducement Offering” above). If the holders of all of our warrants that are outstanding as of the issuance of this report were to exercise all such warrants in full on a cash basis, we would receive an aggregate of approximately \$27.4 million in net proceeds. However, the holders of these warrants may choose to exercise only a portion of the warrants they hold, may choose not to exercise any of the warrants they hold, or may choose to “net” exercise their warrants on a cashless basis to the extent permitted by the warrants. As a result, we may never receive meaningful, or any, proceeds from the exercise of these warrants.

## **Critical Accounting Policies**

### *Accounting for Long-Lived Assets*

We assess the impairment of long-lived assets, consisting of property and equipment, periodically and whenever events or circumstances indicate that the carrying value may not be recoverable. Examples of such circumstances may include: (1) the asset’s ability to continue to generate income from operations and positive cash flow in future periods; (2) loss of legal ownership or title to an asset; (3) significant changes in our strategic business objectives and utilization of the assets; and (4) the impact of significant negative industry or economic trends. If a change were to occur in any of these or similar factors, the likelihood of a material change in our net loss would increase.

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. Although we believe the factors used by management to evaluate future net cash flows are reasonable, this evaluation requires a high degree of judgment, and results could vary if the actual amounts are materially different than management's estimates. In addition, we base estimates of useful lives and related amortization or depreciation expense on our subjective estimate of the period the assets will generate revenue or otherwise be used by us. If long-lived 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.

### ***Stock-Based Compensation***

#### *Equity-Based Awards*

We grant equity-based awards (typically stock options or restricted stock units) under our stock-based compensation plan and outside of our stock-based compensation plan, with terms generally similar to the terms under our stock-based compensation plan. We estimate the fair value of stock option 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 options granted to non-employees are re-measured at each reporting period until fully vested, with any change in fair value expensed. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

We estimate the fair value of restricted stock unit awards based on the closing price of our common stock on the date of grant.

We have issued equity for services or as consideration pursuant to various types of contractual arrangements. Stock-based compensation expense related to such equity issuances is based on the closing price of our stock on the date the liability is incurred, with the stock-based compensation expense adjusted at each reporting period based on our stock price on that date.

#### *Employee Stock Purchase Plan*

Employees may elect to participate in our stockholder approved employee stock purchase plan. The stock purchase plan allows for the purchase of our common stock at not less than 85% of the lesser of (i) the fair market value of a share of stock on the beginning date of the offering period or (ii) the fair market value of a share of stock on the purchase date of the offering period, subject to a share and dollar limit as defined in the plan and subject to the applicable legal requirements. There are two 6-month offering periods during each fiscal year, ending on January 31 and July 31. In accordance with applicable accounting guidance, the fair value of awards under the stock purchase plan is calculated at the beginning of each offering period. 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 beginning of the offering period. Stock-based compensation expense is based on awards expected to be purchased at the beginning of the offering period, and therefore is reduced when participants withdraw during the offering period.

#### *Recent Accounting Pronouncements*

Information regarding recent accounting pronouncements is contained in Note 2 to our condensed consolidated financial statements included in this report.

#### **Off-Balance Sheet Arrangements**

We do not have any 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 investors.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Not applicable.

### **ITEM 4. CONTROLS AND PROCEDURES.**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended, or Exchange Act, is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, or the SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer), as appropriate, 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. In addition, the design of disclosure controls and procedures reflects the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of October 31, 2017. Based on such evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of October 31, 2017, our disclosure controls and procedures were effective.

#### **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting during our fiscal quarter ended October 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II—OTHER INFORMATION**

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

In the ordinary course of business, we may become a party to lawsuits involving various matters. 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, and our properties are not currently subject, to any legal proceedings that, in the opinion of management, are expected to have a material adverse effect on our business, financial condition or results of operations.

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

*Investing in our securities involves a high degree of risk. You should carefully consider each of the following risks and all of the other information contained in this report and the other documents we file with the SEC before making any investment decision with respect to our securities. If any of the risks described below materialize, our business, financial condition, results of operations, prospects or stock price could be materially and adversely affected. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us may also materially and adversely affect our business operations and financial condition or the price of our common stock.*

#### **Risks Related to Our Business**

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

We have not generated any revenue from our operations since our inception, and we do not anticipate generating meaningful, or any, revenue in the near term. During the quarter ended October 31, 2017, we incurred a net loss of \$5.9 million, and from inception through October 31, 2017, we have incurred an aggregate net loss of \$100.8 million. We will need significant additional funding to continue our operations and pursue our strategic plans, including continued development of ImmunoPulse® IL-12. Although we have been and expect to continue to tightly manage our operating expenses, we expect our cumulative operating expenses will continue to increase as we further our development activities and pursue approval by the U.S. Food and Drug Administration, or FDA, for one or more of our product candidates.

Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, many of which are discussed in these risk factors, we are unable to predict the extent of our future losses or when or if we will generate meaningful revenue or become profitable, and it is possible we will never achieve these goals. Our failure to develop our investments in our proprietary technologies and product candidates into revenue-generating operations 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 have limited working capital and a history of losses, which raises substantial doubt as to whether we will be able to continue as a going concern.***

We anticipate that, based on the amount of cash we have on hand (taking into account the aggregate net proceeds from our October and November 2017 equity financings) and our current rate of cash consumption, we could continue operations for the 12 months following the issuance of this report without a significant change in our business plan or reduction in spending. However, we will need additional capital after that time to maintain our current level of operations or before that time to ramp up development or other efforts. As a result, our ability to continue as a going concern will depend upon the availability and terms of future funding. We will continue to assess our cash resources and anticipated needs on a quarterly basis.

Our ability to obtain additional financing will depend on a number of factors, including, among others, our ability to generate positive data from our clinical and pre-clinical studies, the condition of the capital markets and the other risks described in these risk factors. If any one of these factors is unfavorable, we may not be able to obtain additional funding, in which case, our business could be jeopardized and we may not be able to continue our operations or pursue our strategic plans. If we are forced to scale down, limit or cease operations, our stockholders could lose all of their investment in our Company.



***We will need to raise additional capital to continue operating our business, and additional funds may not be available when needed, on acceptable terms or at all.***

As of October 31, 2017, we had cash and cash equivalents of approximately \$14.7 million and, subsequent to October 31, 2017, we received additional net proceeds of approximately \$9.1 million from the exercise of certain warrants. As of November 30, 2017, we had cash and cash equivalents of \$21.4 million. We currently estimate our operating expenses and working capital requirements for our current fiscal year ending July 31, 2018 to be approximately \$21.0 million. As a result, we believe, based on our current cash levels, rate of cash consumption and expectations regarding future expenses, that our cash resources are sufficient to meet our anticipated needs for the 12 months following the issuance of this report. We will continue to assess our cash resources and anticipated needs on a quarterly basis.

However, we have sustained losses in all reporting periods since inception, with an inception-to-date-loss of \$100.8 million as of October 31, 2017. Further, we have never generated any cash from our operations, we do not expect to generate such cash in the near term, and we do not presently have any firm commitments for future capital. Consequently, we will need significant additional capital to continue operating our business and fund our planned operations.

Historically, we have raised the majority of the funding for our business through offerings of our common stock and warrants to purchase our common stock, including our October and November 2017 equity financings. Although we are exploring other ways of funding our operations that involve less dilution to our existing stockholders, including, among others, technology licensing or other collaboration arrangements, debt financings or grants, we have not successfully established or raised any funds through any of these types of arrangements, and we may need to continue to seek funding for our operations through additional dilutive public or private equity financings.

If we issue equity or convertible debt securities to raise additional funds, our existing stockholders would 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, our fixed payment obligations, liabilities and leverage relative to our equity capitalization would increase, which could increase the cost of future capital. Further, the terms of any debt securities we issue or borrowings we incur, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity or other operating restrictions that could adversely affect our ability to conduct our business, and any such debt could be secured by any or all of our assets pledged as collateral. Additionally, we may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other costs.

Moreover, equity or debt financings or any other source of capital may not be available to us when needed or at all, or, if available, may not be available on commercially reasonable terms. Weak economic and capital market conditions generally or uncertain conditions in our industry could increase the challenges we face in raising capital for our

operations. In recent periods, the capital and financial markets for early and development-stage biotechnology and life science company stocks have been volatile and uncertain. If we cannot raise the funds that we need, we could be forced to delay or scale down some or all of our development activities or cease all operations, and our stockholders could lose all of their investment in our Company.

***We are an early-stage, pre-commercial company with a limited operating history and no commercially available or approved products, which makes assessment of our future viability difficult and which may hinder our ability to generate revenue and meet our other 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 pursuing several oncology product candidates, our primary product candidate, ImmunoPulse® IL-12, is in two Phase II combination clinical trials. As a result, none of our product candidates are near commercial availability. Additionally, although we are investigating licensing and partnering opportunities, no such opportunities have been finalized and, even if completed, we do not expect that these potential opportunities would generate any significant near-term revenue. Our operations to date have been limited to organizing, staffing and financing, applying for patent rights, undertaking clinical trials of ImmunoPulse® IL-12 and engaging in other research and development activities, including pre-clinical and other studies of our other product candidates. We have not demonstrated an ability to obtain regulatory approval of a product candidate, manufacture commercial-scale products, or conduct the sales and marketing activities necessary for successful product commercialization. Consequently, the revenue-generating potential of our business is unproven and uncertain.

In addition, because of our short operating history, we have limited insight into trends that may emerge and affect our business or our industry. We will be subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets, and we may not be able to successfully address any or all of these risks and uncertainties. Further, errors may be made in predicting and reacting to relevant business or industry trends. The occurrence of any of these risks could cause our business, results of operations, and financial condition to suffer or fail.

***We are significantly dependent on the success of our ImmunoPulse® technology platform and our product candidates based on this platform, including our lead product candidate ImmunoPulse® IL-12.***

We have invested, and we expect to continue to invest, significant efforts and financial resources in the development of product candidates based on our ImmunoPulse® technology, including primarily our lead primary product candidate ImmunoPulse® IL-12. Our ability to generate revenue, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and commercialization of one or more of these product candidates.

The success of ImmunoPulse® IL-12 or any other product candidates based on our ImmunoPulse® technology will depend on a number of factors, including, among others:

our ability to conduct and complete pre-clinical and clinical studies and trials, including the time, costs and uncertainties associated with all aspects of these trials;

the data we obtain from pre-clinical and clinical testing of the product candidates, including data demonstrating the required level of safety and efficacy of the product candidates (for example, a key factor in determining whether we are able to successfully develop and commercialize our ImmunoPulse® IL-2 platform in melanoma will be the data we obtain from our PISCES/KEYNOTE-695 study, which is our planned registration-directed study of ImmunoPulse® IL-12 in combination with Merck & Co., Inc.'s, or Merck's, approved therapy for melanoma in patients who have shown resistance to or relapse from certain other cancer therapies);

the regulatory approval pathway we choose to pursue for our product candidates in the United States or any other jurisdiction;

our ability to obtain required regulatory approvals for one or more of our product candidates in the United States and in other jurisdictions, and the time required to obtain these approvals;

the manufacturing arrangements we are able to establish with third-party manufacturers, both for the manufacture of the product candidates for clinical trial use and for the manufacture of products, if and when approved, on a commercial basis;

our ability to build an infrastructure capable of supporting product sales, marketing and distribution of any approved products in territories where we pursue commercialization directly;

our ability to establish commercial distribution agreements with third-party distributors for any approved products in territories where we do not pursue commercialization directly;

the labeling requirements for any product candidates that are approved, including obtaining sufficiently broad labels that would not unduly restrict patient access;

acceptance of our products, if and when approved, by patients and the medical community;

the ability of our products, if and when approved, to effectively compete with other cancer treatments;

a continued acceptable safety profile of any product candidates that are approved following such approval;

our level of success in obtaining and maintaining patent and trade secret protection and otherwise protecting our rights in our intellectual property portfolio;

the levels of coverage and reimbursement we are able to secure for any product candidates that receive regulatory approval;

our ability to establish a commercially viable price for our products, if and when approved; and

delays or unanticipated costs, including those related to any of the foregoing.

If one or more of these factors is unfavorable, we could experience significant delays or we may not be able to successfully commercialize ImmunoPulse® IL-12 or any of our other product candidates, which would materially harm our business.

***It may be difficult to identify and enroll metastatic melanoma patients due to clinical trial inclusion-exclusion criteria or other factors, which has in the past, and may in the future, lead to delays in enrollment and in generating clinical data for our trials.***

Our PISCES/KEYNOTE-695 study, along with our other clinical trials, has strict inclusion criteria for patient enrollment. These criteria could present significant obstacles to the timely recruitment and enrollment of a sufficient number of eligible patients into our trials. For example, we experienced slower than expected patient enrollment in our triple negative breast cancer clinical trial, and we may experience similar delays in any of our other existing or future clinical trials. Any inability to successfully enroll the number of patients meeting the criteria for any of our clinical trials could cause significant delays in the trial and increase the costs associated with the trial, which could materially harm our business and prospects.

Patient enrollment in a clinical trial may be affected by many factors, including:

the severity of the disease under investigation;

the design of the study protocol;

the eligibility criteria for the study;

the perceived risks, benefits and convenience of administration of the product candidate being studied;

the competitive disease space with many trials for patients to select from;

the patient referral practices of physicians; and

the proximity and availability of clinical trial sites to prospective patients.

***Certain characteristics of our ImmunoPulse® platform may negatively impact market acceptance of the platform.***

Physicians, patients, and third-party payors may be less accepting of product candidates based on our ImmunoPulse® technology platform due to certain characteristics of this platform. For example, these parties may have concerns about the complexity inherent in a combination therapy approach or the clinical application of electroporation technology, which is less prevalent in the United States than in certain foreign markets. Moreover, our efforts to educate the medical community and third-party payors about the benefits of any of our technologies and product candidates may require significant resources and may never be successful. As a result, even if any of our product candidates achieve regulatory approval, a lack of acceptance by physicians, third-party payors and patients of the products or underlying technologies could prevent their successful commercialization and could materially limit our revenue potential.

***If the commencement or completion of clinical testing for our product candidates is delayed or prevented, we could experience significantly increased costs and our ability to pursue regulatory approval or generate revenue could be delayed or limited.***

Clinical trials are very expensive, time-consuming, unpredictable and difficult to design and implement. Even if we are able to complete our ongoing and currently proposed clinical trials and assuming 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. Even with the Fast Track designation we received from the FDA for ImmunoPulse® IL-12 in February 2017, Phase II and Phase III clinical trials, which can take many years to complete, are still required.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs and business plan. Our PISCES/KEYNOTE-695 study opened to enrollment in October 2017 and is expected to complete enrollment in the 2018 calendar year, but we do not know and cannot predict whether this study, or any of our other ongoing trials or studies, will be completed on schedule or at all. We also do not know and cannot predict whether any other pre-clinical or clinical trials, including Phase III clinical trials to follow completion of the PISCES/KEYNOTE-695 study or our ongoing or any other Phase II clinical trials, will be planned or will begin, and in many cases such future trials would be dependent on obtaining favorable results from preceding studies.

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

obtaining clearance from the FDA or comparable international regulatory body and other applicable agencies, including the U.S. National Institutes of Health, 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, and institutional biological committee, or IBC, 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, which can pose challenges for a variety of reasons, including competition from other clinical trial programs for similar indications, requirements for larger than anticipated patient populations, slower than expected enrollment, or higher than predicted rates of patient drop-out or withdrawal;

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.

With respect to any clinical trial we plan, the FDA could determine it is not satisfied with our plan or the details of our clinical trial protocols and designs and could put a clinical hold on the proposed trials. Any such determination could delay the commencement of the trials and would be a setback for the commercialization strategy for the product candidate that is the subject of the trial. Additionally, changes in applicable regulatory requirements and guidance may occur, in which case clinical trial protocols may need to be amended to reflect these changes. Any such amendments could require us to resubmit our clinical trial protocols to IRBs or IBCs for reexamination, which could impact the costs, timing and successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our ongoing, planned or future clinical trials, the commercial prospects for our product candidates could be harmed, which could 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 these products.***

To the extent our commercialization strategy includes the combination of our product candidates with third parties' products or product candidates, we may decide to conduct clinical studies to evaluate the combinations. This is true of our melanoma combination investigator-sponsored Phase II clinical trial to assess the combination of ImmunoPulse® IL-12 and Merck's anti-PD-1 antibody KEYTRUDA®, as well as our PISCES/KEYNOTE-695 study. Although Merck has agreed to provide KEYTRUDA® in connection with the PISCES/KEYNOTE-695 study, these combination studies involve additional risks due to their reliance on circumstances outside our control, such as those relating to the availability and marketability of the third-party product involved in the study. If the marketability of third-party products such as KEYTRUDA® is impacted, or if we are unable to secure and maintain a sufficient supply of such third-party products when needed on commercially reasonable terms, our clinical studies could be delayed or we could be forced to terminate these studies. Such a delay or termination could have a material negative impact on our development strategy, business, results of operations, financial condition, and prospects.

***We rely on third parties to conduct our clinical trials and other studies, and 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 CROs to help us manage critical aspects of the clinical trials we sponsor. We 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 FDA's regulations for conducting clinical trials and good clinical practice, as well as the guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. We are also required to harmonize standard operating procedures between companies and conduct periodic internal and vendor audits to ensure compliance. Additionally, the FDA and comparable foreign regulators enforce these good clinical practice regulations through periodic inspections of trial sponsors, principal investigators, CRO trial sites, laboratories and any other entity involved in the completion of the study protocol and processing of data.

If we or our CROs fail to comply with applicable good clinical practice or other regulations, the data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulators may require us to perform additional or repeat clinical trials, which could significantly increase costs and delay the regulatory approval process. Additionally, repeated compliance failures could cause the FDA or other regulatory authority to suspend or terminate a clinical trial, which could cause significant approval delays and increased costs. Further, if CROs do not otherwise successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised for any reason, our clinical trials may need to be extended, delayed or terminated or we may not be able to rely on the data produced by the trials. Moreover, if any of our relationships with third-party CROs terminate before completion of a clinical trial, we may not be able to establish arrangements with

alternative CROs on commercially reasonable terms, on a timely basis or at all, which could materially delay or jeopardize the trial. Any such occurrence could delay or prevent us from obtaining regulatory approval for or successfully commercializing our product candidates, which could increase our costs, delay our prospects for generating revenue, and otherwise materially harm our results of operations, financial condition and prospects.

***We have participated in, and continue to participate in, clinical trials conducted under an approved investigator-sponsored investigational new drug application, and we have little or no control over the conduct or timing of, or FDA communications regarding, these trials.***

We have participated in, and continue to participate in, clinical trials conducted under an approved investigator-sponsored investigational new drug, or IND, application, including our melanoma combination investigator-sponsored Phase II clinical trial led by the University of California, San Francisco. In investigator-initiated trials, the investigator typically designs and implements the study and the investigator or its institution acts as the sponsor of the trial. This trial sponsor has control over the design, conduct and timing of the trial, and as a result, we have limited or no control over the commencement, conduct and completion of these investigator-initiated trials. In addition, 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 FDA as it pertains to the safety of the treatment being tested. It is the responsibility of the investigator, as the sponsor of the trial, to be the sole point of contact with the FDA for these communications and to exercise all decision-making authority regarding these or other submissions to the FDA about the trial. Consequently, we have little or no control over the content or timing of these communications, including whether they are timely, accurate or complete. Any failures by the investigator sponsoring these trials could result in reviews, audits, delays or clinical holds by the FDA that could negatively affect the timelines for these trials or jeopardize their completion. As a result, our lack of control over the conduct and timing of, and communications with the FDA regarding, these investigator-sponsored trials exposes us to additional risks, many of which are outside our control and the occurrence of which could severely harm our performance and the commercial prospects for our product candidates.

***Regulatory authorities may not approve our product candidates, or any approvals we achieve may be too limited or too late for us to earn meaningful, or any, revenue.***

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, as well as comparable regulatory bodies in other countries. These regulatory agencies have the authority to delay approval of or refuse to approve our product candidates for a variety of reasons, including, among others, a failure to meet safety and efficacy endpoints in our clinical trials or otherwise to the satisfaction of the regulator, disapproval of our or our partners' trial design, or disagreement with our interpretation of data from pre-clinical studies or clinical trials. As a result, even if our product candidates achieve their endpoints in clinical trials, they still may not be approved by any of these regulatory agencies. Moreover, the requirements to obtain product approvals vary widely from country to country, and the FDA's approval requirements, review procedures and timelines may not be the same as or even similar to the requirements of a comparable foreign regulator. As a result, even if we obtain regulatory approval for a product candidate in one country, we may be required to undertake additional clinical trials or studies, submit additional information, wait for longer review periods or make other efforts in order to obtain regulatory approvals in other desirable geographic markets.

Although we have seen no systemic drug-related adverse events in our trials and studies to date, if we cannot adequately demonstrate through the clinical trial process that a product candidate we are developing is safe and effective, regulatory approval of that product candidate could be delayed or may never be achieved, which could impair our reputation, increase our costs and delay or prevent us from generating revenue. Importantly, success in pre-clinical testing and early clinical studies does not ensure that later clinical trials will generate adequate data to demonstrate the required level of 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 we have, have suffered significant setbacks in clinical trials, even after obtaining promising results in earlier studies. Further, 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.

Furthermore, because of the substantial competition we face, even if we are ultimately able to achieve regulatory approval for one or more of our product candidates, delays in such regulatory approval could delay, limit or prevent our ability to successfully commercialize our product candidates if competing products obtain approvals before ours and gain market traction that we are not able to disrupt. Moreover, we may be forced to reevaluate our development strategies and plans in the face of setbacks or other delays that could jeopardize the value of any regulatory approval that is obtained, which could include abandoning clinical trial efforts for a product candidate that we no longer believe has promising value as a commercial product. If we are not able to obtain or maintain required regulatory approvals for our product candidates or if we decide or are forced to abandon our efforts to obtain or maintain these approvals, we would have expended significant costs on assets that may never generate any return. Such an outcome would have a material adverse effect on our business, results of operations and financial condition, as well as on our continued viability as a company.

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

In addition to our owned proprietary rights, we have also exclusively licensed certain patents that cover our ImmunoPulse® clinical methods. These patents will expire between 2025 and 2027. These method patents protect the use of a product for a specified method under certain defined parameters. This type of patent does not prevent a competitor from making and marketing a product that is identical or similar to the protected product under parameters that are outside the scope of the patented method claims. Moreover, even if competitors do not actively promote such a product for the indications protected by the method patent, physicians could prescribe the products for these methods on an off-label basis. Although such 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 detect, prevent or prosecute.

We entered into a cross-license agreement in 2011 for certain electroporation technology with Inovio, which includes some of our patents protecting our ImmunoPulse® clinical device (and some of which have recently expired or will expire in 2018). Under the terms of the agreement, Inovio has granted us a non-exclusive, worldwide license under certain of its electroporation patents, and in exchange, we have granted to Inovio an exclusive license to certain of our technology in a limited field of use. Although we do not currently rely on the intellectual property we have licensed from Inovio, our product candidates could in the future utilize this intellectual property. This license is non-exclusive and Inovio could use the technology to compete with us or could license the technology to others, including our competitors. Additionally, the license we have granted to Inovio could enable it to develop products that compete against ours, directly or indirectly, in the specific field of use subject to the license.

If we are not able to maintain our existing in-licenses or if we are not able to establish new in-licenses for any other third-party rights we need, we could become subject to significant costs or royalty or other fees to establish alternative license arrangements, if such licenses are available when needed, on acceptable terms or at all, or we could be forced to develop modifications to the affected product candidates or technologies to avoid reliance on the third-party rights, if such modifications are possible. Any inability to secure and maintain adequate rights to any third-party technologies necessary for the development of our product candidates could severely limit our continued research and development activities, our efforts to obtain product approvals and, if such approvals are obtained, our ability to commercialize the approved products, any of which would materially adversely impact our business and prospects.

***We may become involved in litigation or other proceedings in our efforts to protect our patent and other intellectual property rights, which could require significant time and costs and would be subject to unpredictable outcomes.***

We may become aware of activities by third parties, including our competitors, that we believe infringe our issued patents or other intellectual property rights. If we choose to file a lawsuit against a potentially infringing third party to

try to enforce our patents or other intellectual property rights, the third party may seek a ruling that the patents are invalid and/or should not be enforced. Such a ruling could severely limit our ability to protect our rights from use by third parties. The U.S. Supreme Court has recently revised certain tests regarding assessing the validity of patents, which could result in the invalidation of issued patents and/or their claims based on the application of the new patent validity standards. As a result, in the event of any patent infringement litigation or other proceedings involving our patents, our patents could be subject to challenge and subsequent invalidation or significant narrowing of claim scope under the revised standards. Moreover, even if the validity of our patents is upheld in a patent infringement lawsuit, a court could refuse to stop a third party's activities on the grounds that the activities do not infringe the specific claims of our patents. Further, even if we were successful in stopping the infringing activity, patent infringement lawsuits are expensive and could consume significant time, management attention, capital and other resources.

These risks of third parties' infringement of our intellectual property rights may increase if we engage in discussions, collaborations or other strategic arrangements with third parties. Also, new challenges could arise if and to the extent we pursue engagements 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 and could adversely affect our performance and our business prospects.

***Third parties may claim that we infringe their proprietary rights, which could prevent us from pursuing our clinical and other studies and other research and development activities.***

The validity and infringement of patents or proprietary rights of third parties has been the subject of substantial litigation in the biotechnology industry. In the course of our research and development activities, we could become subject to legal claims that we, our activities or our product candidates or technologies infringe the rights of others. This type of patent infringement litigation is costly and time-consuming and diverts the attention of management and technical personnel. In addition, if we or our product candidates or technologies are found to infringe the rights of others, we could lose our ability to continue our development programs or could be forced to pay monetary damages. Although the parties to patent and intellectual property disputes in the biotechnology industry have often settled their disputes by establishing licenses or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. Furthermore, any such licenses may not be available when needed, on commercially reasonable terms or at all. These risks may be amplified due to our small size and limited experience and resources relative to many of our competitors. As a result, any claims of infringement against us, adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could materially delay, hinder or restrict our development efforts or prevent us from continuing to pursue our operational and strategic plans, which could have a material adverse effect on our business, prospects and results of operations.

***The biotechnology industry is highly competitive, and many of our competitors are significantly larger and more experienced than we are.***

The biotechnology industry is intensely competitive. This competitive environment stimulates an ongoing and extensive search for technological innovation and necessitates effective and targeted marketing strategies to communicate the effectiveness, safety and value of products to healthcare professionals in private practice and group practices and payors in managed care organizations, group purchasing organizations, and Medicare and 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 compete against all other developers of cancer treatments, including other immunotherapy treatments as well as other types of treatments for the cancer indications on which we are focused. In particular, a number of companies, some of which are large, well-established pharmaceutical companies, have recently announced development strategies similar to our current focus on our PISCES/KEYNOTE-695 study, namely the combination of a DNA-encoded interleukin-12, or IL-12, and a checkpoint inhibitor to improve response rates in patients who are refractory or who have relapsed on anti-PD-1 therapies either alone or in combination with other therapies, and we view these companies as our most relevant current competitors. These companies include, among others, Bristol Myers-Squibb, Iovance Therapeutics, Syndax, Dynavax Technologies and Idera Pharmaceuticals. In addition, we also compete with other early-stage biotechnology companies for funding and support from healthcare and other investors and potential collaboration relationships with larger pharmaceutical or other companies, as well as for personnel with expertise in our industry. We are smaller, less

experienced and less well-funded than many of our competitors, and we have a shorter and less proven operating history and a less recognizable and established brand name than many of our competitors. In addition, some of our competitors have commercially available products, which provide them with operating revenue and other competitive advantages. Furthermore, recent trends in the biotechnology industry are for large drug companies to acquire smaller outfits and consolidate 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 product candidates more rapidly than we can or may obtain more robust patent protection or other intellectual property rights to protect their product candidates and technologies, which could limit or prevent us from developing or commercializing our product candidates. If we are able to obtain regulatory approval of one or more of our product candidates, we will face competition from approved products or products under development by larger companies that may address our targeted indications. If we directly compete with these very large entities for the same markets and/or customers, their greater resources, brand recognition, sales and marketing experience and financial strength could prevent us from capturing a share of these markets or customers. 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, less costly or more widely accepted for other reasons than any of our products that obtain regulatory approvals, and our competitors may also be more successful than us in manufacturing, distributing and otherwise marketing their products.



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, coverage and reimbursement by third-party payors, extent of adverse side effects and convenience of treatment procedures. We may not be able to effectively compete in any of these areas. Presently, we compete with other biotechnology companies for funding and support on the basis of our technology platforms and the potential value of our product candidates based on the factors described above.

If we are unable to compete effectively, our business, results of operations, financial condition, and prospects may be materially adversely affected.

***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 regarding appropriate product promotion and continuing medical and health education activities. Even though we do not have any FDA approved products, these guidelines apply to our current activities with respect to disclosures, presentations or other communications about our product candidates and technologies at healthcare conferences or in other forums. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General of the U.S. Department of Health and Human Services could disagree, in which case we could 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, any of which could materially harm our business and prospects.

***If we and our contract manufacturers fail to produce our systems and product candidates in the volumes and within the timelines we require, or if they fail to comply with applicable regulations, we could face delays in the development and commercialization of our equipment and product candidates.***

Currently, we assemble certain components of our electroporation system, which is our proprietary delivery mechanism for our ImmunoPulse IL-12® product candidate, and we utilize the services of contract manufacturers to manufacture the remaining components of these systems and for the manufacture, testing and storage of all of our supply of our plasmid product candidate for clinical trials or other studies. We do not own and have no plans to build our own clinical or commercial manufacturing capabilities, and we expect to increase our reliance on third-party manufacturers if and when we commercialize any of our product candidates and systems.

The manufacture of our systems and product supplies requires significant expertise and capital investment, including the use of advanced manufacturing techniques and process controls. Manufacturers often encounter difficulties in production, particularly in scaling up for commercial production if regulatory approvals are obtained. These

difficulties include, among others: problems with production costs and yields; quality control issues, including stability of the equipment and product candidates and quality assurance testing; shortages of qualified personnel; and 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 contractual obligations to us, our ability to provide our electroporation equipment to our partners and product candidates to patients enrolled in our clinical trials, or to commercially launch a product if regulatory approvals are obtained, 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 programs, 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 current good manufacturing practices, which are enforced by the FDA through its facilities inspection programs. These practices include requirements regarding, among other things, quality control, quality assurance and the generation and maintenance of records and documentation. We have little or no control over our manufacturers' compliance with these regulations and standards. Any failure by our manufacturers to comply with these requirements could result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. Additionally, if the safety of any product candidate or approved product is compromised due to our or our manufacturers' failure to adhere to applicable regulatory requirements or for other reasons, we may not be able to obtain or maintain regulatory approval for or successfully commercialize the products, and we may be held liable for any injuries sustained as a result of the failure. Any of these factors could cause delays in clinical trials, regulatory submissions or approvals, entail significant costs or hinder our ability to effectively commercialize our product candidates. 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 we could lose potential revenue.

***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 material disruptions to our commercialization activities, clinical and other development programs, financial and disclosure controls and other reporting functions and the administrative aspects of our business, in addition to possibly requiring substantial expenditures of capital and other resources to remedy. Further, any loss of clinical trial data from completed or future clinical trials as a result of such a disruption could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. Moreover, to the extent any such disruption results in the loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur significant liabilities. The occurrence of any of these circumstances could cause our operations and our performance to suffer.

***We may be unable to acquire or develop new product candidates or technologies, or we may never be able to commercialize any product candidates or technologies we do successfully acquire or develop.***

As part of our business strategy, we plan to expand our clinical pipeline and build our portfolio of product candidates through the development, acquisition or licensing of assets or businesses, product candidates or approved products. The process of identifying, planning, negotiating, implementing and integrating an acquisition or license of a new business, product candidate or approved product can be lengthy and complex and can involve numerous difficulties, including difficulties related to:

identifying new potential product candidates or promising technologies;

competing with other companies for the acquisition or license, including many of our competitors with substantially greater financial, marketing and sales resources;

negotiating the terms of the acquisition or license, at which we have relatively little experience;

accurately judging the value or worth of a potential acquisition or in-license candidate;

paying for an acquisition or license, including the consideration to acquire or license a business, technology or asset (which could include cash and/or issuance of equity or debt securities);

acquisition and integration efforts could disrupt our business and divert the time and attention of management and other internal personnel from existing operations;

any integration failures could result in the loss or impairment of relationships with employees, consultants, suppliers and other vendors and partners;

exposure to unknown or contingent liabilities based on an acquired company's operations or assets;

acquisition and integration efforts and costs could reduce available liquidity and other resources to pursue other acquisitions or strategic transactions;

challenges establishing appropriate controls and procedures for any acquisition by us of a private company;

failing to recoup our investment of time, capital and other resources into a proposed acquisition or license, as a result of failing to complete the transaction or, for transactions that are completed, failing to realize the anticipated benefits of acquired or licensed business or asset;

challenges developing and commercializing any product candidates or technologies that we are successful in acquiring or licensing, which is subject to all of the risks described throughout these risk factors regarding the development of our current product candidates.

As a result of these and other difficulties, any efforts to acquire or develop new product candidates, technologies or businesses may not produce commercially successful products or otherwise result in meaningful revenue or profitability for our business. As a result, the pursuit of these activities could have a material adverse effect on our business, results of operations, financial condition and prospects.

***Any collaboration arrangements we may establish may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.***

We may seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our current and any future product candidates. To the extent we pursue collaboration arrangements, we would face significant risks in connection with establishing and maintaining the arrangements, including, among others:

we could be subject to intense competition in seeking appropriate collaborators;

collaboration arrangements are complex, costly and time-consuming to negotiate, document and implement, and they could require our payment to the collaborator of cash or other consideration, including issuances of equity or debt securities, in order to establish the relationship;

we may be unsuccessful in establishing and implementing any collaboration we desire to pursue, or the terms of the arrangement may not be favorable to us;

collaborations often would require that we relinquish some or all of the control over the future success of the product candidate to the third-party collaborator;

the success of any collaboration arrangements we may establish would depend heavily on the efforts and activities of our collaborators, who would likely have significant discretion in determining the efforts and resources they would apply to these collaborations;

disagreements between collaborators regarding clinical development and commercialization matters can be difficult to resolve and can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, termination of the arrangement; and

any termination of a collaboration arrangement that we are able to establish could adversely affect our performance, particularly to the extent we become reliant upon the collaboration for revenue or important commercialization processes or efforts.

In addition, collaboration arrangements may also include our pursuit of combination trials to develop and commercialize our product candidates as combination products, such as our PISCES/KEYNOTE-695 study with Merck's KEYTRUDA®. To the extent we continue to pursue this or any other similar collaborative arrangement, we will face certain additional risks and uncertainties in development, as 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. Additionally, combination products face continued risk and uncertainty post-development in connection with manufacturing and supply until a commercial supply chain is validated and proven.

The occurrence of any of these risks with respect to any collaboration arrangements we pursue or establish could materially adversely affect our performance, financial condition and reputation.

***We may not be successful in executing our sales and marketing strategy for the commercialization of any of our product candidates, in which case we may not be able to generate significant, or any, revenue.***

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. Moreover, we have no experience with these activities. While we currently expect that any approved products would be marketed to a relatively small patient population, we might not be able to create an effective sales force to address even a niche market. In addition, some of our product candidates could require, if approved, a large sales force to call on, educate and support physicians and patients. We could decide in the future to pursue collaborations with one or more pharmaceutical companies to sell, market and distribute any approved products, but we may not be able to establish any such arrangement when desired, on acceptable terms or at all. Further, any such collaboration we do establish may not be effective in generating meaningful revenue to us.

We may be unsuccessful in implementing the commercialization strategies we have planned. Further, we have not proven our ability to succeed in the biotechnology industry and are not certain that our commercialization strategies, even if implemented as we envision, would lead to significant revenue. If we are unable to successfully implement our commercialization plans and drive adoption by patients and physicians of any product candidates that obtain regulatory approval, then we will not generate meaningful, or any, revenue, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

***If any product candidate that receives regulatory approval does not achieve broad market acceptance, our revenue potential may be limited.***

The commercial success of any product candidate that obtains marketing approval from the FDA or comparable foreign regulatory authorities will depend on the acceptance of these products by physicians, patients, third-party payors and the medical community. The degree of market acceptance of any product candidate that receives 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 or other regulator-approved labeling;

the clinical indications for which the product is approved;

the availability and perceived advantages of alternative treatments;

any negative publicity related to the product or any competing product;

the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;

pricing and cost effectiveness;

our ability to obtain adequate third-party payor coverage or reimbursement; and

the willingness of patients to pay out-of-pocket in the absence of adequate third-party payor coverage and reimbursement.



Failures with respect to any one of these factors could severely limit the commercial potential of any product candidate that obtains regulatory approval, which could materially adversely affect our performance and prospects.

***We may not be able to establish adequate coverage and reimbursement by third-party payors for any product candidate that achieves regulatory approvals, which could severely limit our market potential, performance and prospects.***

Cost containment has become a significant trend in the U.S. healthcare industry. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for certain 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 and treatments. In addition, recent trends in U.S. politics suggest that the U.S. healthcare insurance framework may experience significant changes in the near term. For all of these and other reasons, coverage and reimbursement at adequate or any levels may not be available for any product candidate that achieves regulatory approval. If coverage and reimbursement is not available or is not available at an adequate level for any approved product, the demand for or price of the product could be materially negatively affected, which could severely limit our revenue potential and prospects.

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 government control even after initial approval is granted. As a result, even if we obtain regulatory approval for a product candidate in a particular country, we could be subject to continuing pricing regulations that could delay our commercial launch of the product or negatively impact the revenue potential for the product in that country.

***Future growth, including growth in international operations, could strain our resources, and if we are unable to manage any growth we may experience, we may not be able to successfully implement our business plans.***

In late 2016, we established a subsidiary corporation in Australia in preparation for planned clinical trials in that country. In addition, our business plan includes continued growth of our operations, including, among other things, growth in our workforce, expansion of our clinical trial efforts within and outside of the United States, and expansion of our portfolio of product candidates. This growth could place an additional strain on our management, administrative, operational and financial infrastructure, and will require that we incur significant additional costs and hire and train additional personnel to support our expanding operations. Further, we must maintain and continue to improve our operational, financial and management controls and reporting systems and procedures, which can be more challenging during periods of expansion. As a result, our future success will depend in part on the ability of management to effectively manage any of this growth we may experience. If we fail to successfully manage any

growth we may experience, we may be unable to execute on our business plan.

In connection with any geographic expansion we may pursue, international operations would involve substantial additional risks, including, among others:

difficulties complying with the U.S. Foreign Corrupt Practices Act and other applicable anti-bribery laws;

difficulties maintaining compliance with the varied laws and regulations of multiple jurisdictions that may be applicable to our business, many of which may be unfamiliar to us;

more complexity in our regulatory and accounting compliance;

differing or changing obligations regarding taxes, duties or other fees;

limited intellectual property protection in some jurisdictions;

risks associated with currency exchange and convertibility, including vulnerability to appreciation and depreciation of foreign currencies against the U.S. dollar;

uncertainty related to developing legal and regulatory systems and standards for economic and business activities in some jurisdictions;

trade restrictions or barriers, including tariffs or other charges and import-export regulations, which are subject to increased uncertainty following the results of the 2016 U.S. presidential election and the trade policies of the current administration regarding existing and proposed trade agreements and the ability to import goods into the United States;

changes in applicable laws or policies;

the impact of and response to natural disasters; and

potential for war, civil or political unrest and economic and financial instability.

The occurrence of any of these risks could limit our ability to pursue international expansion, increase our costs or expose us to fines or other legal sanctions, any of which could negatively impact our business, reputation and financial condition.

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

In order to successfully implement and manage our business plans, we depend on, among other things, successfully recruiting and retaining qualified executives, managers, scientists and other employees with relevant experience in life sciences and the biotechnology industry. Competition for qualified individuals is intense, particularly in our industry, due to the many larger and 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 heavily rely on consultants and advisors, including scientific, clinical and regulatory advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by others or 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, consultants and/or advisors, and find, attract and retain new qualified personnel, consultants and/or advisors on acceptable terms and in a timely manner to coincide with our needs, we may not be able to successfully maintain or grow our operations and our business and prospects could suffer.

Additionally, although we have employment agreements with each of our executive officers, these agreements are terminable by them at will. The loss of the services of any one or more members of our current senior management team could, among other things, disrupt or divert our focus from pursuing our business plans while we seek to recruit other executives, impact the perceptions of our existing and prospective employees, partners and investors regarding our business and prospects, cause us to incur substantial costs in connection with managing transitions and recruiting suitable replacements and, if the departing personnel are crucial to any of our clinical or other development programs,

delay or prevent the development and commercialization of the affected product candidates. These risks would be amplified if we are not able to recruit suitable replacements for any departing personnel on acceptable terms and in a timely manner. The occurrence of any of these or other potential consequences could cause significant harm to our business.

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

Biotechnology companies are subject to extensive, complex, costly and evolving government regulation relating to the ability to market and sell any therapeutic or medical device. In the United States, these regulations are principally administered and enforced by the FDA and, to a lesser extent, by the U.S. Drug Enforcement Agency, or DEA, and comparable state government agencies, and outside the United States, these regulations are typically administered by various regulatory agencies comparable to the FDA in foreign countries where products or product candidates are researched, tested, manufactured and/or marketed.

The U.S. federal Food, Drug and Cosmetic Act, or FDCA, Controlled Substances Act and other federal statutes and regulations, as well as similar state and foreign statutes and regulations, govern or influence, among other things, the research, development, testing, manufacture, storage, record-keeping, approval, labeling, promotion, marketing, distribution, post-approval monitoring and reporting, sampling, import and export of product candidates such as ours. Under these regulations, we and our contract manufacturers may become subject to periodic inspection of our facilities, quality control and other procedures, and operations and/or the testing of our product candidates by the FDA, DEA and other authorities during and after the approval process for a product candidate, to confirm compliance with all applicable regulations, including current good manufacturing practices and other applicable requirements. Further, even if regulatory approval of a product candidate is obtained, such approval would usually impose limitations on the indicated uses for which the product may be marketed, which limitations could materially limit a product's market and revenue potential. Additionally, we would be subject to pervasive and continuing regulation by the FDA and/or comparable foreign regulators with respect to any approved product. Moreover, we could be required to conduct potentially costly post-approval studies or surveillance programs to monitor the effect of any approved products, and the FDA and comparable foreign regulators have the authority to stop or limit further marketing of a product or impose more stringent labeling restrictions based on the results of these post-approval tests and programs or in the event of any unexpected or serious health or safety concern regarding any approved product.

Possible penalties or other consequences for failure to comply with these regulatory requirements include, among others, observations, notices, citations and/or warning letters that could force us to modify our clinical programs or other activities; clinical holds on our ongoing clinical programs; adverse publicity from the FDA or others; the FDA's suspension of its review of pending applications; fines; product recalls or seizures; total or partial suspension of production and/or distribution; labeling changes; withdrawal of previously granted product approvals; enforcement actions; injunctions and civil or criminal prosecution. Any such sanctions, if imposed, could have a material adverse effect on our business, operating results and financial condition. Any such sanctions, if imposed, could have a material adverse effect on our business, operating results and financial condition.

Moreover, the regulations, policies and guidance of the FDA or other regulatory agencies could change and new or additional statutes or regulations could be enacted. If changes or new laws are more stringent or impose additional or more challenging requirements, our costs of compliance could increase, regulatory approval of our product candidates could be delayed or jeopardized, or post-approval activities for any product candidates that obtain regulatory approval could be further restricted or regulated. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market any of our product candidates, which would materially adversely affect our prospects to generate revenue.

***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.***

The healthcare industry is heavily regulated, constantly evolving and subject to significant change and fluctuation. The U.S. federal and state healthcare laws and regulations that impact our business include, among others:

the laws and regulations administered and enforced by the FDA, including the FDCA, Controlled Substances Act and other federal statutes and regulations, discussed above;

the federal Anti-Kickback Statute, which generally prohibits, among other things, soliciting, receiving or providing remuneration to induce the referral of an individual for an item or service or the purchasing or ordering of an item or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

the federal false claims laws, which generally prohibit, among other things, knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;

the federal Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, referred to collectively as the Affordable Care Act, which, in general and among other things, expands the government's investigative and enforcement authority, including requiring pharmaceutical companies to record and disclose to government agencies any transfers of value to doctors and teaching hospitals, and increases the penalties for fraud and abuse, including amendments to the federal False Claims Act and the Anti-Kickback Statute to make it easier to file lawsuits under these statutes;

the federal Health Insurance Portability and Accountability Act of 1986, or HIPAA, as amended by the federal Health Information Technology for Economic and Clinical Health Act, or HITECH, which, in general and among other things, establish comprehensive federal standards with respect to the privacy, security and transmission of individually identifiable health information and impose requirements for the use of standardized electronic transactions with respect to transmission of such information;

The federal Foreign Corrupt Practices Act, or FCPA, and other applicable anti-bribery laws; and

state law equivalents of each of these federal laws, such as anti-kickback and false claims laws that 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 may not be preempted by applicable federal laws, thus complicating compliance efforts.

Additionally, the healthcare compliance environment is continuously changing, with proposed revisions to or replacement of the Affordable Care Act at the federal level and with some states mandating implementation of compliance programs, compliance with industry ethics codes, spending limits and reporting to state governments of gifts, compensation and other remuneration to physicians. This shifting regulatory environment, as well as our obligation to comply with different reporting and other compliance requirements, in multiple jurisdictions, including foreign laws and regulations comparable to the U.S. laws and regulations described above, to the extent we continue to pursue operations in foreign countries, such as our clinical activities in Australia, or if we seek to sell any product that obtains regulatory approval in a foreign country, increases the possibility that we may violate one or more of these laws. In addition, these conditions may also adversely affect our ability to obtain regulatory approval for any of our product candidates, the availability of capital, our ability to generate meaningful or any revenue and, if any of our product candidates achieve regulatory approval, our ability to establish a price we believe is fair for the approved product. 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, if any of our product candidates obtain regulatory approval and become commercially available.

All of these laws impose penalties for non-compliance, some of which may be severe. If we or our operations are found to be in violation of any of these laws or any other governmental regulations that apply to us, we may be subject to fines or other monetary damages or orders forcing us to curtail or restructure our operations. Any such penalties could adversely affect our ability to operate our business and pursue our strategic plans. Additionally, 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 management's attention from the operation of our business. Moreover, achieving and sustaining compliance with the various U.S. federal and state and foreign laws and regulations that apply to our business could prove costly. The occurrence of any of these risks could cause our performance and financial condition to materially suffer.

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

The clinical use of our product candidates and, if any of our product candidates achieves regulatory approval, any future commercial use of the approved products, exposes us to the risk of product liability claims. Any side effects, manufacturing defects, misuse, or abuse associated with our product candidates or any approved products could result in injury to a patient or even death. In addition, a liability claim could be brought against us even if our product candidates or any approved products merely appear to have caused an injury. These product liability claims could be brought against us by consumers, healthcare providers, pharmaceutical companies or others that come into contact with our product candidates or any approved products.



Regardless of merit or potential outcome, product liability claims against us could result in, among other effects, the inability to continue clinical testing of our product candidates or, for any approved products, commercialization of the products, impairment of our business reputation, withdrawal of clinical trial participants and distraction of management's attention from our primary business activities. In addition, if we cannot successfully defend against product liability claims, we could incur substantial liabilities, including liabilities that may be beyond the scope or limits of any applicable insurance policies we may have in place. Any of these outcomes could severely harm our business, financial condition and prospects.

***Our business depends in large part on our ability to protect our proprietary rights and technologies, and we may be unsuccessful in these efforts.***

We believe our success and ability to compete depends in large part on obtaining and maintaining patent, trademark and trade secret protection of our product candidates and their respective components and underlying technologies, including devices, formulations, manufacturing methods and methods of treatment, as well as successfully defending our intellectual property rights against third-party challenges. Our ability to stop third parties from making, using or selling products that infringe on our intellectual property rights depends on the extent to which we have secured and properly safeguarded these rights under valid and enforceable patents or trade secrets. Although we have previously obtained patent protection for our ImmunoPulse® clinical device, our primary U.S. patent providing such protection expired in September 2017 and our international patent providing such protection will expire in 2018. As a result, we have limited ability to enforce these rights against third parties to prevent them from making or selling competing products that rely upon the protected technology, which could significantly harm our competitive position and prospects. To the extent our existing patents or pending or planned patent applications expire before we are able to commercialize product depending on the technology or do not otherwise provide sufficient protection, we could be subject to substantially increased competition and our business and ability to commercialize or license our technology or product candidates could be materially adversely affected.

Even if we secure patents that cover our proprietary technology, our efforts to protect our intellectual property rights with patents may prove inadequate. For instance, the breadth of claims in a patent application is often restricted during patent prosecution, resulting in granted claims with a more limited scope than the claims in the original application. Additionally, pending or future patent applications may not result in issued patents. Laws and regulations for the prosecution of patents are continuously evolving, and the U.S. Supreme Court has recently revised certain tests regarding granting patents that could make it more difficult to obtain issued patents. Also, any patents that are granted could be subject to post-grant proceedings that could limit their scope or enforceability, and claims that are amended during post-grant proceedings may not be broad enough to provide meaningful protection. Moreover, any patents that are issued to us or any future collaborators may be circumvented or invalidated by third-party efforts, may expire before or shortly after obtaining necessary regulatory approvals, or may not provide sufficient proprietary protection or competitive advantage for other reasons. Further, 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. These risks may be amplified in some foreign jurisdictions, where patent protection may not be as strong or as effective as it is in the United States.

Our reliance on unpatented proprietary rights, including trade secrets and know-how, may also pose significant risks. For instance, it can be difficult to protect these rights and they may lose their value if they are independently developed by a third party or if their secrecy is lost. Although we have taken measures to protect these rights, including establishing confidentiality agreements with employees, consultants and other third parties, these measures may not sufficiently safeguard our unpatented proprietary rights and may not provide adequate remedies in the event of unauthorized use or disclosure of the confidential information. For instance, enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming and the outcome would be unpredictable.

If we are unable to secure patent protection for our patentable technologies, if any of our issued patents are limited or found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our patented or unpatented proprietary rights, our business and prospects could be materially negatively affected.

***If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results and stockholders and the investment community could lose confidence in our financial reporting, which could harm our business.***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Although management has determined that our internal control over financial reporting was effective as of October 31, 2017, 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 maintain effective internal control over financial reporting, including failures to implement new or improved controls as needed in a timely and effective manner or remediate any significant deficiency or material weakness that is identified in the future, could cause noncompliance with our public reporting obligations, an inability to produce reliable financial reports or material misstatements in our financial statements or other public disclosures. If any of these circumstances were to occur, investors could lose confidence in our financial and other reported information, our reputation could otherwise be harmed, the investment of our stockholders in our company could be negatively affected and the costs to us of raising additional capital could materially increase, any of which could harm our business and prospects.

***Maintaining compliance with our reporting and other obligations as a public company could strain our resources and distract management.***

As a public company, we experience significant demands that are not applicable to private companies. For example, the Sarbanes-Oxley Act of 2002 and related and other rules implemented by the SEC and the Nasdaq Stock Market LLC, which maintains the securities exchange on which our common stock is listed for trading, impose a number of requirements on public companies, including with respect to corporate governance practices, periodic reporting and other disclosure requirements and financial and disclosure controls and procedures. Further, the SEC and other regulators have continued to adopt new rules and make changes to existing regulations that require our compliance, such as the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the corporate governance and executive compensation-related disclosure requirements of this legislation.

Maintaining compliance with the rules and regulations applicable to public companies involves significant legal, accounting and financial costs. Additionally, if we grow as anticipated, we may need to hire additional personnel and implement new and more sophisticated financial and accounting systems and procedures to continue to meet our public company obligations. Our management and other personnel devote substantial attention to maintaining our compliance with these obligations, which diverts attention from other aspects of our business. Any failure to comply with these public company requirements could have a material adverse effect on our business and prospects and could materially harm our stockholders' investment in our Company.

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

If a corporation undergoes an “ownership change” within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended, the corporation’s net operating loss carryforwards and certain other tax attributes arising prior to the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation’s equity ownership by certain stockholders that exceeds 50% over a rolling three-year period. Similar rules may apply under state tax laws. If we experience such an ownership change, our net operating loss carryforwards generated prior to the ownership change would be subject to annual limitations that could reduce, eliminate or defer the utilization of these losses.

Moreover, the recognition and measurement of net operating loss carryforwards may include estimates and judgments by management, and the Internal Revenue Service could, upon audit or other investigation, disagree with the amount of net operating loss carryforwards or the determination of whether an ownership change has occurred. Additionally, future legislative changes could negatively impact the ability to use any tax benefits associated with net operating loss carryforwards. Any inability to use net operating loss carryforwards to reduce our U.S. federal or state income tax liability could materially harm our financial condition and results of operations.

## Risks Related to Our Common Stock

*The price and trading volume of our common stock may be subject to extreme volatility, and stockholders could lose all or part of their investment in our company.*

The trading volume and market price of our common stock has experienced, and is likely to continue to experience, significant volatility. This volatility could negatively impact our ability to raise additional capital or utilize equity as consideration in any acquisition transactions we may seek to pursue, and could make it more difficult for existing stockholders to sell their shares of our common stock at a price they consider acceptable or at all. This volatility is caused by a variety of factors, including, among the other risks described in these risk factors:

adverse research and development or clinical trial results;

our liquidity and ability to obtain additional capital, including the market's reaction to any capital-raising transaction we may pursue;

declining working capital to fund operations, or other signs of financial uncertainty;

any negative announcement by the FDA or comparable regulatory bodies outside the United States, including that it has denied any request to approve any of our product candidates for commercialization;

conducting open-ended clinical trials, which could lead to results (either positive or negative) being available to the public prior to a formal announcement;

market assessments of any strategic transaction or collaboration arrangement we may pursue;

potential negative market reaction to the terms or volume of any issuance of shares of our common stock or other securities to new investors pursuant to strategic or capital-raising transactions or to employees, directors or other service providers;

sales of substantial amounts of our common stock, or the perception that substantial amounts of our common stock may be sold, by stockholders in the public market;

issuance of new or updated research or reports by securities analysts or changed recommendations for our common stock;

significant advances made by competitors that adversely affect our competitive position;

the loss of key personnel and the inability to attract and retain additional highly-skilled personnel; and

general market and economic conditions, including factors not directly related to our operating performance or the operating performance of our competitors, such as increased uncertainty in the U.S. healthcare regulatory environment following the results of the 2016 U.S. presidential election.

In addition, the stock market in general, and the market for stock of companies in the life sciences and biotechnology industries in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of specific companies. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against the company. This type of litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

***If our common stock is delisted from the Nasdaq Capital Market or we are found to be noncompliant with Nasdaq rules, the market price and liquidity of our common stock could be materially negatively impacted.***

The listing of our common stock on the Nasdaq Capital Market, or Nasdaq, is contingent upon our compliance with all of Nasdaq's continued listing requirements. If we are found to be noncompliant with these requirements, our common stock could be subject to delisting from Nasdaq. In such event, the market price of our common stock could be negatively impacted, the liquidity of our common stock could be reduced and our ability to complete equity financings in the future may be limited or prevented.

***If we issue additional equity securities in the future, our existing stockholders would be diluted.***

Our articles of incorporation authorize the issuance of up to 160,000,000 shares of our common stock. In addition to capital-raising activities, on which we have historically relied for cash to fund our operations, including with our recent October and November 2017 equity financings, other possible business and financial uses for our authorized common stock include, among others, stock splits, acquiring other businesses or assets in exchange for shares of our common stock, issuing shares of our common stock to collaborators in connection with strategic alliances, attracting and retaining employees with equity compensation or other transactions and corporate purposes that our Board of Directors deems to be in the best interest of our Company. Additionally, issuances of common stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of our Company. Any future issuances of our common stock may be consummated on terms that are not favorable, may not enhance stockholder value and may adversely affect the trading price of our common stock. Further, any such issuance will reduce the book value per share of our common stock and reduce the proportionate ownership and voting power of our existing stockholders.

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

As of October 31, 2017, we had outstanding (i) options to purchase 3.7 million shares of our common stock, (ii) warrants to purchase 12.5 million shares of our common stock and (iii) 1.1 million restricted stock units. In addition, as of October 31, 2017, there were 0.7 million shares reserved for future issuance under our stock incentive and stock purchase plans. The exercise of options and warrants, the vesting and settlement of restricted stock units or the issuance of additional equity awards under our stock incentive and stock purchase plans could have an adverse effect on the market for our common stock, including the price that any stockholder could obtain for its shares. Further, our existing stockholders could experience significant dilution in the net tangible book value of their investment upon the issuance of additional shares of our common stock through the exercise of derivative securities that are currently outstanding or that we may issue in the future.

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

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 equity offerings, 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.**

On October 2, 2017, we entered into an agreement with a third-party firm to provide certain business and advisory consulting services for us. Pursuant to the terms of the agreement, we agreed to issue to such firm, over time and subject to continued service for us, an aggregate of 300,000 shares of our common stock as partial compensation for these consulting services. Such shares were offered and sold without registration under the Securities Act of 1933, as amended, or the Securities Act, pursuant to the exemption provided in Section 4(a)(2) under the Securities Act as a transaction not involving a public offering as well as similar exemptions under applicable state laws, in reliance on the following facts: no general solicitation was used in the offer or sale of such shares; the recipient of such shares represented that it was acquiring the shares for investment for its own account and not with a view to or for resale in connection with any distribution thereof within the meaning of the Securities Act; the recipient of such shares had adequate access to information about us; the recipient of such shares represented that it had a preexisting business or personal relationship with us or had the capacity to protect its own interests in connection with acquiring such shares; and such shares were issued as restricted securities with restricted legends referring to the Securities Act. On October 31, 2017, we issued 100,000 shares of our common stock to the third-party firm at a market price of \$1.09 per share for services rendered.



**ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

**ITEM 4. MINE SAFETY DISCLOSURES.**

None.

**ITEM 5. OTHER INFORMATION.**

None.

**ITEM 6. EXHIBITS.**

The following exhibits are being filed or furnished with or incorporated by reference in this report:

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
3.1	<u>Articles of Incorporation of OncoSec Medical Incorporated, as amended (incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10-K, filed on October 25, 2017)</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.6 to our Current Report on Form 8-K, filed on March 6, 2012)</u>
4.1	<u>Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on October 24, 2017)</u>
4.2	<u>Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on October 26, 2017)</u>
10.1	

Securities Purchase Agreement, dated October 22, 2017, by and between the Company and each purchaser named therein (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on October 24, 2017)

10.2 Engagement Letter, dated October 20, 2017, by and between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed on October 24, 2017)

10.3 Securities Purchase Agreement, dated October 25, 2017, by and between the Company and the purchaser named therein (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on October 26, 2017)

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\* Condensed consolidated financial statements included in the Quarterly Report on Form 10-Q of OncoSec Medical Incorporated for the three months ended October 31, 2017 and 2016, formatted in XBRL, consisting of the following: (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statements of Comprehensive Loss; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements

\* Filed herewith.

\*\* Furnished herewith.

**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**

By: */s/ Daniel J. O'Connor*  
Daniel J. O'Connor  
*(Principal Executive Officer)*

Dated: December 7, 2017

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

Dated: December 7, 2017

