ONCOSEC MEDICAL Inc
Form 10-Q
June 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED APRIL 30, 2016

OR

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

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NO. 000-54318

ONCOSEC MEDICAL INCORPORATED

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

NEVADA	**98-0573252**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
5820 NANCY RIDGE DRIVE SAN DIEGO, CA	**92121**
(Address of principal executive offices)	(Zip Code)

(855) 662-6732

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer [ ]	Accelerated filer [X]
Non-accelerated filer [ ] (Do not check if a smaller reporting company)	Smaller reporting company [ ]

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

The number of shares outstanding of the Registrant's Common Stock, $0.0001 par value, was 17,636,263 as of June 1, 2016.

OncoSec Medical Incorporated

Form 10-Q

for the Quarterly Period Ended April 30, 2016

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS:

OncoSec Medical Incorporated

Condensed Balance Sheets

	April 30, 2016 (unaudited)	July 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$24,018,782	$32,035,264
Prepaid expenses and other current assets	1,000,503	1,532,717
Total Current Assets	25,019,285	33,567,981
Property and equipment, net	3,062,459	1,807,982
Other long-term assets	188,841	214,127
Total Assets	$28,270,585	$35,590,090
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	$3,160,331	$2,360,505
Accrued compensation	517,170	501,446
Total Current Liabilities	3,677,501	2,861,951
Other long-term liabilities	606,173	32,518
Total Liabilities	4,283,674	2,894,469
Commitments and Contingencies		
Stockholders' Equity		
Common stock authorized - 160,000,000 common shares with a par value of $0.0001, common stock issued and outstanding — 16,971,214 and 14,820,854 common shares as of April 30, 2016 and July 31, 2015, respectively	25,162	24,947
Additional paid-in capital	81,783,814	71,572,714
Warrants issued and outstanding — 3,000,875 and 1,895,102 warrants as of April 30, 2016 and July 31, 2015, respectively	9,110,598	7,704,103
Accumulated deficit	(66,932,663)	(46,606,143)
Total Stockholders' Equity	23,986,911	32,695,621
Total Liabilities and Stockholders' Equity	$28,270,585	$35,590,090

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

OncoSec Medical Incorporated

Condensed Statements of Operations (unaudited)

	Three Months Ended April 30, 2016	Three Months Ended April 30, 2015	Nine Months Ended April 30, 2016	Nine Months Ended April 30, 2015
Revenue	$—	$—	$—	$—
Expenses:				
Research and development	3,376,757	3,932,322	11,149,652	9,293,484
General and administrative	2,874,362	2,053,964	9,174,406	5,371,245
Loss from operations	(6,251,119)	(5,986,286)	(20,324,058)	(14,664,729)
Provision for income taxes	290	1,059	2,462	1,969
Net loss	$(6,251,409)	$(5,987,345)	$(20,326,520)	$(14,666,698)
Basic net loss per common share	$(0.37)	$(0.48)	$(1.27)	$(1.19)
Diluted net loss per common share	$(0.37)	$(0.48)	$(1.27)	$(1.19)
Weighted average shares used in computing basic net loss per common share	16,971,214	12,349,693	15,955,116	12,347,450
Weighted average shares used in computing diluted net loss per common share	16,971,214	12,349,693	15,955,116	12,347,450

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

OncoSec Medical Incorporated

Condensed Statements of Cash Flows (unaudited)

	Nine Months Ended April 30, 2016	Nine Months Ended April 30, 2015
Operating activities		
Net loss	$(20,326,520)	$(14,666,698)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	253,664	601,777
Loss on disposal of property and equipment	41,989	4,325
Stock-based compensation	4,676,215	1,650,550
Common stock issued for services	—	59,250
Changes in operating assets and liabilities:		
Decrease (Increase) in prepaid expenses and other current assets	532,214	(550,688)
Decrease in other long-term assets	25,286	6,625
Increase in accounts payable and accrued liabilities	461,617	466,051
Increase in accrued compensation	15,724	—
Increase in other long-term liabilities	573,654	—
Net cash used in operating activities	(13,746,157)	(12,428,808)
Investing activities		
Purchases of property and equipment	(1,156,420)	(761,693)
Net cash used in investing activities	(1,156,420)	(761,693)
Financing activities		
Proceeds from issuance of common stock and warrants	7,500,010	—
Payment of financing and offering costs	(613,915)	—
Proceeds from exercise of warrants and stock options	—	776,995
Net cash provided by financing activities	6,886,095	776,995
Net (decrease) in cash	(8,016,482)	(12,413,506)
Cash and cash equivalents, at beginning of period	32,035,264	37,852,694
Cash and cash equivalents, at end of period	$24,018,782	$25,439,188
Supplemental disclosure for cash flow information:		
Cash paid during the period for:		
Interest	$—	$—
Income taxes	$2,463	$1,969
Noncash investing and financing transaction:		
Fair value of placement agent warrants issued in the public offering	$242,143	$—
Issuance of common stock in connection with a contractual agreement	$55,500	$—
Noncash expiration of March 2011 warrants	$431,981	$—
R&D Equipment in use, but, financed through accounts payable and accrued liabilities	$393,718	$—

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

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

Note 1—Nature of Operations and Basis of Presentation

OncoSec Medical Incorporated (the “Company”) began its operations as a biotechnology company in March 2011, following its completion of the acquisition of certain technology and related assets from Inovio Pharmaceuticals, Inc. (“Inovio”) pursuant to an Asset Purchase Agreement (the “Asset Purchase Agreement”) dated March 14, 2011. The Company has not produced any revenues, nor has it commenced planned principal operations. The Company’s technology includes intellectual property relating to certain delivery technologies including ImmunoPulse™, an electroporation delivery device that is used in combination with the Company’s therapeutic product candidates, including DNA plasmids that encode for immunologically active agents, to deliver the therapeutic directly into the tumor and promote an inflammatory response against the cancer. The Company 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 has no subsidiaries.

During the quarter, the Company continued to enroll patients in the following clinical programs: ImmunoPulse™ IL-12 with pembrolizumab combination trial in patients with advanced, metastatic melanoma and the biomarker-focused pilot study of ImmunoPulse™ IL-12 in triple negative breast cancer. The Company presented positive melanoma clinical data at the American Association for Cancer Research Annual Meeting in April 2016 (“AACR”). The data presented at AACR was longterm, followup data of patients who were treated with ImmunoPulse™ IL-12 and later went on to receive an anti-PD-1/PD-L1 therapy. The data suggest that ImmunoPulse™ IL-12 may prime and enhance response rates to PD-1/PD-L1 blockade. Also at AACR the Company with Heat Biologics, Inc. (“Heat”) presented preclinical results in a poster presentation in which researchers concluded that combining Heat’s *ComPACT* vaccine with the Company’s intratumoral DNA electroporation delivery platform stimulated an expansion of neoantigen-specific $CD8^{+}$ T cells, leading to a regression in both treated and untreated cancer lesions in two mouse studies (melanoma and colorectal cancer). With regard to the Company’s Phase 2 clinical trial in Merkel cell carcinoma (“OMS-I110”), enrollment is complete. The Company is currently in the process of collecting and cleaning all of the available data and expects to officially close OMS-I110 by July 2016. In addition, enrollment in the extension study of the Company’s Phase 2 metastatic melanoma monotherapy clinical trial (“OMS-I100”) is complete. These data are being collected and OMS-I100 is expected to close by August 2016. Final clinical study reports for both the OMS-I100 and OMS-I110 studies are expected to be finalized before the end of calendar year 2016. In addition, the Company continued work to advance its own proprietary technology toward a prototype of its next generation electroporation device and continued advancing its efforts in discovery research to identify new proprietary gene combinations for use with the ImmunoPulse™ platform. The Company’s ImmunoPulse™ product candidates are based on the Company’s proprietary DNA-based immunotherapy technology, which is designed to stimulate the human immune system, resulting in systemic anti-tumor immune responses.

The accompanying unaudited condensed financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The condensed balance sheet as of April 30, 2016, condensed statements of operations for the three and nine months ended April 30, 2016 and 2015 and the condensed statements of cash flow for the nine months ended April 30, 2016 and 2015, are unaudited, but include all adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the three and nine months ended April 30, 2016 shown herein are not necessarily indicative of the results that may be expected for the year ending July 31, 2016, or for any other period. These financial statements, and notes thereto, should be read in conjunction with the audited financial statements for the year ended July 31, 2015, included in the Company's Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on October 14, 2015. The balance sheet at July 31, 2015 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

Reverse Stock Split

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

Reclassifications

Certain amounts in the condensed balance sheet for the year ended July 31, 2015 and the condensed statement of cash flows for the nine-month period ended April 30, 2015 have been reclassified to conform the interim presentation of accrued compensation and other long-term liabilities.

Note 2—Significant Accounting Policies

Segment Reporting

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

Concentrations and Credit Risk

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

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts in the financial statements and disclosures made in the accompanying notes to the financial statements. The Company's significant estimates pertain to stock-based compensation expense — see Note 9. Actual results could differ materially from the estimates.

Recent Accounting Pronouncements

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

In February 2016, the FASB issued new lease accounting guidance in Accounting Standards Update (or, ASU) No. 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Lessor accounting, however, remains largely unchanged. In addition, the new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. Lessees will no longer be provided with a source of off-balance sheet financing. The new lease guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted, however, the Company does not intend to early adopt. The Company also believes that adoption of this new guidance will not have a material impact on the Company's financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The amendments cover both public and private companies that issue share-based payment awards to their employees. Under the amendment several aspects of the accounting for share-based payment award transactions are simplified, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. For public companies, the amendments are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early application is permitted, however, the Company does not intend to early adopt and the Company does not believe that adoption of these clarifying amendments will have a material impact on the Company's financial statements.

In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing. The amendments clarify the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. The amendments do not change the core principle of the guidance in Topic 606. The effective date and transition requirements for the amendments are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within those fiscal years. Early application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company does not intend to early adopt and the Company does not believe that adoption of these clarifying amendments will have a material impact on the Company's financial statements.

Note 3—Cash and Cash Equivalents and Liquidity

The Company considers all liquid investments with maturities of ninety days or less when purchased to be cash equivalents. As of April 30, 2016 and July 31, 2015, cash and cash equivalents were primarily comprised of cash in checking, savings and money market accounts.

The Company's activities to date have been primarily supported by equity financing. It has sustained losses in previous reporting periods with an inception to date loss of $66.9 million as of April 30, 2016.

As of April 30, 2016, the Company had cash and cash equivalents of approximately $24.0 million. The Company believes based on its projected fiscal year 2016 cash requirements that its cash resources are sufficient to meet its anticipated needs at least through the next twelve months from the date of this filing. The Company will require additional financing to fund its future planned operations, including research and development, clinical trials and commercialization of its product candidate. In addition, the Company will require additional financing in order to license or acquire new assets, research and develop any potential patents and the related compounds, and obtain any further intellectual property that the Company may seek to acquire. Additional financing may not be available to the Company when needed or, if available, it may not be obtained on commercially reasonable terms. If the Company is not able to obtain the necessary additional financing on a timely basis, the Company will be forced to delay or scale down some or all of its development activities or perhaps even cease the operation of its business. Historically, the Company has funded its operations primarily through equity financings and it expects that it will continue to fund its operations through equity and possibly debt financings. If the Company secures additional financing by issuing equity securities, its existing stockholders' ownership will be diluted. Obtaining loans, assuming those loans would be available, would increase the Company's liabilities and future cash commitments. The Company also expects to pursue non-dilutive financing sources. However, obtaining such financing would require significant efforts by the Company's management team, and such financing may not be available, and if available, could take a long period of time to obtain.

Note 4—Stockholders' Equity

A summary of the changes in stockholders' equity for the nine months ended April 30, 2016 and 2015 is provided below:

	April 30, 2016	April 30, 2015
Stockholders' equity at beginning of period	$32,695,621	$38,068,058
Net loss	(20,326,520)	(14,666,698)
Public Offering on November 9, 2015, net of issuance costs of $613,915	6,886,095	—
Stock-based compensation	4,676,215	1,650,550
Common stock issued in connection with a contractual agreement	55,500	—
Common stock issued for services	—	59,250
Exercise of common stock warrants	—	775,257
Exercise of common stock options	—	1,738
Stockholders' equity at end of period	$23,986,911	$25,888,155

Note 5—Intangible Asset Acquisition and Cross License Agreement

On March 14, 2011, the Company entered into the Asset Purchase Agreement with Inovio, whereby the Company acquired technology and related assets related to the use of drug-medical device combination products for the treatment of various cancers. In return, the Company agreed to pay Inovio $3,000,000 in scheduled payments and a royalty on commercial product sales related to the SECTA technology. The transaction closed on March 24, 2011. The Asset Purchase Agreement was later amended by the parties to modify the schedule of payments to Inovio (see Note 6).

In connection with the closing of the Asset Purchase Agreement, the Company entered into a cross-license agreement with Inovio. Under the terms of the agreement, the Company granted Inovio a fully paid-up, exclusive, worldwide license to certain of the acquired technology patents in the field of use of electroporation. No consideration was received by the Company, nor will Inovio be liable for future royalty fees related to this arrangement. Inovio also granted the Company a non-exclusive, worldwide license to certain other technology patents held by it in consideration for the following: (a) a fee for any sublicense of the Inovio technology, not to exceed 10%; (b) a royalty on net sales of any business the Company develops with the Inovio technology, not to exceed 1.5%; and (c) payment to Inovio of any amount Inovio pays to one licensor of the Inovio technology that is a direct result of the license. In addition, the Company agreed not to transfer this non-exclusive license apart from the assigned intellectual property.

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

As of July 31, 2015, the patents were fully amortized. Amortization expense for the three- and nine- month periods ended April 30, 2016 and 2015 was approximately $0 and $0 and $116,000 and $465,000, respectively. In addition, during the three- and nine- month period ended April 30, 2016 and 2015, no impairment was recorded.

Note 6—Acquisition Obligation

On March 24, 2011, the Company recorded an acquisition obligation for amounts due to Inovio in accordance with the Asset Purchase Agreement (see Note 5). The Company entered into two subsequent amendments to the Asset Purchase Agreement, each of which modified the Company’s payment terms. In addition, the Company issued to Inovio a warrant to purchase 50,000 shares of common stock pursuant to the first amendment and a warrant to purchase 150,000 shares of common stock pursuant to the second amendment. The Company evaluated these warrants and determined that each met the criteria for equity classification.

The scheduled payments for the $3,000,000 obligation under this arrangement, as amended, were completed by December 31, 2013. At April 30, 2016 and April 30, 2015 there were no payment obligations outstanding under the Asset Purchase Agreement.

Note 7—Balance Sheet Details

Property and Equipment

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

	April 30, 2016	July 31, 2015
Computers and Equipment	$2,873,801	$1,589,914
Office Furniture	476,791	—
Computer Software	18,701	18,701
Leasehold Improvements	80,102	112,469
Construction In Progress	111,102	417,440
Property and Equipment, gross	3,560,497	2,138,524
Accumulated Depreciation and Amortization	(498,038)	(330,542)
	$3,062,459	$1,807,982

Depreciation and amortization expense recorded for the three- and nine- months period ended April 30, 2016 and 2015, was approximately $102,000 and $254,000 and approximately $54,000 and $137,000, respectively.

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities are comprised of the following:

	April 30, 2016	July 31, 2015
Research & Development Costs	$2,242,784	$1,865,087
Professional Services Fees	341,202	213,122
Lab/Office Equipment	396,899	69,900
Rent-related	13,136	—
Other	166,310	212,396
	$3,160,331	$2,360,505

Accrued Compensation

Accrued compensation is comprised of the following:

	April 30, 2016	July 31, 2015
Separation Costs	$303,940	$353,909
Payroll Accrual	212,311	—
Relocation Costs	—	76,884
Stock Issuance Liability	—	55,500
401K Payable	—	14,329
Other	919	824
	$517,170	$501,446

Other Long-Term Liabilities

Other long-term liabilities is comprised of the following:

	April 30, 2016	July 31, 2015
Deferred rent	$606,173	$32,518

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Note 8—Recent Other Equity and Common Stock Transactions

At April 30, 2016, the Company had outstanding warrants to purchase 3,000,875 shares of common stock, with exercise prices ranging from $4.375 to $24.00, all of which were classified as equity instruments. These warrants expire at various times between June 2016 and May 2021.

November 2015 Public Offering

On November 9, 2015, the Company closed the registered public offering of an aggregate of 2,142,860 shares of Common Stock and warrants to purchase an aggregate of 1,071,430 shares of Common Stock (the “Warrants”) at a purchase price of $3.50 per unit pursuant to a Securities Purchase Agreement with investors dated November 3, 2015 (the “November 2015 Public Offering”). Each purchaser was issued a warrant to purchase up to that number of shares of the Company’s Common Stock equal to 50% of the shares issued to such purchaser. The Warrants have an exercise price of $4.50 per share, became exercisable six months after issuance, and expire on May 9, 2021. The Company received aggregate gross proceeds of approximately $7.5 million and net proceeds, after deducting the Placement Agent Fee (described below) and other estimated offering expenses payable by the Company, of approximately $6.9 million in the November 2015 Public Offering.

On November 3, 2015, the Company entered into a Placement Agent Agreement (the “Placement Agent Agreement”) with H.C. Wainwright & Co., LLC (“Wainwright”), pursuant to which Wainwright agreed to act as the Company’s placement agent in connection with the November 2015 Public Offering. The Company agreed to pay an aggregate cash fee for placement agent and financial advisory services equal to six percent (6%) of the gross proceeds of the November 2015 Public Offering (the “Placement Agent Fee”), as well as a non-accountable expense allowance equal to one percent (1%) of the gross proceeds of the November 2015 Financing and certain other expense reimbursements. In addition, the Company agreed to issue warrants to purchase an aggregate of up to five percent (5%) of the aggregate number of shares of Common Stock sold in the November 2015 Public Offering, or 107,143 shares, to the placement agent or its designees (the “Placement Agent Warrants”). The Placement Agent Warrants have substantially the same terms as the Warrants, except that they have an exercise price of $4.375 and expire on November 9, 2020.

The net proceeds from the November 2015 Public Offering are being used for general corporate purposes, including clinical trial expenses and research and development expenses. The fair value of Warrants, based on their fair value relative to the common stock issued, was approximately $1.6 million (based on the Black-Scholes Option Pricing Model assuming no dividend yield, a 5.5 year life, volatility of 88.63%, and a risk-free interest rate of 1.75%). The Company completed an evaluation of these warrants and determined the warrants should be classified as equity within the condensed balance sheet.

The fair value of the Placement Agent Warrants was $0.2 million (based on the Black-Scholes Option Pricing Model assuming no dividend yield, a 5 year life, volatility of 89.08%, and a risk-free interest rate of 1.75%). The Company completed an evaluation of these warrants and determined the warrants should be classified as equity within the condensed balance sheet.

June 2015 Public Offering

On June 8, 2015, the Company closed a registered direct public offering of an aggregate of 2,469,091 shares of its common stock at a purchase price of $5.50 per share, for gross proceeds of approximately $13.6 million (the "June 2015 Public Offering"). After deducting for fees and expenses, the aggregate net proceeds from the sale of the common stock in the June 2015 Public Offering were approximately $12.5 million. In connection with the June 2015 Public Offering, the Company paid placement agent fees consisting of (i) a cash fee equal to six percent (6%) of the gross proceeds of the offering, as well as a non-accountable expense allowance equal to one percent (1%) of the gross proceeds, and (ii) warrants to purchase up to an aggregate of five percent (5%) of the aggregate number of shares of common stock sold in the offering, or 123,455 shares of our common stock. The warrants issued to the placement agent are exercisable at an exercise price of $6.88 per share, became exercisable beginning December 8, 2015, and will expire on May 12, 2019. The warrants were classified as equity with a fair market value of approximately $0.6 million recorded in our balance sheet.

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

Note 9—Stock-Based Compensation

Stock Options

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period are defined pursuant to the terms of the consulting agreement. Stock-based compensation expense for awards granted during the three- and nine-month periods ended April 30, 2016 and 2015, were based on the grant date fair value estimated using the Black-Scholes Option Pricing Model. Share-based compensation expense related to stock option grants to consultants, in which the grant was not entirely vested at the grant date, are generally re-valued each month. The Company's expected volatility is derived from the historical daily change in the market price of its common stock since it exited shell status and became available for trading, as well as the historical daily changes in the market price for the peer group as determined by the Company. The Company uses the simplified method to calculate the expected term of options issued to employees and directors. The Company's estimation of the expected term for stock options granted to parties other than employees or directors is the contractual term of the option award. The risk-free interest rate used in the Black-Scholes calculation is based on the prevailing U.S. Treasury yield in effect at the time of grant, commensurate with the expected term. Stock-based compensation expense recognized in the Company's condensed statements of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. Authoritative guidance requires forfeitures to be estimated at the time of grant, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Because the Company records stock-based compensation monthly and utilizes cliff vesting and/or monthly vesting, the Company has estimated the forfeiture rate of its outstanding stock options as zero since the Company can adjust stock-based compensation due to terminations in the month of termination. The Company has never paid any dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future.

During the three months ended April 30, 2016, the Company granted options to purchase 637,000 shares of the Company's common stock, of which 589,500 and 37,500 options were to employees and directors, respectively, and 10,000 options were to a consultant under the 2011 Plan. The options issued to employees and directors have a ten-year term, vest over a range of one to three years, and have exercise prices ranging from $1.64 to $2.35. The options issued to a consultant have ten-year terms, vest in accordance with the terms of the applicable agreement, and have an exercise price of $2.02 per share.

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

During the nine months ended April 30, 2016, the Company granted options to purchase 2,689,250 shares of the Company's common stock, of which 1,955,750 and 655,500 options were to employees and directors, respectively, and 78,000 options were to consultants under the 2011 Plan. The options issued to employees and directors have a ten-year term, vest over a range of one to three years, and have exercise prices ranging from $1.64 to $6.21. The options issued to consultants have terms ranging from three to ten years, vest in accordance with the terms of the applicable agreement, and have an exercise price ranging from $2.02 to $6.21 per share.

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

The following assumptions were used to calculate the fair value of stock-based compensation during the three months ended April 30, 2016 and 2015:

	April 30, 2016		April 30, 2015	
Expected volatility	84.59% - 87.87	%	87.68%-117.51	%
Risk-free interest rate	1.17% - 1.87	%	0.87%-1.86	%
Expected forfeiture rate	0.00	%	0.00	%
Expected dividend yield	—		—	
Expected term	5.0 - 10 years		3 - 6.5 years	

The following assumptions were used to calculate the fair value of stock-based compensation during the nine months ended April 30, 2016 and 2015:

	April 30, 2016		April 30, 2015	
Expected volatility	83.57% - 89.70	%	87.68%-117.51	%
Risk-free interest rate	0.83% - 2.01	%	0.40%-2.13	%
Expected forfeiture rate	0.00	%	0.00	%
Expected dividend yield	—		—	
Expected term	2.3 - 10 years		2 - 6.5 years	

Stock-based compensation expense recorded in the Company’s condensed statement of operations for the three- and nine- month periods ended April 30, 2016 resulting from stock options awarded to the Company’s employees, directors and consultants was approximately $1.6 million and $4.6 million, respectively. Of this balance, $0.3 million and $0.8 million was recorded to research and development, respectively, and $1.3 million and $3.8 million, respectively, was recorded in general and administrative in the Company’s condensed statement of operations for the period ended April 30, 2016.

Stock-based compensation expense recorded in the Company’s condensed statement of operations for the three- and nine-month periods ended April 30, 2015 resulting from stock options awarded to the Company’s employees, directors and consultants was approximately $0.6 million and $1.7 million , respectively. Of this balance, $0.3 million and $0.8 million were recorded in research and development, respectively, and $0.3 million and $0.9 million, respectively, were recorded in general and administrative in the Company’s condensed statement of operations for the periods ended April 30, 2015.

The weighted-average grant date fair value of stock options granted during the three- and nine- month periods ended April 30, 2016 and 2015 were $1.44 and $3.49, respectively, and $6.20 and $6.60, respectively.

Restricted Stock Units

On March 4, 2016, under the 2011 Plan, the Compensation Committee of the Board of Directors approved the issuance of a total of 680,000 restricted stock units (“RSUs”), each of which is equivalent to one share of stock, to certain employees and a consultant. The RSUs have three (3)-year cliff vesting and are intended to be treated as equity, and, thus, will only allow for settlement in shares. Stock-based compensation expense is measured at the grant date quoted market price of the underlying stock, recognized ratably over the vesting period and adjusted for actual forfeitures. Stock-based compensation expense recorded in the Company’s condensed statement of operations for the three- and nine- month periods ended April 30, 2016 was approximately $76,000.

Employee Stock Purchase Program

Pursuant to the Company’s December 2015 Annual Shareholders Meeting, the Company’s shareholders approved the Company’s 2015 Employee Stock Purchase Plan (“2015 ESPP”). The 2015 ESPP provides an incentive to attract, retain and reward eligible employees to contribute to the growth and profitability of the Company through the opportunity to acquire Company stock at a discount. The ESPP allows for the purchase of Company stock at not less than 85% of the lesser of (a) the fair market value of a share of stock on the offering date of the offering period or (b) 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 2015 ESPP and subject to the requirements of IRS code section 423. The first 2015 ESPP offering period commenced on February 7, 2016 and it will last approximately six (6) months, with the first purchase date on July 31, 2016.

Under FASB issued ASC 718 Compensation –Stock Compensation, the Company's 2015 ESPP would be considered a Type B plan 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 2015 ESPP enables the participant to "buy-up" to the plan's share limit, if the stock price is lower on the purchase date.

Because the 2015 ESPP is considered a Type B plan, the fair value of the award would be calculated at the beginning of the offering period as the sum of:

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

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

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

The fair market value of the 6-month call and 6-month put are based on the Black-Scholes option pricing model, using the following assumptions: six (6) month maturity, 0.45% risk free interest, 81.06% volatility, 0% forfeitures and $0 dividends.

Stock-based compensation expense recorded in the Company's condensed statement of operations for the three- and nine- month periods ended April 30, 2016 was approximately $20,000, adjusting for withdrawals and terminations.

Note 10—Commitments and Contingencies

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

On April 15, 2016, Dr. Robert Pierce notified the Company that he will resign as Chief Scientific Officer of the Company effective June 18, 2016. He will remain an officer and an employee of the Company until that date. Immediately thereafter, Dr. Pierce will transition to the role of Chief Scientific Strategist and continue to support the Company in a consulting capacity. Dr. Pierce and the Company entered into a Separation, Release, and Consulting Agreement (the "Agreement") on April 15, 2016. Under the Agreement, Dr. Pierce's employment with the Company, and the Executive Employment Agreement between the Company and Dr. Pierce, will terminate on June 18, 2016. Dr. Pierce will not receive any severance pay from the Company relating to his employment agreement. The Agreement includes a release signed by Dr. Pierce in favor of the Company (subject to his statutory rights). Pursuant to the Agreement, as Chief Scientific Strategist, Dr. Pierce will provide the Company certain services beginning on June 18, 2016, including reviewing data and advising on the Company's preclinical and clinical development strategies, providing medical and scientific guidance, fostering relationships with collaborators and key opinion leaders, and serving as the chair of the Company's Scientific Advisory Board. Dr. Pierce will be compensated for services at a rate of $30,000 per month, plus certain reimbursable expenses. His equity awards will, by their terms, continue to vest during the time he is serving as Chief Scientific Strategist. The term of the Agreement is one (1) year from June 18, 2016 unless the Agreement is (a) terminated earlier by either party in the event of an uncured breach of the Agreement, or (b) terminated earlier by either party for convenience. Under the Agreement, Dr. Pierce is entitled to receive the compensation he would have earned during the remainder of the term if the Agreement terminates due to a breach by the Company or if the Company terminates for convenience.

On December 31, 2014, the Company entered into a lease agreement for approximately 34,000 rentable square feet located at 5820 Nancy Ridge Drive, San Diego, California to serve as the Company's new corporate headquarters and research and development laboratory. The lease term commenced on October 19, 2015 and expires 120 months after commencement. The Company has an option to extend the lease for an additional five (5) years, if notice is given within 12 months prior to the expiration of the lease term. The Company also has the right to terminate the lease after the expiration of the 84th month after the lease commencement so long as the Company delivers to the landlord a written notice of its election to exercise its termination right no less than 12 months in advance. The lease agreement provides for base rent at $2.65 per rentable square feet, subject to a 3% rate increase on each annual anniversary of the first day of the first full month during the term of the lease agreement. Upon commencement of the lease, 12 months of rent abatement is provided. The Company's corporate relocation was completed in October 2015 and its research and development lab relocation was completed in November 2015. In addition, the Company is required to share in certain operating expenses of the premises. In December 2014, pursuant to the lease agreement, the Company delivered a security deposit of approximately $90,000.

Note 11—Related Party Transactions

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

Note 12—Subsequent Events

On May 26, 2016 the Company's stock price closed at $1.62 and the Company closed an "at-the-market registered direct offering" with a single healthcare-dedicated institutional fund for the purchase of 5,509,642 shares of its common stock at a price of $1.815, or pre-funded warrants in lieu thereof at a price of $1.805 with an exercise price of $0.01, and warrants to purchase up to an aggregate of 5,509,642 shares of common stock at an exercise price of $1.69 per share for a term of nine (9) years. The warrants are immediately exercisable on the date of issuance. At the closing, the placement agents were also issued warrants to purchase an aggregate of up to five percent (5%) of the aggregate number of shares of common stock and pre-funded warrants sold in this offering, or 275,482 shares. The placement agent warrants have an exercise price of $2.26875, are immediately exercisable and expire on May 24, 2021. The gross proceeds of the offering were $9.9 million. Net proceeds, after deducting the placement agent's fee, financial advisory fees, and other estimated offering expenses payable by the Company, are expected to be approximately $9.1 million. The Company intends to use proceeds from the offering for general corporate purposes, including clinical trial expenses and research and development expenses.

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

Cautionary Statement

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our Unaudited Condensed Financial Statements and the related notes thereto contained in Part I, Item 1 of this Report. The information contained in this Quarterly Report on Form 10-Q is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this Report and in our other reports filed with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for the fiscal year ended July 31, 2015, our subsequent quarterly reports on Form 10-Q and our subsequent reports on Form 8-K, which discuss our business in greater detail.

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

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

Company Overview

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

In August 2015, we enrolled the first patient into the Phase II investigator sponsored clinical trial led by the University of California, San Francisco to assess the anti-tumor activity, safety, and tolerability of the combination of ImmunoPulse™ IL-12, and Merck's approved anti-PD-1 agent, KEYTRUDA® (pembrolizumab), in patients with unresectable metastatic melanoma. The primary endpoint is the best Overall Response Rate (bORR) of the combination regimen in patients whose tumors are characterized by low numbers of tumor-infiltrating lymphocytes. We expect to complete enrollment by the end of calendar year 2016.

In September 2015, we announced the results from a Phase II clinical trial of ImmunoPulise™ IL-12 in patients with Merkel cell carcinoma ("MCC"). In the MCC study led by the University of Washington, 79% of patients (11/14) showed an increase in IL-12 protein levels in tumor biopsy samples obtained approximately 22 days after treatment compared to baseline, indicating that ImmunoPulse™ IL-12 leads to successful DNA transfection and sustained protein expression within the tumor microenvironment. ImmunoPulse™ IL-12 was well-tolerated, with no treatment-related adverse events above Grade 2 and no treatment-related serious adverse events. The most common adverse event was Grade 1 transient pain associated with the treatment procedure. This was a proof-of-concept study and with our announcement of these results, we do not plan to further advance the MCC program.

Toward the end of October 2015, we enrolled the first patient in our biomarker-focused pilot study of ImmunoPulse™ IL-12 in patients with triple negative breast cancer ("TNBC"). We anticipate enrolling approximately 10 patients in the TNBC pilot study, led by Stanford University, with the primary objective of the study to evaluate the potential of ImmunoPulse™ IL-12 to promote a pro-inflammatory molecular and histological signature in tumor samples and the secondary objectives include the evaluation of safety and tolerability; evaluation of local ablation effect (% of necrosis) and description of other evidence of anti-tumor activity. We currently are on track to complete enrollment by the end of calendar year 2016.

In the second quarter of fiscal year 2016, we decided to pause further enrollment in our head and neck clinical trial to focus our development efforts toward a potential registration pathway for metastatic melanoma and to pursue clinically relevant data in breast cancer and additional combination trials.

In the third quarter of fiscal year 2016, we announced positive melanoma clinical data presented at the American Association for Cancer Research Annual Meeting 2016 (“AACR”). The data suggest that ImmunoPulse™ IL12 may prime and enhance response rates to PD-1/PD-L1 blockade. Also at AACR we presented with Heat Biologics, Inc. (“Heat”) preclinical results in a poster presentation in which researchers concluded that combining Heat’s *ComPACT* vaccine with our intratumoral DNA electroporation delivery platform stimulated an expansion of neoantigen-specific $CD8^{+}$ T cells, leading to a regression in both treated and untreated cancer lesions in two mouse studies (melanoma and colorectal cancer). With regard to our MCC study, enrollment is complete. The Company is currently in the process of collecting and cleaning all of the available data and expects to officially close the MCC study by July 2016. In addition, enrollment in the extension study of our Phase II metastatic melanoma monotherapy study is complete. These data are being collected and our metastatic melanoma monotherapy study is expected to close by August 2016. Final clinical study reports for both these studies are expected to be finalized before the end of calendar year 2016.

Critical Accounting Policies

Accounting for Long-Lived Assets / Intangible Assets

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

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

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

Stock-Based Compensation

Stock Options

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

Restricted Stock Units

We grant restricted stock units under our stock-based compensation plan. The fair value of restricted stock units is based on our closing stock price on the date of grant. The vesting of all outstanding restricted stock units is three (3)-years cliff vesting. Stock-based compensation expense is based on awards ultimately expected to vest, and therefore is reduced by forfeitures.

Employee Stock Purchase Plan

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

Results of Operations for the Three Months Ended April 30, 2016 Compared to the Three Months Ended April 30, 2015

The unaudited financial data for the three-month periods ended April 30, 2016 and April 30, 2015 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	April 30, 2016 ($)	April 30, 2015 ($)	Increase/ (Decrease) ($)	Increase/ (Decrease) %
Revenue	—	—	—	—
Operating expenses				
Research and development	3,376,757	3,932,322	(555,565)	(14)
General and administrative	2,874,362	2,053,964	820,398	40
Net loss before income taxes	(6,251,119)	(5,986,286)	264,833	4
Tax provision	290	1,059	(769)	(73)
Net loss	(6,251,409)	(5,987,345)	264,064	4

Research and Development Expenses

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

The $0.6 million decrease in research and development expenses for the three-month period ended April 30, 2016, as compared to the three-month period ended April 30, 2015, is primarily the result of a decrease of $0.6 million in salary related expenses due to the engineering department restructuring and bonuses paid out in the prior year period and a decrease of $0.1 million in engineering supplies primarily related to prototype development, offset by an increase in patient treatment costs of $0.1 million primarily related to additional patient enrollment in the IST combination trial.

General and Administrative

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

The $0.8 million increase in general and administrative expenses for the three-month period ended April 30, 2016, as compared to the three-month period ended April 30, 2015, was primarily the result of an increase of $1.0 million in salary related costs, inclusive of stock-based compensation primarily due to stock options and restricted stock units granted in March to management and the Board of Directors, offset by a decrease of $0.2 million in outside services primarily related to corporate communications and IT consulting as we continue to leverage our internal resources in these areas.

Results of Operations for the Nine Months Ended April 30, 2016 Compared to the Nine Months Ended April 30, 2015

The unaudited financial data for the nine-month periods ended April 30, 2016 and April 30, 2015 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	April 30, 2016 ($)	April 30, 2015 ($)	Increase/ (Decrease) ($)	Increase/ (Decrease) %
Revenue	—	—	—	—
Operating expenses				
Research and development	11,149,652	9,293,484	1,856,168	20
General and administrative	9,174,406	5,371,245	3,803,161	71
Net loss before income taxes	(20,324,058)	(14,664,729)	5,659,329	39
Tax provision	2,462	1,969	493	25
Net loss	(20,326,520)	(14,666,698)	5,659,822	39

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Research and Development Expenses and Operational Milestones

The $1.9 million increase in research and development expenses for the nine-month period ended April 30, 2016, as compared to the nine-month period ended April 30, 2015 is primarily the result of an increase of $1.2 million primarily related to the progression of patient treatments in our clinical trials and CMC work, an increase of $1.0 million in outside services to further assist in the research of next-generation devices, novel electroporation technologies and combination studies, an increase of $0.1 million in depreciation primarily on laboratory equipment and an increase of $0.1 million in facility related expenses, offset by a decrease of $0.5 million in amortization expense due to our intangible assets being fully amortized.

We expect to use our working capital for the advancement of our operational milestones. Our significant milestones currently include generating clinically relevant data in TNBC and our current combination trial, designing additional combination trials, continuing our discovery research focus on a novel gene combination and developing an ImmunoPulse IL-12 registration pathway for metastatic melanoma.

Activities related to the above milestones are primarily conducted by our Engineering, Clinical and R&D (“discovery research”) departments. We estimate we may incur engineering and quality assurance costs of $2.8 million, clinical costs of $3.2 million and discovery research costs of $4.0 million, in each case exclusive of personnel costs, stock-based compensation and depreciation, during our current fiscal year ending July 31, 2016 (“Fiscal 2016”).

General and Administrative

The $3.8 million increase in general and administrative expenses for the nine-month period ended April 30, 2016, as compared to the nine-month period ended April 30, 2015, was primarily the result of an increase of $3.6 million in salary related costs due to hiring additional personnel to support business and product development and stock-based compensation primarily related to stock options and restricted stock units granted to management and the Board of Directors, an increase of $0.2 million in audit fees related to our fiscal-year end 2015 internal controls attestation and an increase of $0.6 million related primarily to rent expense and other operational costs related to our new corporate headquarters, offset by a decrease of $0.3 million in outside services primarily due to corporate communications services, IT consulting and product development consulting as we continue to leverage our internal resources in these areas and a decrease of $0.3 million related to conference fees and travel related expenses.

We expect our general and administrative expenses related to stock-based compensation will continue to increase as we expect to continue to grant annual stock options to our employees, directors, and, as appropriate, to consultants.

Liquidity and Capital Resources

Working Capital

Our working capital as of April 30, 2016 and July 31, 2015 is summarized as follows:

	At April 30, 2016 ($)	At July 31, 2015 ($)
Current assets	25,019,285	33,567,981
Current liabilities	3,677,501	2,861,951
Working capital	21,341,784	30,706,030

Current Assets

Current assets as of April 30, 2016 decreased to approximately $25.0 million, in comparison to current assets of approximately $33.6 million as of July 31, 2015. This decrease in our current assets was primarily due to a decrease in cash from $32.0 million as of July 31, 2015, to $24.0 million as of April 30, 2016, which is attributable to the cash used in operating and investing activities during the nine-month period ended April 30, 2016, offset by the $6.9 million of net proceeds from the November 2015 financing.

Current Liabilities

Current liabilities as of April 30, 2016 increased to approximately $3.7 million, in comparison to our approximate current liabilities of $2.9 million as of July 31, 2015. This increase was due to an increase of $0.6 million in research and development related accruals primarily related to our clinical programs and lab equipment payable and $0.2 million related to salary accrual as we moved from bi-monthly to bi-weekly payroll.

Cash Flow

Cash Used in Operating Activities

Cash used in operating activities for the nine-month period ended April 30, 2016 was $13.7 million, as compared to $12.4 million for the nine-month period ended April 30, 2015. This increase was primarily related to the progression of our on-going clinical trials, discovery research efforts, and an increase in personnel costs.

Cash Used in Investing Activities

Cash used in investing activities for the nine-month period ended April 30, 2016 was $1.2 million, as compared to $0.8 million for the nine-month period ended April 30, 2015. Investing activities relate to the purchase of furniture and equipment for our new corporate headquarters, inclusive of the laboratory equipment.

Cash Flow Provided by Financing Activities

Cash provided by financing activities was $6.9 million for the nine-month period ended April 30, 2016, as compared to $0.8 million for the comparable nine-month period ended April 30, 2015. The increase is due to the proceeds from the November 2015 financing, whereas in the prior year period proceeds resulted from option and warrant exercises.

Recent Equity Financings

May 2016 “At-the-Market Registered Direct Offering”

On May 26, 2016 our stock price closed at $1.62 and we closed an “at-the-market registered direct offering” with a single healthcare-dedicated institutional fund for the purchase of 5,509,642 shares of its common stock at a price of $1.815, or pre-funded warrants in lieu thereof at a price of $1.805 with an exercise price of $0.01, and warrants to purchase up to an aggregate of 5,509,642 shares of common stock at an exercise price of $1.69 per share for a term of nine (9) years. The warrants are immediately exercisable on the date of issuance. At the closing, the placement agents were also issued warrants to purchase an aggregate of up to five percent (5%) of the aggregate number of shares of common stock sold in this offering, or 275,482 shares. The placement agent warrants have an exercise price of $2.26875, are immediately exercisable, and expire on May 24, 2021. The gross proceeds of the offering were $9.9 million. Net proceeds, after deducting the placement agent’s fee, financial advisory fees, and other estimated offering expenses payable by us, are expected to be approximately $9.1 million. We intend to use proceeds from the offering for general corporate purposes, including clinical trial expenses and research and development expenses.

November 2015 Public Offering

On November 9, 2015, we closed a registered direct offering of an aggregate of 2,142,860 shares of our common stock at a purchase price of $3.50 per share and warrants to purchase an aggregate of 1,071,430 shares of our common stock in the November 2015 Public Offering. The warrants have an exercise price of $4.50 per share, are exercisable on May 9, 2016 and expire on May 9, 2021. The warrants were classified as equity at a relative fair market value to common stock of approximately $1.6 million recorded in our balance sheet. The gross proceeds to us from the November 2015 Public Offering was approximately $7.5 million. After deducting for fees and expenses, the aggregate net proceeds from the sale of the common stock in the November 2015 Public Offering were approximately $6.9 million. In connection with the November 2015 Public Offering, we paid placement agent fees consisting of (i) a cash fee equal to six percent (6%) of the gross proceeds of the offering, as well as a non-accountable expense allowance equal to one percent (1%) of the gross proceeds, and (ii) warrants to purchase up to an aggregate of five percent (5%) of the aggregate number of shares of common stock sold in the offering, or 107,143 shares of our common stock. The warrants issued to the placement agent are exercisable at an exercise price of $4.375 per share, have a term of five (5) years became exercisable on May 9, 2016, and expire on November 9, 2020.

June 2015 Public Offering

On June 8, 2015, we closed a registered direct public offering of an aggregate of 2,469,091 shares of our common stock at a purchase price of $5.50 per share, for gross proceeds to us of approximately $13.6 million (the "June 2015 Public Offering"). After deducting for fees and expenses, the aggregate net proceeds from the sale of the common stock in the June 2015 Public Offering were approximately $12.5 million. In connection with the June 2015 Public Offering, we paid placement agent fees consisting of (i) a cash fee equal to six percent (6%) of the gross proceeds of the offering, as well as a non-accountable expense allowance equal to one percent (1%) of the gross proceeds, and (ii) warrants to purchase up to an aggregate of five percent (5%) of the aggregate number of shares of common stock sold in the offering, or 123,455 shares of our common stock. The warrants issued to the placement agent became exercisable at an exercise price of $6.88 per share, are exercisable beginning December 8, 2015, and will expire on May 12, 2019. The net proceeds from the June 2015 Public Offering are being used for general corporate purposes, including clinical trials and research and development expenses.

Cash Requirements

Our primary objectives for the next twelve-month period are to continue the advancement of our ImmunoPulse™ platform, inclusive of developing an ImmunoPulse™ IL-12 registration pathway for metastatic melanoma, completing the triple negative breast cancer pilot study and the melanoma combination study, and developing a new combination trial. In addition, we expect to pursue raising sufficient capital to fund our operations and to acquire and develop additional assets and technology consistent with our focus on innovative gene therapies, therapeutics and proprietary medical approaches to stimulate and guide an anti-tumor immune response for the treatment of cancer.

As we continue to focus on reducing expenses through leveraging our in-house capabilities to reduce reliance on consultants and outside service providers and as we continue to pursue our business plan, we currently estimate our cash-based operating expenses and working capital requirements for Fiscal 2016 to be approximately $20.3 million, although we may modify or deviate from our estimates and it is likely that our actual results for certain categories of operating expenses and working capital requirements will vary from the estimates as set forth in the table below.

Cash Requirements	Amount
Product development	$9,961,000
Employee compensation	7,097,000
General and administration	1,631,000
Professional services fees	1,579,000
	$20,268,000

During the nine-month period ended April 30, 2016, our operating cash outflow was approximately $13.7 million. Based on our current operating costs and our operational goals, we expect our monthly cash outflows for the remainder of Fiscal 2016 to be approximately $1.6 million per month. In general, our cash outflows for future periods may increase as we continue to operate our business and pursue our mission to discover and develop novel immuno-oncology therapies. We expect our current funds to be sufficient to allow us to continue to operate our business for at least the next twelve months from the date of filing these financial statements.

During the nine-month period ended April 30, 2016, there were no exercises of warrants previously issued to investors of our equity securities. At April 30, 2016, if the holders of warrants to purchase our common stock were to exercise their remaining outstanding warrants in full on a cash basis, we would receive an aggregate of approximately $25.5 million in proceeds. However, the warrant holders may choose not to exercise any of the warrants they hold, may choose to net exercise their warrants as provided in such warrants under certain limited circumstances, or may choose to exercise only a portion of the warrants issued. In addition, currently all 3,000,875 warrants outstanding are out-of-the-money. As a result, we may never receive proceeds from the exercise of such warrants.

Since the inception of our current business in March 2011, we have funded our operations primarily through equity financings and we expect to continue to pursue capital-raising transactions in future periods. If we obtain additional financing by issuing equity securities, our existing stockholders' ownership will be diluted. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments and may subject us to financial covenants and other restrictions applicable to our business. We may be unable to maintain operations at a level sufficient for investors to obtain a return on their investments in our common stock. Further, we may continue to be unprofitable.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Cash and cash equivalents as of April 30, 2016 were $24.0 million and were primarily invested in interest bearing money market, checking and savings accounts. A hypothetical 10% adverse change in the average interest rate on our cash and cash equivalents would not have had a material effect on net loss for the three and nine months ended April 30, 2016.

ITEM 4. CONTROLS AND PROCEDURE

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Our Controls

There were no changes in our internal controls over financial reporting during our fiscal quarter ended April 30, 2016 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

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PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q. If any of the following events, risks or uncertainties actually occur, either alone or taken together, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. These Risk Factors may be important to understanding any statement in this Form 10-Q or elsewhere. The following information should be read in conjunction with the condensed consolidated financial statements and related notes in Part I, Item 1, “Financial Statements” and Part I, Item 2, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Form 10-Q.

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

We do not generate any cash from operations and will need to raise additional funds in future periods in order to continue operating our business. We estimate our cash requirements for the next 12 months to be approximately $24.0 million. As of April 30, 2016, we had cash and cash equivalents of approximately $24.0 million. We completed a registered direct financing in May 2016, with net proceeds expected to be approximately $9.1 million.

We have a history of raising funds through offerings of our common stock, and we may in the future raise additional funds through public or private equity offerings, debt financings, grants or corporate collaborations and licensing arrangements. We expect to continue to fund our operations primarily through equity financings in the near future. If additional capital is not available, we may not be able to continue to operate our business or we may have to significantly change our business plan.

We will require additional financing to fund our planned operations, including developing and commercializing our intellectual property, seeking to license or acquire new assets, researching and developing any potential patents, related compounds and other intellectual property, funding potential acquisitions, and supporting clinical trials and seeking regulatory approval relating to our assets and any assets we may acquire in the future. Additional financing may not be available to us when needed or, if available, may not be available on commercially reasonable terms. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments.

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

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

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

- successfully identifying potential product candidates;
- developing potential product candidates;

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

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

acquiring, developing, testing, and manufacturing products in compliance with regulatory standards in a timely manner or at all;

being subject to legal actions brought by our competitors, which may delay or prevent the development and commercialization of new products;

significant and unpredictable changes in the payor landscape, coverage, and reimbursement for any products we successfully develop and commercialize; and

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

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

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

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

Delays in the commencement or completion of clinical testing could significantly affect our product development costs and business plan. We do not know whether our Phase 2 clinical trials will be completed on schedule, if at all; however, current enrollment in the clinical trials suggest possible completion by the end of calendar 2016. We do not know whether any other pre-clinical or clinical trials will begin on time or be completed on schedule, if at all. In addition, a number of pre-clinical and clinical trials related to our product candidates are investigator-initiated and sponsored. An investigator-initiated trial is a research effort in which the investigator designs and implements the study and the investigator or the institution acts as the study sponsor. The trial sponsor has control over the design, conduct and timing of such trials, and we have limited or no control over the commencement and completion of such trials.

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

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

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

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

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

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

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

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

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

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

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

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

Our success depends in large part on our ability to protect our intellectual property using a combination of patents, trade secrets, and confidentiality agreements. Certain of our patents will expire in the near future, and we may have difficulties protecting our proprietary rights and technology and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark, and trade secret protection of our product candidates and their respective components, including devices, formulations, manufacturing methods, and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell, or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. As we describe in our Annual Reports on Form 10-K, most recently filed on October 14, 2015, we have patent protection for components of our ImmunoPulse™ product candidates. Our current device portfolio includes US6,014,584, US6,055,453, US6,068,650, US6,181,964, US6,216,034, US6,233,482, US6,241,701,US6,516,233, US7,412,284, and EP999867, which cover our current clinical device. These patents will expire between 2017 and 2018, at which point we can no longer enforce these against third parties to prevent them from making, using, selling, offering to sell, or importing our current clinical device. This could expose us to substantially more competition and have a material adverse impact on our business and our ability to commercialize or license our technology and products.

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

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

We have not generated any revenue from operations since our inception. During the quarter ended April 30, 2016, we incurred a net loss of approximately $6.3 million. From inception through April 30, 2016, we have incurred an aggregate net loss of approximately $66.9 million. We expect that our operating expenses will continue to increase as we expand our current headcount, further our development activities, and continue to pursue FDA approval for our product candidates.

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

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of our product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. The FDA and other foreign regulatory agencies can delay approval of or refuse to approve our product candidates for a variety of reasons, including failure to meet safety and efficacy endpoints in our clinical trials. Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, may disagree with our or our partners' trial design and our interpretation of data from preclinical studies and clinical trials. Clinical trials of our product candidates may not demonstrate that they are safe and effective to the extent necessary to obtain regulatory approvals. We have one clinical trial currently open for enrollment to assess our ImmunoPulse™ IL-12 single-agent therapy in patients with metastatic melanoma and one biomarker-focused pilot study of ImmunoPulse™ IL-12 in patients with triple negative breast cancer open for enrollment. In addition, a Phase 2 investigator sponsored clinical trial led by the University of California San Francisco to assess the combination of ImmunoPulse™ IL-12 and Merck's anti-PD-1 antibody, KEYTRUDA® is also enrolling. If we cannot adequately demonstrate through the clinical trial process that a therapeutic product we are developing is safe and effective, regulatory approval of that product would be delayed or prevented, which would impair our reputation, increase our costs and prevent us from earning revenues. Even if a product candidate is approved, it may be approved for fewer or more limited indications than requested or the approval may be subject to the performance of significant post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any limitation, condition or denial of approval would have an adverse effect on our business, reputation and results of operations.

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

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

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

We are an early-stage, pre-commercial company with only a limited operating history upon which to base an evaluation of our current business and future prospects and how we will respond to competitive, financial, or technological challenges. Although we plan to investigate licensing and partnering opportunities, we are not currently planning on generating any significant near term revenue; therefore, the income potential of our business is unproven. In addition, because of our limited operating history, we have limited insight into trends that may emerge and affect our business. Errors may be made in predicting and reacting to relevant business trends and we will be subject to the risks, uncertainties, and difficulties frequently encountered by early-stage companies in evolving markets. We may not be able to successfully address any or all of these risks and uncertainties. Failure to adequately do so could cause our business, results of operations, and financial condition to suffer or fail.

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

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

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

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

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

- exposure to unknown liabilities;
- disruption of our business and diversion of our management’s time and attention to manage the acquisition and develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership; and
- inability to retain key employees of any acquired business.

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

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

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

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither party has final decision-making authority. Collaborations with third parties often are terminated or allowed to expire by the third party, which would adversely affect us financially and could harm our business reputation.

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

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

If we and the contract manufacturers upon whom we rely fail to produce our systems and product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations, we may face delays in the development and commercialization of our electroporation equipment and product candidates.

We currently assemble certain components of our electroporation systems, which is our delivery mechanism for our biologic to a patient's cell. We utilize the services of contract manufacturers to manufacture the remaining components of these systems and our product supplies for clinical trials. We expect to increase our reliance on third party manufacturers if and when we commercialize our product candidates and systems. The manufacture of our systems and product supplies requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers often encounter difficulties in production, particularly in scaling up for commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the equipment and product candidates and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we or our manufacturers were to encounter any of these difficulties or our manufacturers otherwise fail to comply with their obligations to us, our ability to provide our electroporation equipment to our partners and products to patients in our clinical trials or to commercially launch a product would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial program, and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

In addition, all manufacturers of our products must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance, and the generation and maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state, and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product is compromised due to our or our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals, or commercialization of our products, entail higher costs, or result in our being unable to effectively commercialize our products. Furthermore, assuming we are successful in commercializing one or more of our product candidates, if our manufacturers fail to deliver the required commercial quantities on a timely basis, pursuant to provided specifications and at commercially reasonable prices, we may be unable to meet demand for our products and would lose potential revenues.

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

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

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

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

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

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the prevalence and severity of adverse side effects;

limitations or warnings contained in a product’s FDA-approved labeling;

the clinical indications for which the product is approved;

availability and perceived advantages of alternative treatments;

any negative publicity related to our or our competitors’ products;

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

pricing and cost effectiveness;

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

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

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

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

Our efforts to educate the medical community and third-party payors on the benefits of any of our potential product candidates may require significant resources and may never be successful. If our potential products do not achieve an adequate level of acceptance by physicians, third-p