ONCOSEC MEDICAL Inc
Form 10-Q
March 09, 2018

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 JANUARY 31, 2018

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)

Not applicable

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

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

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

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

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

The number of shares outstanding of the Registrant's Common Stock, $0.0001 par value, was 51,482,206 as of March 7, 2018.

OncoSec Medical Incorporated

Form 10-Q

for the Quarterly Period Ended January 31, 2018

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements:

OncoSec Medical Incorporated

Condensed Consolidated Balance Sheets

	January 31, 2018 (unaudited)	July 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$17,903,581	$11,444,676
Prepaid expenses and other current assets	1,680,461	1,068,947
Total Current Assets	19,584,042	12,513,623
Property and equipment, net	2,224,934	2,410,099
Other long-term assets	313,229	309,187
Total Assets	$22,122,205	$15,232,909
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	$2,751,299	$3,281,133
Accrued compensation	161,127	114,841
Total Current Liabilities	2,912,426	3,395,974
Other long-term liabilities	1,178,708	1,140,953
Total Liabilities	4,091,134	4,536,927
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 — 35,827,912 and 21,618,194 common shares as of January 31, 2018 and July 31, 2017, respectively	3,583	2,162
Additional paid-in capital	118,123,124	93,866,088
Warrants issued and outstanding — 9,283,059 and 9,044,740 warrants as of January 31, 2018 and July 31, 2017, respectively	11,465,127	11,775,807
Accumulated other comprehensive income	20,245	(3,620)
Accumulated deficit	(111,581,008)	(94,944,455)

Total Stockholders' Equity	18,031,071	10,695,982
Total Liabilities and Stockholders' Equity	$22,122,205	$15,232,909

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

OncoSec Medical Incorporated

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended		Six Months Ended	
	January 31, 2018	January 31, 2017	January 31, 2018	January 31, 2017
Revenue	$ -	$ -	$ -	$ -
Expenses:				
Research and development	2,994,937	2,882,611	6,408,086	5,982,351
General and administrative	5,290,096	2,547,354	7,804,135	5,095,924
Loss from operations	(8,285,033)	(5,429,965)	(14,212,221)	(11,078,275)
Other income (expense), net	15,279	42,654	42,015	88,772
Warrant inducement expense	(2,465,396)	-	(2,465,396)	-
Loss before income taxes	(10,735,150)	(5,387,311)	(16,635,602)	(10,989,503)
Provision for income taxes	951	-	951	1,391
Net loss	$ (10,736,101)	$ (5,387,311)	$ (16,636,553)	$ (10,990,894)
Basic and diluted net loss per common share	$ (0.31)	$ (0.27)	$ (0.58)	$ (0.57)
Weighted average shares used in computing basic and diluted net loss per common share	34,794,004	19,733,015	28,561,809	19,376,998

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

OncoSec Medical Incorporated

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

	Three Months Ended		Six Months Ended	
	January 31, 2018	January 31, 2017	January 31, 2018	January 31, 2017
Net Loss	$(10,736,101)	$ (5,387,311)	$(16,636,553)	$ (10,990,894)
Foreign currency translation adjustments	30,610	23	23,865	14
Comprehensive Loss	$(10,705,491)	$ (5,387,288)	$(16,612,688)	$ (10,990,880)

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

OncoSec Medical Incorporated

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six Months Ended	
	January 31, 2018	January 31, 2017
Operating activities		
Net loss	$(16,636,553)	$(10,990,894)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	190,973	189,039
Loss on disposal of property and equipment	15,498	-
Warrant inducement expense	2,465,396	-
Stock-based compensation	2,981,509	2,596,280
Common stock issued for services	843,250	-
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other current assets	(308,123)	(122,428)
Decrease in other long-term assets	(4,042)	(163,064)
Increase/(decrease) in accounts payable and accrued liabilities	(846,318)	73,497
Increase (decrease) in accrued compensation	46,286	(125,994)
Increase in other long-term liabilities	37,756	305,936
Net cash used in operating activities	(11,214,368)	(8,237,628)
Investing activities		
Purchases of property and equipment	(8,213)	(9,578)
Net cash used in investing activities	(8,213)	(9,578)
Financing activities		
Proceeds from issuance of common stock through ESPP	19,048	25,615
Proceeds from issuance of common stock and warrants	9,283,443	-
Payment of financing and offering costs	(1,396,531)	-
Proceeds from exercise of options	157,928	-
Proceeds from exercise of warrants	9,593,733	16,808
Net cash provided by financing activities	17,657,621	42,423
Effect of exchange rate changes on cash	23,865	14
Net increase (decrease) in cash	6,458,905	(8,204,769)
Cash and cash equivalents, at beginning of period	11,444,676	28,746,224
Cash and cash equivalents, at end of period	$17,903,581	$20,541,455
Supplemental disclosure for cash flow information:		
Cash paid during the period for:		
Interest	$-	$-
Income taxes	$951	$1,391

Noncash investing and financing transaction:

Noncash expiration of warrants	$1,200,742	$309,477

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

OncoSec Medical Incorporated

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Note 1—Nature of Operations and Basis of Presentation

OncoSec Medical Incorporated (together with its subsidiaries, unless the context indicates otherwise, being collectively referred to as the "Company") began its operations as a biotechnology company in March 2011, following its completion of the acquisition of certain technology and related assets from Inovio Pharmaceuticals, Inc. ("Inovio"). The Company has not produced any revenues since its inception. The Company was incorporated in the State of Nevada on February 8, 2008 under the name of Netventory Solutions, Inc. and changed its name in March 2011 when it began operating as a biotechnology company.

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

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

The Company also intends to continue to pursue other ongoing or potential new trials and studies related to ImmunoPulse® IL-12, all with the goal of obtaining requisite regulatory approvals from the FDA and comparable regulators in certain other jurisdictions to market and sell this product candidate. For instance, the Company is in collaboration with the University of California, San Francisco ("UCSF"), the sponsor of a multi-center Phase II clinical trial evaluating ImmunoPulse® IL-12 in combination with Merck's KEYTRUDA® for the treatment of advanced, metastatic melanoma in patients who are predicted to not respond to anti-PD-1 therapy alone. Merck is manufacturing and supplying its drug KEYTRUDA® to UCSF to support this trial.

In addition, the Company is pursuing a biomarker-focused pilot study of ImmunoPulse® IL-12 in triple negative breast cancer (TNBC), which is focused on evaluating the ability of ImmunoPulse® IL-12 to alter the tumor microenvironment and promote a pro-inflammatory response. In January 2018, the Company reported observational data in two patients that showed clinical response with the sequential treatment of one cycle of ImmunoPulse IL-12 and an anti-PD1 checkpoint inhibitor. The Company is currently evaluating a clinical development strategy in TNBC in this combination approach while the current study is open for enrollment and is ongoing. Additionally, the Company's Phase II clinical trials of ImmunoPulse® IL-12 as a monotherapy in Merkel Cell carcinoma, melanoma, and head and neck squamous cell carcinoma are now closed and filed. Monotherapy melanoma is closed and the clinical study report is pending.

In addition, the Company is developing its next-generation electroporation devices, including advancements toward prototypes, pursuing discovery research to identify other product candidates that, like IL-12, can be encoded into DNA, delivered intratumorally using electroporation and used to reverse the immunosuppressive mechanisms of a tumor, and aiming to expand our ImmunoPulse® pipeline beyond the delivery of plasmid-DNA encoding for cytokines to include other molecules that may be critical to key pathways associated with tumor immune subversion.

Basis of Presentation

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

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The condensed consolidated balance sheet as of January 31, 2018, and condensed consolidated statements of operations, condensed consolidated statements of comprehensive loss, and condensed consolidated statements of cash flows for the six months ended January 31, 2018 and 2017, are unaudited, but include all adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of the Company's financial position, results of operations and cash flows for the periods presented. The condensed consolidated results of operations for the three and six months ended January 31, 2018 shown herein are not necessarily indicative of the consolidated results that may be expected for the year ending July 31, 2018, or for any other period. These condensed consolidated financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements for the fiscal year ended July 31, 2017, included in the Company's Annual Report on Form 10-K (the "Annual Report") filed with the U.S. Securities and Exchange Commission ("SEC") on October 25, 2017. The consolidated balance sheet at July 31, 2017 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

Reclassifications

Certain amounts in the accompanying condensed consolidated balance sheet for the year ended July 31, 2017 have been reclassified to conform to an interim presentation, but there was no effect on net loss at July 31, 2017.

Note 2—Significant Accounting Policies

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

Use of Estimates

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

Segment Reporting

The Company operates in a single 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.

Australia Research and Development Tax Credit

The Company's Australian, wholly-owned, subsidiary incurs research and development expenses, primarily in the course of conducting clinical trials. The Company's Australian research and development activities qualify for the Australian government's tax credit program, which provides a 43.5 percent credit for qualifying research and development expenses. The tax credit does not depend on the Company's generation of future taxable income or ongoing tax status or position. Accordingly, the credit is not considered an element of income tax accounting under ASC 740 and is recorded against qualifying research and development expenses.

Tax Reform

The Tax Cuts and Jobs Act ("the Act") was signed into law in December 2017, impacting federal corporate tax rates. While the Act will impact certain aspects in the calculation of the Company's tax provision, the Company maintains a full valuation allowance and does not anticipate any net impact to the Company's financial statements in 2018.

Recent Accounting Pronouncements

There were no accounting pronouncements during the three and six months ended January 31, 2018 that the Company anticipates will have a material impact on the Company's financial condition, results of operations or related disclosures. See Note 2 to the Annual Report for a discussion of certain recent accounting pronouncements not yet adopted by the Company.

Note 3—Cash and Cash Equivalents and Liquidity

The Company considers all liquid investments with maturities of three months or less when purchased to be cash equivalents. As of January 31, 2018 and July 31, 2017, cash and cash equivalents were primarily comprised of cash in savings and checking accounts.

As of January 31, 2018, the Company had cash and cash equivalents of $17.9 million. Additionally, subsequent to January 31, 2018, the Company received additional net proceeds of approximately $20.8 million from an equity financing of its common stock (see Note 10). As of February 28, 2018, the Company had cash and cash equivalents of $36.7 million. The Company currently estimates its operating expenses and working capital requirements for the current fiscal year ending July 31, 2018 to be approximately $21.0 million, although the Company may modify or deviate from this estimate and it is likely that actual operating expenses and working capital requirements will vary from this estimate. Based on these expectations regarding future expenses, as well as the current cash levels and rate of cash consumption, the Company believes that current cash resources are sufficient to meet the Company's anticipated needs for the 12 months following the issuance of this report. The Company will continue to assess its cash resources and anticipated needs on a quarterly basis.

The Company has sustained losses in all reporting periods since inception, with an inception-to date-loss of $111.6 million as of January 31, 2018. Further, the Company has never generated any cash from its operations, does not expect to generate such cash in the near term, and does not presently have any firm commitments for future capital. Consequently, the Company will need additional capital to continue operating its business and fund its planned operations, including research and development, clinical trials and, if regulatory approval is obtained, commercialization of its product candidates. In addition, the Company will require additional financing if it desires to in-license or acquire new assets, research and develop new compounds or new technologies and pursue related patent protection, or obtain any other intellectual property rights or other assets.

Historically, the Company has raised the majority of the funding for its business through offerings of its common stock and warrants to purchase its common stock. The Company's most recent February 2018 offering consisted of common stock only. If the Company issues equity or convertible debt securities to raise additional funds, its existing stockholders would experience further dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of its existing stockholders. If the Company incurs debt, its fixed payment obligations, liabilities and leverage relative to our equity capitalization would increase, which could increase the cost of future capital. Further, the terms of any debt securities the Company issues or borrowings it incurs, if available, could impose significant restrictions on its operations, such as limitations on its ability to incur additional debt or issue additional equity or other operating restrictions that could adversely affect its ability to conduct its business, and any such debt could be secured by any or all of the Company's assets pledged as collateral. Additionally, the Company may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other costs.

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

Note 4—Stockholders' Equity