ONCOSEC MEDICAL Inc
Form 10-K
October 19, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended July 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 number 000-54318

ONCOSEC MEDICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Nevada	**98-0573252**
(State or other jurisdiction	(I.R.S. Employer
of incorporation or organization)	Identification Number)

24 North Main Street
Pennington, NJ 08534

3565 General Atomics Court, Suite 100
San Diego, CA 92121
(Address of principal executive offices) (Zip Code)

(855) 662-6732

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	**Name of Exchange on which Registered:**
Common Stock, par value $0.0001 per share	**Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [ ] No [X]

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, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§229.405 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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 [ ] 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 aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of January 31, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $63,514,594, computed by reference to the price at which the registrant's common stock was last sold on such date, as reported by the Nasdaq Capital Market. Shares of common stock held by the registrant's officers and directors and holders of 10% or more of the outstanding shares of the registrant's common stock have been excluded from this calculation because such persons may be deemed to be affiliates of the registrant; however, this determination of affiliate status is not, and shall not be considered, a determination of affiliate status for any other purpose.

As of October 19, 2018, there were 59,213,947 outstanding shares of the Company's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for the 2018 Annual Meeting of Stockholders, which is expected to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended July 31, 2018, are incorporated by reference in Part III of this Annual Report on Form 10-K to the extent stated herein.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER MATTERS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. Forward-looking statements relate to future events or circumstances or our future performance and are based on our current assumptions, expectations and beliefs about future developments and their potential effect on our business. All statements in this report that are not statements of historical fact could be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “expects,” “plans,” “intends,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the nega terms or other comparable terminology. The forward-looking statements in this report include statements about, among other things: the status, progress and results of our clinical programs; our ability to obtain regulatory approvals for, and the level of market opportunity for, our product candidates; our business plans, strategies and objectives, including plans to pursue collaboration, licensing or other similar arrangements or transactions; our expectations regarding our liquidity and performance, including our expense levels, sources of capital and ability to maintain our operations as a going concern; the competitive landscape of our industry; and general market, economic and political conditions.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- the success and timing of our clinical trials, including safety and efficacy of our product candidates, patient accrual, unexpected or expected safety events, and the usability of data generated from our trials;
- our ability to successfully file and obtain timely marketing approval from the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory agency for one or more Biologics License Applications, or BLAs, or New Drug Applications, or NDAs;
- our ability to obtain and maintain marketing approval from regulatory agencies for our products in the U.S. and foreign countries;
- our ability to adhere to ongoing compliance requirements of all health authorities, in the U.S. and foreign countries;
- our ability to obtain and maintain adequate reimbursement for our products;
- our ability to obtain the desired labeling of our products under any regulatory approval we might receive;
- our plans to develop and commercialize our products;
- the successful development and implementation of sales and marketing campaigns;
- the loss of key scientific or management personnel;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;

our ability to successfully compete in the potential markets for our product candidates, if commercialized;

regulatory developments in the United States and foreign countries;

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- the rate and degree of market acceptance of any of our product candidates;
- new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;
- market conditions in the pharmaceutical and biotechnology sectors;
- our available cash and investments;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain additional funding;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to maintain license agreements for our licensed product candidates;
- the success and timing of our preclinical studies, including those intended to support an Investigational New Drug, or IND, application;
- the ability of our product candidates to successfully perform and advance in clinical trials;
- our ability to obtain and maintain authorization from regulatory authorities for use of our product candidates for initiation and conduct of clinical trials;
- our ability to manufacture and supply our products, gain access to products we plan to use in combination studies and the performance of and reliance on third-party manufacturers and suppliers;
- the performance of our clinical research organizations, clinical trial sponsors, and clinical trial investigators; and
- our ability to successfully implement our strategy.

Forward-looking statements are only predictions and are not guarantees of future performance, and they are subject to known and unknown risks, uncertainties and other factors, including the risks described under “Risk Factors” in Part I, Item IA of this report and similar discussions contained in the other documents we file from time to time with the Securities and Exchange Commission, or the “SEC.” Moreover, we operate in a rapidly evolving industry in which new risks and uncertainties continuously emerge, and it is not possible for us to predict all of the risks we may face or assess the impact of all uncertainties or other factors on our business or the extent to which any factor or combination of factors could cause actual results to differ from our current expectations, assumptions or beliefs. In light of these risks, uncertainties and other factors, the forward-looking events and circumstances described in this report may not occur and our results, levels of activity, performance or achievements could differ materially from those expressed in or implied by any forward-looking statements we make. As a result, you should not place undue reliance on any of our forward-looking statements. Forward-looking statements speak only as of the date they are made, and unless required to by law, we undertake no obligation to update or revise any forward-looking statement for any reason, including to reflect new information, future developments, actual results or changes in our expectations.

We qualify all of our forward-looking statements by this cautionary note.

* * * * *

Unless the context indicates otherwise, all references to OncoSec, our Company, we, us and our in this report refer to OncoSec Medical Incorporated and its consolidated subsidiaries.

We own registered trademark rights in the United States to ImmunoPulse®, and we have filed applications in the United States and in certain foreign jurisdictions to register trademark rights to ImmunoPulse, OncoSec and NeoPulse. Other service marks, trademarks or trade names used in this report are the property of their respective owners. We do not use the ® or ™ symbol in each instance in which one of our registered or common law trademarks appears in this report, but this should not be construed as any indication that we will not assert our rights thereto to the fullest extent permissible under applicable law.

We make available, free of charge, on our website, www.oncosec.com, our reports on Forms 10-K, 10-Q, 8-K and amendments thereto, as soon as reasonably practical after we file such materials with the SEC. Any information that we include on or link to our website is not, and should not be considered, part of this report.

PART I

ITEM 1. BUSINESS

Overview

We are a biotechnology company focused on designing, developing and commercializing innovative therapies and proprietary medical approaches to stimulate and to guide an anti-tumor immune response for the treatment of cancer. Our core platform technology, ImmunoPulse®, is a drug-device therapeutic modality comprised of a proprietary intratumoral electroporation delivery device. The ImmunoPulse® platform is designed to deliver plasmid DNA-encoded drugs directly into a solid tumor and promote an immunological 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. Our lead product candidate, ImmunoPulse® IL-12, uses our electroporation device to deliver a plasmid DNA-encoded interleukin-12 ("IL-12"), called tavokinogene telseplasmid ("TAVO"), with the aim of reversing the immunosuppressive microenvironment in the treated tumor. The activation of the appropriate inflammatory response can drive a systemic anti-tumor response against untreated tumors in other parts of the body. In February 2017, we received Fast Track designation from the U.S. Food and Drug Administration ("FDA") for TAVO in metastatic melanoma, which could qualify TAVO for expedited FDA review, a rolling Biologics License Application review and certain other benefits.

Our current focus is to pursue our study of TAVO in combination with KEYTRUDA® (pembrolizumab) for melanoma patients who are definitive anti-PD-1 non-responders. The trial is referred to as the PISCES/KEYNOTE-695. In May 2017, we 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. Pursuant to the terms of the agreement, both companies will bear their own costs related to manufacturing and supply of their product, as well as be responsible for their own internal costs. We will sponsor the study and be responsible for external costs. The PISCES/KEYNOTE-695 study is currently enrolling patients and we plan to provide a topline preliminary data update at The Society for Immunotherapy of Cancer ("SITC") 2018. This study is a registrational-directed, Phase 2b open-label, single-arm, multicenter study in the United States, Canada and Australia.

We are also pursing development in triple negative breast cancer ("TNBC"). On May 8, 2018, we entered into a second clinical trial collaboration and supply agreement with Merck with respect to a Phase 2 study of TAVO in combination with KEYTRUDA® to evaluate the safety and efficacy of the combination in patients with inoperable locally advanced or metastatic TNBC, who have previously failed at least one systemic chemotherapy or immunotherapy. This study is referred to as KEYNOTE-890. Pursuant to the terms of the agreement, both companies will bear their own costs related to manufacturing and supply of their product, as well as be responsible for their own internal costs. We will sponsor the study and be responsible for external costs. The KEYNOTE-890 study is opened for enrollment. The study is a Phase 2 open-label, single-arm, multicenter study in the United States and Australia.

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We intend to continue to pursue other ongoing or potential new trials and studies related to TAVO, in various tumor types including melanoma, TNBC and head and neck cancers. In addition, we are also developing our next-generation electroporation device and applicator, including advancements toward prototypes, pursuing discovery research to identify other product candidates that, in addition to IL-12, can be encoded into propriety plasmid-DNA, delivered intratumorally using electroporation. Using our next-generation technology, our goal is to reverse the immunosuppressive mechanisms of a tumor, as well as to expand our ImmunoPulse® pipeline. We believe that the flexibility of our propriety plasmid-DNA technology allows us to deliver other immunologically relevant molecules into the tumor microenvironment in addition to the delivery of plasmid-DNA encoding for IL-12. These other immunologically relevant molecules may compliment IL-12's activity by limiting or enhancing key pathways associated with tumor immune subversion.

Cancer Immunotherapy Treatments: Background

Many traditional modalities for treating cancer have limited clinical efficacy and are frequently associated with significant negative side effects. Immunotherapy, a relatively new therapeutic modality that has received significant attention in recent years, focuses on modulating the immune system to treat cancer rather than directly killing the cancer cells. Systemic delivery of immune-modulating proteins, such as interleukin-2 and interleukin-10, or IL-2, and IL-10, has shown early indications of efficacy, but with significant mechanism-based toxicity.

Recent attention has also focused on the development of monoclonal antibody drugs, which target critical "immune checkpoint" proteins and augment anti-tumor immunity. Therapies using monoclonal antibodies, such as anti-CTLA-4 (cytotoxic T-lymphocyte-associated protein-4), anti-PD-1 (program cell-death-1) and anti-PD-L1 (programmed death-ligand-1), are being developed for the treatment of several cancers and have been approved for the treatment of multiple sold tumor cancers. Although these new immuno-oncology agents have shown clinical benefit for patients with late-stage cancer across multiple tumor types, only a small subset of the overall patient population responds to these therapies. Certain tumors are able to evade the immune system. We believe that when tumors do not have any immune cells inside (immune desert) or surrounding the tumor (immune excluded), immune checkpoint therapies are less effective or ineffective. These tumors are sometimes referred to as "cold" tumors.

We believe that if we can convert an inactive, or "cold," tumor with a low frequency of tumor infiltrating lymphocytes, or TILs, that limit the anti-tumor response and remove the interferon signature, into an active, or "hot," tumor that can activate the anti-PD-1 or anti-PD-L1 pathway, then we can potentially increase the number of patients who respond to these therapies. We believe our TAVO platform addresses this objective, as it has the potential to reshape the tumor microenvironment in patients with an immunologically cold tumor into a highly-inflamed tumor with a fully engaged PD-1 / PD-L1 axis. The immunological components that enable this conversion relates to the intratumoral delivery of TAVO, which increases the density of TILs, and in the presence of an anti-PD-1 antibody, adaptive resistance can be neutralized allowing for the maximal T cell cytotoxicity.

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There is a significant unmet medical need for patients who may not respond well to these therapies on their own. In particular, for patients who have “cold” tumors and would be unlikely to respond to an immune checkpoint therapy alone, our focus is to develop a therapeutic that has the ability to directly modulate the microenvironment of the tumor by stimulating a local immune reaction through the intratumoral delivery of IL-12 or other immune-modulating molecules. This immune cascade allows anti-tumor immune cells to infiltrate the lesion, turning the tumor “hot” and ultimately generates a productive systemic immune response. In doing so, we believe intratumoral delivery of immune-modulating molecules, such as IL-12 provides a strong biological rationale for treatment in combination with immune checkpoint inhibitors, such as anti-PD-1 or anti-CTLA-4.

CLINICAL PROGRAMS

Our Lead Product Candidate: TAVO

Our lead product candidate, TAVO, is a drug-device combination. The drug consists of a plasmid construct called tavokinogene telseplasmid, or TAVO, with plasmid DNA-encoded, IL-12, and is delivered into a tumor using our proprietary electroporation device. Our clinical data indicates that the in vivo gene transfer of plasmid DNA-encoded IL-12 using electroporation is well-tolerated and anti-tumor activity has been observed after a single cycle of treatment. Importantly, regression in distant, non-injected/non-electroporated lesions has also been observed (“abscopal effect”) in different solid cancers.

Our Clinical Pipeline

MELANOMA

Melanoma is a deadly form of skin cancer with rapidly rising incidences both in the U.S. and internationally. The National Cancer Institute ("NCI") Surveillance, Epidemiology and End Results ("SEER") Program estimates that 87,110 new melanoma cases were diagnosed in 2017, representing 5.2% of all new cancer cases in the U.S. Overall, the five-year survival rate for melanoma, regardless of disease stage, is high (91.7%); however, according to SEER 2017, for patients who present with metastatic disease and receive systemic treatment, the five-year survival rate is considerably lower at less than 20%. Despite recent advances in therapy, advanced metastatic melanoma continues to present a major and increasing burden with significant morbidity and mortality.

PISCES/KEYNOTE-695 Study (OMS-103) (ongoing)

The PISCES/KEYNOTE-695 study is a Phase 2b, open-label, single-arm, multi-center study of TAVO in combination with an intravenous anti-PD-1 antibody, Merck's KEYTRUDA®, in patients with histological diagnosis of melanoma with progressive locally advanced or metastatic disease defined as stage III/IV.

PISCES/KEYNOTE-695 study enrolled its first patient in December 2017 and is actively enrolling patients in the United States, Canada and Australia across 19 sites.

PISCES/KEYNOTE-695 enrollment criteria with respect to anti-PD-1 checkpoint failure is highly restrictive. In order to be considered an anti-PD-1 checkpoint failure, all patients must have Stage III or Stage IV metastatic melanoma, be refractory to anti-PD-1 monoclonal antibodies, namely KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab), as either monotherapy or in combination with other approved checkpoint inhibitors or targeted therapies according to their approved label, and must have relapsed as documented disease progression within 24 weeks of the last dose of anti-PD-1 monoclonal antibodies according to RECIST v1.1, measured by radiologic assessment, with confirmation of progression by second assessment. Patients can have with no intervening therapies between failure of anti-PD-1 therapy and the TAVO / KEYTRUDA® combination treatment. Patients that are BRAF eligible must receive and progress following BRAF treatment. The primary endpoint of the study, by blinded independent central review, is to assess the best overall response rate (BORR) during 24 weeks of TAVO in combination with KEYTRUDA® in patients with unresectable or metastatic melanoma.

PISCES/KEYNOTE-695 is a registration enabled clinical trial. In order to be eligible for accelerated approval, the TAVO / KEYTRUDA® combination must treat a serious condition and provide a meaningful advantage over available therapies. In early 2017, and prior to the commencement of the study, the Company reviewed the patient inclusion criteria and other study requirements with FDA so that KEYNOTE-695 could be submitted to FDA for accelerated approval. In light of this review, we strictly defined the patient population to be enrolled in

PISCES/KEYNOTE-695 to include only those patients who have definitively failed prior anti-PD-1 checkpoint therapy, as determined by the above-described rigor, and who have exhausted all available treatment options.

We plan to provide a topline preliminary data update at the Society for Immunotherapy of Cancer ("SITC") 2018. Based on the preliminary tumor response data and safety profile observed to date, we have eliminated the formal interim Simon stage 1 analysis. The distinguishing feature of the Simon 2-stage design is sample size minimization. Phase 2 clinical trials using this design enroll a relatively small number of patients to allow a preliminary assessment of a new intervention before conducting a larger trial. Since preliminary tumor responses and correlative immunological data have been observed, we believe that eliminating the formal analysis and expanding the sample size is warranted. We believe that this may also accelerate the completion of the study and avoid any unwarranted interruption in continuous enrollment which may occur. We are planning to increase the number of patients to be enrolled from 48 to approximately 80 patients. We believe this will provide for a more robust data set and may further enhance our ability to seek an accelerated approval, should the final data results support doing so. We continue planning to complete enrollment of all patients by mid-2019.

Lastly, based on the outcome of the study and feedback from FDA, we plan to file for accelerated approval with the FDA for this patient population by the end of 2019 or early 2020.

OMS-102 (completed)

OMS-102 was an open-label, multi-center, Phase 2 trial of TAVO and KEYTRUDA® (pembrolizumab) in patients with advanced, metastatic melanoma. In August 2015, we enrolled the first patient in our Phase 2 investigator-sponsored clinical trial led by the clinicians at the University of California, San Francisco, or UCSF. Huntsman Cancer Institute in Utah was the second clinical site. The primary endpoint of this study was to assess the anti-tumor efficacy of the combination of TAVO and KEYTRUDA® in patients with stage III/IV metastatic melanoma whose tumors are characterized by low frequency of $CD8^+/PD\text{-}1^+/CTLA\text{-}4^+$ TILs (tumor infiltrating lymphocytes). The primary endpoint of the study was best overall response rate by RECIST of the combination regimen. Recent data suggests that patients whose tumors are lacking TILs or $CD8^+$ T-cells at the tumor margin or generally have a low frequency of $CD8^+/PD\text{-}L1^+/CTLA\text{-}4^+$ TILs are unlikely to respond to anti-PD-1 therapies such as KEYTRUDA®, while tumors with a frequency of $CTLA\text{-}4^+/PD\text{-}L1^+/CD8^+$ >20% in the tumor are likely to have a clinical benefit. Therapies, such as TAVO, that promote TIL generation and PD-L1 positivity play an important role in augmenting the clinical efficacy of the anti-PD1/PD-L1 agents.

Initial data were presented in February 2017 at ASCO-SITC and the trial stopped enrolling patients in September 2017, allowing the Company to progress on PICSES/KEYNOTE-695. The final data was selected for prominence at SITC 2017 and was presented during the oral poster session. The overall response rate in the 22-patient population was 43% by RECIST v1.1. at week 24 (best overall response rate was 50% by clinical assessment), with one Grade-3 adverse event of cellulitis that resolved with antibiotics. Based on these results, we believe the combination of TAVO and KEYTRUDA® demonstrated efficacy in this low TIL metastatic melanoma patient population and was well-tolerated. Further, long-term follow up has shown responses with significant durability, with all patients who experienced a response remaining in responding status. To date only one patient has required additional surgery to maintain remission.

OMS-100 (completed)

OMS-100 was an open-label Phase 2 trial of TAVO monotherapy in patients with metastatic melanoma. On December 5, 2014, we released top-line six-month data from a Phase 2 repeat dose trial of TAVO in patients with stage III/IV metastatic melanoma. We will present final data at the Melanoma Bridge Conference in 2018. This study is now locked with the data collected at 6 clinical centers. Thirty (30) patients with stage III/IV melanoma received up to four cycles of TAVO delivered by electroporation on days one, five and eight of each 12-week cycle. Of the 28 patients in the study who were evaluable, an objective response rate of 35.7% (10/28 patients) was observed. Five patients (17.9%) had a CR, 5 patients (17.9%) had a PR, 12 patients (42.9%) had SD. Of the distant untreated and assessed lesions that decreased in longest dimension by ≥ 30%, 17.4% (20/115) were assessed. Of the 26 patients with ≥ 1 assessed lesion, 12 patients (46.2%) had ≥ 1 assessed distant lesion with major regression (≥ 30%). Two patients were not evaluated due to not having evaluable distant untreated lesions. Other clinical endpoints included objective response rate, local and distant lesion regression, duration of response, overall survival and safety. The results of this study demonstrated that multiple treatment cycles of TAVO were well-tolerated, with no treatment-limiting toxicities. The majority of adverse events were localized to the treatment site and were Grade-1 or -2 in severity.

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In order to continue to acquire clinical and immune correlational data on melanoma patients treated with TAVO, the protocol of the OMS-I100 study was amended in February 2014 to enroll up to an additional 30 patients. Enrollment in OMS-I100 Addendum was completed in March 2016. The study is now completed and the Company plans to present final data at the Melanoma Bridge Conference being held on November 29 – December 1, 2018. These data were selected for an oral presentation and will include new data demonstrating that local treatment with TAVO alone led to whole-body immune responses associated with regression of untreated lesions in almost half of the 50 patients treated on the study.

Following this trial, a retrospective analysis of the patients who went on to receive an anti-PD-1/PD-L1 therapy was conducted. Results from this retrospective analysis suggested that TAVO primes and enhances response rates to PD-1/PD-L1 blockade. Specifically, of the 29 patients who completed TAVO, 14 subsequently received an anti-PD-1/PD-L1 treatment. Overall, five of these 14 patients (36%) experienced a complete response and four patients experienced a partial response (29%), for an overall response rate of 65% (75% without intervening therapies). Two patients experienced stable disease (14%) and three patients experienced progressive disease (21%). We believe this retrospective sequential data could suggest combinatorial potential of an immune-priming effect with TAVO prior to anti-PD-1/PD-L1 therapy. Data from this retrospective analysis formed the clinical rationale for conducting OMS-I102.

OMS-104 (planned)

The Company plans to initiate a Phase 2 neoadjuvant clinical trial of TAVO in combination with an anti-PD-1 in surgically resectable melanoma in 2019.

TRIPLE NEGATIVE BREAST CANCER (TNBC)

Breast cancer is the most common cancer diagnosed among U.S. women and is the second leading cause of cancer-related deaths. Worldwide, approximately 170,000 new cases of TNBC are diagnosed each year, with TNBC representing one of the four main molecular subtypes of invasive breast cancer, accounting for approximately 10 -20% of all breast cancer.

TNBC frequently affects younger women (less than 40 years old) and is characterized by higher relapse rates than estrogen receptor positive breast cancers. TNBC is also associated with an increased risk of recurrence, both locally and in distant sites including the lungs and brain. Advanced TNBC remains a significant area of unmet medical need and there is no established standard-of-care. Chemotherapy is the current standard-of-care treatment in the adjuvant, neoadjuvant, and metastatic settings. Due to the loss of the tumor cell receptors, patients with TNBC do not benefit from hormonal therapy or treatments targeting the oncogenic HER2 pathway. The standard of care for patients with

recurrent and/or metastatic disease is cytotoxic chemotherapy, leading to a median survival of approximately 13 months from the time of recurrence or diagnosis of distant metastases. Importantly, for patients with metastatic TNBC, the traditional chemotherapeutic treatment approach has undergone limited advance in the last decades, and no regimen is specifically indicated in this unique patient population.

OMS-141/KEYNOTE-890 (ongoing)

OMS-141/KEYNOTE-890 is a Phase 2, open-label, single-arm, multi-center study in the United States and Australia of TAVO in combination with an intravenous anti-PD-1 antibody, Merck's KEYTRUDA®, in patients with histologically confirmed diagnosis of inoperable locally advanced or metastatic TNBC who have received at least one prior line of approved systemic chemotherapy or immunotherapy.

In collaboration with Merck, OMS-141/KEYNOTE-890 is opened for enrollment. Based on the outcome of the study and feedback from FDA, we may choose to expand the study and seek accelerated approval with the FDA for this patient population.

OMS-140 (ongoing)

OMS-140 is a Phase 2, monotherapy biomarker study in patients with advanced or metastatic TNBC. The study is being conducted at Stanford University and is designed to assess whether TAVO increases TNBC tumor immunogenicity by driving a pro-inflammatory cascade that leads to increases in cytotoxic TILs. The presence and number of TILs is thought to be a key requirement for promoting the anti-tumor activity of anti-PD-1. By driving cytotoxic immune cells into the tumor, TAVO could be used in combination with checkpoint blockade therapies, which have reported some, but limited, activity in TNBC.

The primary objective of the study is to evaluate the potential of TAVO to promote a pro-inflammatory molecular and histological signature, 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. The study has been subsequently amended to capture the post TAVO treatments and outcomes.

Preliminary data was presented at the American Association of Cancer Research ("AACR") annual meeting 2018 relating to the first five patients enrolled in the study. Unrelated to the protocol, two of these five patients were subsequently treated with single agent Opdivo® (nivolumab) as their immediate next therapy. Both of these patients, who were heavily pretreated metastatic TNBC patients with chemotherapy refractory disease, were empirically observed to have experienced robust objective responses in both TAVO treated and untreated lesions. Enrollment in this trial (n=10) is now complete and the Company plans to provide a preliminary immunological data update by the end of this calendar year.

These clinical observations prompted the Company to conduct OMS-I141/KEYNOTE-890.

Other Trials and Studies

In addition to the trials and studies described above, we have also pursued and closed Phase 2 clinical trials in patients with Merkel cell carcinoma, head and neck cancer and cutaneous T-cell lymphoma, although we do not have any active clinical programs related to these indicators at this time.

Our ImmunoPulse® Platform

The effectiveness of many drugs and DNA-based therapeutics is dependent upon their crossing the cell membrane. In the 1970s, it was discovered that the brief application of high-intensity, pulsed electric fields to the cell resulted in a temporary and reversible increase in the permeability of the cell membrane, a mechanism known as “electroporation.”

The transient, reversible nature of the electrical permeabilization of cell membranes and the resulting increase in intracellular delivery of therapeutic agents is the underlying basis of our ImmunoPulse® therapeutic approach. Our electroporation delivery system consists of an electrical generator, a reusable applicator handle and disposable tips. While the extent of membrane permeabilization depends on various electrical, physical, chemical, and biological parameters, research with electroporation delivery has demonstrated an improvement in cellular uptake of chemical molecules such as chemotherapeutic agents (e.g., bleomycin and cisplatin), and nucleic acids (e.g., DNA and RNA).

Multiple viral and non-viral delivery modalities have been developed to deliver nucleic acids into cells, however, many of these methods have faced challenges related to the safe and efficient expression of the DNA-encoded biologic into the intended target cells. For example, viral mediated delivery technologies appear to be efficient at transfecting cells, but they have suffered from significant safety issues related to the immunogenicity of the viral vector, shedding of the virus, and potential integration of the viral DNA into the host genome. Other non-viral delivery methods have employed the use of nanotechnology to coat the DNA with fat molecules, called lipids. Although these lipid nanoparticle technologies have been used extensively in the clinic to deliver DNA-encoded biologic agents, few particles have been developed with the ability to specifically target cancer cells; instead, many of these particles naturally target the liver, which can lead to potential liver toxicities.

Like viral vectors and lipid nanoparticle technologies, electroporation has been used extensively in the clinic to deliver multiple therapeutic agents, including DNA. However, unlike these other technologies, electroporation has not seen the same safety concerns. In fact, the use of electroporation to deliver bleomycin intratumorally has been approved for use in Europe for cancers, such as basal cell carcinoma, and has been accepted across many European countries, including the United Kingdom.

Our ImmunoPulse® platform employs an electroporation system designed to create favorable conditions to deliver plasmid DNA encoding immunotherapeutic cytokines directly into cells of the tumor microenvironment. The cytokine-encoding plasmid is first injected into the tumor. A needle-electrode array then delivers the electrical pulses produced in the pulse generator.

Our lead product candidate, TAVO, consists of a plasmid construct encoding the proinflammatory cytokine IL-12 that is injected into the tumor and delivered into the tumor cells through in vivo electroporation using our ImmunoPulse®

technology. We are also researching other DNA-encoded, immunologically-active molecules, with an aim of developing additional immunotherapeutic drugs that, when delivered through electroporation using our ImmunoPulse® platform, may be capable of breaking the immune system's tolerance to cancer.

Commercialization

Strategy

Our primary focus is to continue our clinical development strategy for TAVO, including our planned and ongoing clinical trials discussed under “Clinical Programs” above and potentially other trials we may pursue in the future.

As a part of our commercialization strategy, we also regularly investigate and evaluate potential collaboration opportunities, to identify rational combinations with existing and emerging monoclonal antibody therapies and other drugs. For instance, we may seek to collaborate with pharmaceutical or biotechnology companies to provide us with access to complementary technologies and/or greater resources. In addition, we may seek to expand the applications of our technologies through strategic collaborations or other opportunities, such as in-licensing or strategic acquisitions, and we may seek to out-license our intellectual property to other companies to leverage our technologies for applications that we may not choose to internally and independently develop.

Manufacturing and Supply

Currently, we assemble and store certain components of our electroporation system, which is our proprietary delivery mechanism for our TAVO product candidate, and we utilize the services of qualified contract manufacturers to make the remaining components of these systems and for the manufacture, testing, packaging and storage of our plasmid product candidate for clinical trials or other studies. The manufacture of our systems and product supplies requires significant expertise and capital investment, including the use of advanced manufacturing techniques and process controls. We do not own and have no plans to build our own clinical or commercial Good Manufacturing Practices (“GMP”) manufacturing capabilities for device or drug substance or product. We expect to increase our reliance on third-party manufacturers if and when we commercialize any of our product candidates and systems.

We rely upon a small number of suppliers and manufacturers for our clinical activities. For manufacturing and distributing we use Cryosite, Sherpa, Richter Helm, VGXI, Baxter Oncology GmbH, SGS, Minnetronix and EG Medacys, which collectively account for approximately 90% of clinical materials and electroporation systems support and materials. We believe there are alternate sources of raw material supply and finished goods manufacturing to satisfy our requirements, although transitioning to other vendors, if necessary, could result in significant delay or material additional costs. In addition, for combination trials, we typically rely exclusively on one supplier of the non-company-owned product used in the trial, such as our reliance upon Merck for the supply of KEYTRUDA® in the PISCES/KEYNOTE-695 and OMS-141/KEYNOTE-890 studies.

We are ISO 134852016 certified and comply to all appropriate standards and authorities for the assembly, manufacturing and activities we conduct, and we have established an audited quality management system for these activities. In addition, all contract manufacturers that we use must comply with various requirements enforced by the FDA through its facilities inspection programs. See “Regulation” below for more information.

Competition

The biotechnology industry is intensely competitive. This competitive environment stimulates an ongoing and extensive search for technological innovation and necessitates effective and targeted marketing strategies to communicate the effectiveness, safety and value of products to healthcare professionals in private practice and group practices and payors in managed care organizations, group purchasing organizations, and Medicare and Medicaid services.

We face competition from a number of sources, including large pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions. We compete against all other developers of cancer treatments, including other immunotherapy treatments as well as other types of treatments for the cancer indications on which we are focused. In particular, a number of companies, some of which are large, well-established pharmaceutical companies, have development strategies similar to our current focus. These companies include, among others, Bristol Myers-Squibb, Iovance Therapeutics, Syndax, Dynavax Technologies, Checkmate and Idera Pharmaceuticals. In addition, we also compete with other clinical-stage biotechnology companies for funding and support from healthcare and other investors and potential collaboration relationships with larger pharmaceutical or other companies, as well as for personnel with expertise in our industry. We are smaller and less well-funded than many of our competitors, and we have a shorter and less proven operating history and a less recognizable and established brand name than many of our competitors. In addition, some of our competitors have commercially available products, which provide them with operating revenue and other competitive advantages.

Our competitors may obtain regulatory approval of their product candidates more rapidly than we can or may obtain more robust patent protection or other intellectual property rights to protect their product candidates and technologies, which could limit or prevent us from developing or commercializing our product candidates. If we are able to obtain regulatory approval of one or more of our product candidates, we will face competition from approved products or products under development by larger companies that may address our targeted indications. If we directly compete with these very large entities for the same markets and/or customers, their greater resources, brand recognition, sales and marketing experience and financial strength could prevent us from capturing a share of these markets or customers. Our competitors may also develop products that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed, less costly or more widely accepted for other reasons than any of our products that obtain regulatory approvals, and our competitors may also be more successful than us in manufacturing, distributing and otherwise marketing their products.

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

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Intellectual Property

We believe our success and ability to compete depends in large part on our ability to protect our proprietary rights and technologies, including obtaining and maintaining patent, trademark and trade secret protection of our product candidates and their respective components and underlying technologies, including devices, formulations, manufacturing methods and methods of treatment, and appropriately safeguarding unpatented proprietary rights, including trade secrets and know-how. As of October 2018, we owned 13 issued patents (7 U.S. and 6 foreign) and 42 pending patent applications (11 U.S. and 31 foreign). We are currently prosecuting pending patent applications in various jurisdictions. In addition, we have licensed intellectual property rights that allow us to use certain electroporation technology to deliver DNA-based cytokines as an immunotherapy, as well as catheter-based delivery devices. From these in-licensed portfolios, we have access to 50 issued U.S. and foreign issued patents (3 from USF and 47 from Inovio) and 24 U.S. and foreign pending patent applications (24 from Inovio). We expect to continue to file additional patent applications, if and when appropriate, as our research and development efforts continue. The majority of the patents in our portfolio, including owned and in-licensed patents and fundamental patents directed toward our proprietary technology, expire between 2019 and 2038. We have previously obtained patent protection through an asset purchase agreement with Inovio covering our original clinical electroporation device. The primary patents providing protection of this original device have expired or will expire in 2019. However, the company has filed and will continue to file patent applications this year, on its next generation electroporation devices and applicator handles.

In addition, we have entered into a cross-license agreement for certain electroporation technology with Inovio, including patent protection for some of our clinical electroporation devices (some of which, as noted above, have recently expired or will soon expire). Under the terms of the agreement, Inovio has granted us a non-exclusive, worldwide license under certain of its electroporation patents, and in exchange, we have granted to Inovio an exclusive license to certain of our purchased technology in a limited field of use.

Regulation

Commercialization Approval for our Product Candidates

Biotechnology companies are subject to extensive, complex, costly and evolving government regulation relating to the ability to market and sell any therapeutic or medical device. In the United States, these regulations are principally enforced by the FDA and state government agencies. Outside the United States, these regulations are typically administered by various health authorities comparable to the FDA in countries where products or product candidates are researched, tested, manufactured and/or marketed.

United States

General

In the United States, the federal Food, Drug and Cosmetic Act, or FDCA, other state statutes and regulations, many of which are administered and enforced by the FDA, govern or influence, among other things, the research, development, testing, manufacture, storage, record-keeping, approval, labeling, promotion, marketing, distribution, post-approval monitoring and reporting, sampling, import and export of product candidates such as ours. Under these regulations, we and our contract manufacturers may be subject to periodic inspection of our facilities, quality control and other procedures, and operations and/or the testing of our product candidates during and after the approval process for a product candidate, to confirm compliance with all applicable regulations, including current good manufacturing practices and other applicable requirements.

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

Approval Process

Before any new drug, device or dosage form, including a new use of a previously approved drug or biologic, can be marketed in the United States, FDA approval is required. The process required by the FDA before a product may be marketed in the United States generally involves, among other things:

- completion of non-clinical testing;
- completion of chemistry, manufacturing, and control testing, commonly known as CMC;
- submission to the FDA of an investigational new drug application (IND) for human clinical testing, which must be accepted and effective before human clinical trials may begin in the United States;
- performance of adequate human clinical trials in accordance with good clinical practices to establish the safety and efficacy of the proposed product for each intended use;
- for a stand-alone medical device, submission to the FDA of a premarket approval application(PMA) or 510(k) premarket notification, which the FDA must review and approve; and
- for a therapeutic, submission to the FDA of a new drug application(NDA), or biologic license application (BLA), which the FDA must review and approve.

The pre-clinical and clinical testing and approval process can take many years and requires substantial company time, effort and financial resources. The receipt and timing of approval, if any, is uncertain. The results of pre-clinical tests, together with certain manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Once an IND is in effect, the protocol for each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of the investigational new drugs or biologics to human subjects under the supervision of qualified investigators in accordance with good clinical practice requirements. For purposes of an NDA or BLA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

Phase 1: The product candidate is initially introduced to healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its safety, tolerability and effectiveness.

Phase 2: The product candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications, and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted.

Phase 3: The product candidate is administered in an expanded patient population at multiple, geographically-dispersed clinical trial sites, to obtain additional evidence of clinical efficacy and safety and to establish the overall risk-benefit relationship of the product candidate.

Phase 4: In some cases, the FDA may condition approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional post-approval clinical trials to further assess the safety and efficacy of the drug or biologic.

The results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. NDAs or BLAs must also contain extensive information relating to the product's pharmacology, chemistry, manufacture, controls, and proposed labeling, among other things.

Once the NDA or BLA submission has been accepted, the FDA begins an in-depth substantive review. Pursuant to the FDA's performance goals, NDA and BLA standard reviews are to be completed within 10 months, subject to extensions by the FDA. Before approving an NDA or BLA, the FDA often inspects the facility or facilities where the product is manufactured and will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with good manufacturing practices. Additionally, the FDA will typically inspect one or more clinical sites to assure compliance with good clinical practices before approving an NDA or BLA. If the FDA determines that an NDA or BLA is not approvable, then the FDA may outline the deficiencies and often will request that additional information be provided or additional clinical trials be completed. Notwithstanding the submission of any requested additional testing or information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Further, even if regulatory approval of a product candidate is obtained, such approval would specify the indicated uses for which the product may be marketed. Additionally, we would be subject to pervasive and continuing regulation by the FDA with respect to any approved product, including requirements related to, among other things, drug or device listing, record-keeping, periodic reporting, product sampling and distribution, manufacturing practices, labeling, advertising, promotion, and reporting of adverse events associated with any approved products. Moreover, we could be required to conduct post-approval studies, such as Phase 4 clinical trials, or surveillance programs to monitor the safety of any approved products. FDA has the authority to stop or limit further marketing of a product or impose more stringent labeling restrictions based on the results of these post-approval programs or in the event of any unexpected or serious health or safety concern regarding any approved product.

Non-U.S. Regulation

If we pursue research and/or commercialization activities for our product candidates outside the United States, we would need to obtain necessary approvals from the regulatory authorities comparable to the FDA in applicable jurisdictions before we could commence clinical trials or marketing of our product candidates in these jurisdictions. In addition, we would become subject to a variety of foreign regulations regarding safety and efficacy of our product candidates and governing, among other things, clinical trials, commercial activities, manufacture and distribution of our product candidates. The requirements to obtain product approvals vary widely from country to country, and the FDA's approval requirements, review procedures and timelines may not be the same as or even similar to the requirements or a comparable foreign regulator. As a result, even if we obtain regulatory approval for a product candidate in one country, we may be required to undertake additional clinical trials or studies, submit additional information, wait for longer review periods or make other efforts in order to obtain regulatory approvals in other desirable geographic markets.

Healthcare Laws and Regulations

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

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

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

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

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

analogous state and foreign laws and regulations, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by applicable federal laws, thus complicating compliance efforts.

Additionally, the healthcare compliance environment is continuously changing, with proposed revisions to or replacement of the Affordable Care Act at the federal level and with some states mandating implementation of compliance programs, compliance with industry ethics codes, spending limits and reporting to state governments of gifts, compensation and other remuneration to physicians. Further, to the extent we continue to pursue operations in foreign countries, such as our clinical activities in Australia, or in Canada, or if we seek to sell any product that obtains regulatory approval in a foreign country, we would be subject to different reporting and other compliance requirements in multiple jurisdictions, including foreign laws and regulations comparable to the U.S. laws and regulations described above.

All of these laws impose penalties for non-compliance, some of which may be severe. If we or our operations are found to be in violation of any of these laws or any other governmental regulations that apply to us, we may be subject to civil or criminal penalties, fines or other monetary damages or orders forcing us to curtail or restructure our operations.

Other Regulatory Requirements and Environmental Matters

We are or may become subject to various laws and regulations regarding laboratory practices and the experimental use of animals, as well as environmental laws and regulations governing, among other things, any use and disposal by us of hazardous or potentially hazardous substances in connection with our research. In each of these areas, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and withdraw approvals.

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In addition, to the extent we continue to pursue operations in foreign jurisdictions, we will be subject to anti-bribery laws in the United States and applicable foreign jurisdictions, including the U.S. Foreign Corrupt Practices Act, or FCPA, and comparable foreign laws. Further, we are subject to a variety of laws and regulations relating to other matters, including workplace health and safety, labor and employment, public reporting and taxation, among others, and our failure to comply with these laws and regulations may result in a variety of administrative, civil and criminal enforcement measures, including monetary penalties or imposition of sanctions or other corrective requirements.

Our Team

Our senior management team and board of directors have decades of experience, each demonstrating a strong track record of success in the biotechnology and pharmaceutical industries, including in research and development, commercialization and financing activities. In addition, we have assembled a clinical and regulatory team experienced in developing and advancing novel therapeutic approaches through clinical testing and regulatory approvals, including extensive technical, manufacturing, analytical and quality experience to oversee our clinical, manufacturing and testing activities. Our team consists of a relatively small number of employees, as well as consultants and advisors regarding research and development, regulatory, compliance, healthcare and investor and public relations matters. We also expect to engage experts in healthcare and in general business to advise us in various capacities. For instance, we have in the past consulted with various oncology researchers and clinicians to provide counsel as part of our advisory panels for our clinical programs, and we expect to continue to establish consulting and advisory relationships with scientific, clinical and medical experts in academia and industry to assist us with FDA submissions, clinical testing and identification and development of new product candidates.

As of July 31, 2018, we had a total of 34 employees, including 33 full-time employees and one part-time employee. None of our employees is represented by a labor union or covered by a collective bargaining agreement, and we believe that our relations with our employees are good.

Corporate Information

We were incorporated under the laws of the State of Nevada in February 2008 under the name Netventory Solutions Inc. to pursue the business of inventory management solutions. In March 2011, we completed a merger with our subsidiary to change our name to “OncoSec Medical Incorporated,” and we commenced operations as a biotechnology company upon our acquisition of assets from Inovio related to the use of drug-medical device combination products for the treatment of various cancers. Our principal executive offices are located at 24 North Main Street, Pennington, NJ 08534 and 3565 General Atomics Court, Suite 100, San Diego, California 92121. The telephone number for our principal executive offices is (855) 662-6732. Our website address is www.oncosec.com. Information contained on our website is not, and should not be considered, part of this report. We will make available free of charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or

furnish such material to, the Securities and Exchange Commission, or SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. You may read and copy any materials we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov/.

In addition, we intend to use our media and investor relations website, SEC filings press releases, public conference calls and webcasts as wells as social media to communicate with our subscribers and the public about the Company, its services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, in light of the SEC's guidance, we encourage investors, the media and others interested in the Company to review the information we post on the U.S. social media channels listed on our website.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business

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

We have not generated any revenue from our operations since our inception, and we do not anticipate generating meaningful, or any, revenue in the near term. During our fiscal year ended July 31, 2018, we incurred a net loss of approximately $39.1 million, and from inception through July 31, 2018, we have incurred an aggregate net loss of approximately $134.1 million. We will need significant additional funding to continue our operations and pursue our strategic plans, including continued development of ImmunoPulse® IL-12. Although we have been and expect to continue to tightly manage our operating expenses, we expect our operating expenses will continue to increase as we further our development activities and pursue FDA approval for one or more of our product candidates.

Because of the numerous risks and uncertainties associated with our product development and planned commercialization efforts, many of which are discussed in these risk factors, we are unable to predict the extent of our future losses or when or if we will generate meaningful revenue or become profitable, and it is possible we will never achieve these goals. Our failure to develop our investments in our proprietary technologies and product candidates into revenue-generating operations would have a material adverse effect on our business, results of operations, financial condition, and prospects and could result in our inability to continue operations.

We have limited working capital and a history of losses, which raises substantial doubt as to whether we will be able to continue as a going concern.

We anticipate that, based on the amount of cash we have on hand (taking into account the net proceeds from our February 2018 and October 2018 equity offerings) and our current rate of cash consumption, we believe that our current cash resources are sufficient to meet our anticipated needs for more than 12 months following the issuance of

this report without a significant change in our business plan or reduction in spending. However, we will need additional capital after that time to maintain our current level of operations or before that time to ramp up development or other efforts. As a result, our ability to continue as a going concern will depend upon the availability and terms of future funding.

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

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

As of July 31, 2018, we had cash, cash equivalents, and investment securities of approximately $27.0 million and, as of that date, we estimated our cash requirements for the following 12 months to be approximately $25.0 million. We do not generate any cash from our operations.

Historically, we have raised the majority of the funding for our business through offerings of our common stock and warrants to purchase our common stock, including our February 2018 and October 2018 equity offerings. We are exploring other ways of funding our operations that involve less dilution to our existing stockholders, including, among others, technology licensing or other collaboration arrangements, debt financings or grants. We may need to continue to seek funding for our operations through additional dilutive public or private equity financings.

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

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

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We are a clinical-stage, pre-commercial company with a limited operating history and no commercially available or approved products, which makes assessment of our future viability difficult and which may hinder our ability to generate revenue and meet our other objectives.

We are a clinical-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. None of our product candidates are commercially available. Additionally, although we are investigating licensing and partnering opportunities, no such opportunities have been finalized and, even if completed, we do not expect that these potential opportunities would generate any significant near-term revenue. Our operations to date have been limited to organizing, staffing and financing, applying for patent rights, undertaking clinical trials of ImmunoPulse® IL-12 and engaging in other research and development activities, including pre-clinical and other studies of our other product candidates. We have not demonstrated an ability to obtain regulatory approval of a product candidate, manufacture commercial-scale products, or conduct the sales and marketing activities necessary for successful product commercialization. Consequently, the revenue-generating potential of our business is unproven and uncertain.

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

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

We have invested, and we expect to continue to invest, significant efforts and financial resources in the development of product candidates based on our ImmunoPulse® technology, including primarily our lead product candidate ImmunoPulse® IL-12. Our ability to generate revenue, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and commercialization of one or more of these product candidates, and such regulatory approval and commercialization may never occur.

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

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

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

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

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

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

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

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

the labeling requirements for any product candidates that are approved, including obtaining sufficiently broad labels that would not unduly restrict our ability to market the product;

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

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

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

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

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

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

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

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

We may not be successful in our efforts to identify or discover additional product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize product candidates based on our programs. If we do not successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new product candidates require substantial technical, financial and human resources.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for a product candidate could be inaccurate, and our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our clinical trials may have strict inclusion criteria for patient enrollment. These criteria could present significant obstacles to the timely recruitment and enrollment of a sufficient number of eligible patients into our trials. We may experience slower than expected patient enrollment in our existing or future clinical trials. Any inability to successfully enroll the number of patients meeting the criteria for any of our clinical trials could cause significant

delays in the trial and increase the costs associated with the trial, which could materially harm our business and prospects.

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

the severity of the disease under investigation;

the design of the study protocol;

the eligibility criteria for the study;

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

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

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

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

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

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

Clinical trials are very expensive, time-consuming, unpredictable and difficult to design and implement. Even if we are able to complete our ongoing and currently proposed clinical trials and assuming the results are favorable, clinical trials for product candidates based on our technology are planned to continue for several years and may take significantly longer than expected to complete. Even with the Fast Track designation we received from the FDA for TAVO in metastatic melanoma in February 2017, additional clinical trials, which can take many years to complete, are still required.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs and business plan. We do not know and cannot predict whether any of our ongoing or planned trials or studies will be completed on schedule or at all. We also do not know and cannot predict whether any other pre-clinical or clinical trials, including Phase 3 clinical trials to follow completion of our ongoing or any other Phase 2 clinical trials, will be planned or will begin, and in many cases such future trials would be dependent on obtaining favorable results

from preceding studies.

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

- obtaining clearance or approval from the FDA or a comparable international regulatory body and other applicable agencies, including the U.S. National Institutes of Health, to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, clinical investigators and trial sites;
- obtaining institutional review board, or IRB, and institutional biological committee, or IBC, approval to initiate and conduct a clinical trial at a prospective site;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling subjects to participate in clinical trials, which can pose challenges for a variety of reasons, including competition from other clinical trial programs for similar indications, requirements for larger than anticipated patient populations, slower than expected enrollment, or higher than predicted rates of patient drop-out or withdrawal;
- retaining patients who have initiated a clinical trial but who may be prone to withdraw due to side effects from the therapy, lack of efficacy, personal issues, death or for any other reason, or who are lost to further follow-up; and
- identifying and maintaining a sufficient supply of necessary products or product candidates, including those produced by third parties, on commercially reasonable terms.

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

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

To the extent our commercialization strategy includes the combination of our product candidates with third parties' products or product candidates, we will likely be required to conduct clinical studies to evaluate the combinations. We

have several ongoing and planned combination trials, and these combination studies involve additional risks due to their reliance on circumstances outside our control, such as those relating to the availability and marketability of the third-party product involved in the study. If the marketability of third-party products such as KEYTRUDA® is impacted, or if we are unable to secure and maintain a sufficient supply of such third-party products when needed on commercially reasonable terms, our clinical studies could be delayed or we could be forced to terminate these studies. Such a delay or termination could have a material negative impact on our development strategy, business, results of operations, financial condition, and prospects.

If serious adverse or unacceptable side effects are identified during the development of one or more of our product candidates or any future product candidate, we may need to abandon or limit our development of some of our product candidates.

If one or more of our product candidates or any future product candidate are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing have later been found to cause serious side effects that prevented further development of the compound. In the event that our clinical trials reveal a high or unacceptable severity and prevalence of side effects, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of one or more of our product candidates or any future product candidate for any or all targeted indications. The FDA could also issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve a product candidate. The number of requests for additional data or information issued by the FDA in recent years has increased and has resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by one or more of our product candidates or any future product candidate could also result in the inclusion of unfavorable information in our product labeling, denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating market acceptance and revenues from the sale of that product candidate. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

Additionally, if one or more of our product candidates or any future product candidate receives marketing approval and we or others later identify undesirable side effects caused by this product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any of our product candidates or any future product candidate or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

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

We have entered into, and expect to continue to enter into, agreements with third-party CROs to help us manage critical aspects of the clinical trials we sponsor. We rely on these third parties for the execution of certain of our clinical and pre-clinical studies, and we only control certain aspects of their activities. We and our CROs are required to comply with the FDA's regulations for conducting clinical trials and good clinical practice, as well as the guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. We are also required to harmonize standard operating procedures between companies and conduct periodic internal and vendor audits to ensure compliance. Additionally, the FDA and comparable foreign regulators enforce these good clinical practice regulations through periodic inspections of trial sponsors, principal investigators, trial sites, laboratories and other entities involved in the completion of the study protocol and processing of data.

If we or our CROs fail to comply with applicable good clinical practice or other regulations, the data generated in our clinical trials may be deemed unreliable and/or the FDA or comparable foreign regulators may refuse to accept the data, and these regulators may require us to perform additional or repeat clinical trials, which could significantly increase costs and delay the regulatory approval process. Additionally, repeated compliance failures could prompt the FDA or other regulatory authority to suspend or terminate a clinical trial, which could cause significant approval delays and increased costs. Further, if CROs do not otherwise successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised for any reason, our clinical trials may need to be extended, delayed or terminated or we may not be able to rely on the data produced by the trials. Moreover, if any of our relationships with third-party CROs terminate before completion of a clinical trial, we may not be able to establish arrangements with alternative CROs on commercially reasonable terms, on a timely basis or at all, which could materially delay or jeopardize the trial. Any such occurrence could delay or prevent us from obtaining regulatory approval for our product candidates or successfully commercializing our product candidates, which could increase our costs, delay or eliminated our prospects for generating revenue, and otherwise materially harm the results of our operations, financial condition and prospects.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of the strategy implemented to mitigate development risk, we seek to develop product candidates with validated mechanisms of action and we utilize biomarkers to assess potential clinical efficacy early in the

development process. This strategy necessarily relies upon clinical data and other results produced or obtained by third parties, which may ultimately prove to be inaccurate or unreliable. If the third party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates, we could make inaccurate assumptions and conclusions about the product candidates, and our research and development efforts could be compromised and called into question during the review or any marketing applications we submit.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their other clients or former employers.

As is common in the biopharmaceutical industry, we engage the services of consultants to assist in the development of product candidates. Many of these consultants were previously employed at or may have previously been or are currently providing consulting services to, other pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims related to whether these consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending these claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

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

Although we have seen no systemic drug-related adverse events in our trials and studies to date, if we cannot adequately demonstrate through the clinical trial process that a product candidate we are developing is safe and effective, regulatory approval of that product candidate may never be achieved, which could impair our reputation, increase our costs and delay or prevent us from generating revenue. Importantly, success in pre-clinical testing and early clinical studies does not ensure that later clinical trials will generate adequate data to demonstrate the required level of efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including many with greater resources and experience than we have, have suffered significant setbacks in clinical trials, even after obtaining promising results in Phase 2, and earlier studies. Further, even if a product candidate is approved, it may be approved for fewer or more limited indications than requested, may include substantial safety warnings or the approval may be subject to the performance of significant post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any limitation, condition or denial of approval could have an adverse effect on our business, reputation and results of operations.

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

condition, as well as on our continued viability as a company.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the US or other countries until we have completed a rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the US Patent and Trademark Office (PTO). The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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

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

We entered into a cross-license agreement in 2011 for certain electroporation technology with Inovio, which includes some of our patents protecting our ImmunoPulse® clinical device (and some of which have recently expired or will expire in 2019). Under the terms of the agreement, Inovio has granted us a non-exclusive, worldwide license under certain of its electroporation patents, and in exchange, we have granted to Inovio an exclusive license to certain aspects of our technology in a limited field of use. Although we do not currently rely on the intellectual property we have licensed from Inovio, our product candidates could in the future utilize this intellectual property. This license is non-exclusive and Inovio could use the technology to compete with us or could license the technology to others, including our competitors. Additionally, the license we have granted to Inovio could enable it to develop products that compete against ours, directly or indirectly, in the specific field of use subject to the license. In the future, if we raise additional funds through licensing or sublicensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

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

If we are not able to maintain our existing in-licenses or if we are not able to establish new in-licenses for any other third-party rights we need, we could become subject to significant costs or royalty or other fees to establish alternative license arrangements, if such licenses are available when needed, on acceptable terms or at all, or we could be forced to develop modifications to the affected product candidates or technologies to avoid reliance on the third-party rights, if such modifications are possible. If there is any conflict, dispute, disagreement or issue of non-performance between us and the respective licensing partner regarding the rights or obligations under the license agreements, including any conflict, dispute or disagreement arising from a failure to satisfy payment obligations under such agreements, the ability to develop and commercialize the affected product candidate may be adversely affected. Any inability to secure and maintain adequate rights to any third-party technologies necessary for the development of our product candidates could severely limit our continued research and development activities, our efforts to obtain product approvals and, if such approvals are obtained, our ability to commercialize the approved products, any of which would materially adversely impact our business and prospects.

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

We may become aware of activities by third parties, including our competitors, that infringe our issued patents or other intellectual property rights. If we choose to file a lawsuit against a potentially infringing third party to try to enforce our patents or other intellectual property rights, the third party may seek a ruling that the patents are invalid and/or should not be enforced. Such a ruling could severely limit our ability to protect our rights from use by third parties. The U.S. Supreme Court has recently revised certain tests regarding assessing the validity of patents, which could result in the invalidation of issued patents and/or their claims based on the application of the new patent validity standards. As a result, in the event of any patent infringement litigation or other proceedings involving our patents, our patents could be subject to challenge and subsequent invalidation or significant narrowing of claim scope under the revised standards. Moreover, even if the validity of our patents is upheld in a patent infringement lawsuit, a court could refuse to stop a third party’s activities on the grounds that the activities do not infringe the specific claims of our patents. Further, even if we were successful in stopping the infringing activity, patent infringement lawsuits are expensive and could consume significant time, management attention, capital and other resources. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents; or provoke those parties to petition the United States Patent and Trademark Office, or PTO, to institute inter partes review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid.

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These risks of third parties' infringement of our intellectual property rights may increase if we engage in discussions, collaborations or other strategic arrangements with third parties. Also, new challenges could arise if and to the extent we pursue engagements with third parties located outside the United States. These factors could increase the risks and costs associated with building and protecting our intellectual property portfolio and could adversely affect our performance and our business prospects. Despite efforts to protect our proprietary information during such discussions, third parties may unintentionally or willfully disclose or convert our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

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

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

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we or our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the PTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business; even if we comply with such laws and regulations, they may result in higher costs for us in the form of higher raw material, energy, freight and compliance costs.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Increased environmental legislation or regulation could also result in higher costs for us in the form of higher raw materials, as well as energy and freight costs. It is possible that certain materials might cease to be permitted to be used in our processes. We could also incur additional compliance costs for monitoring and reporting emissions and for maintaining permits.

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

The biotechnology industry is intensely competitive. This competitive environment stimulates an ongoing and extensive search for technological innovation and necessitates effective and targeted marketing strategies to communicate the effectiveness, safety and value of products to healthcare professionals in private practice and group practices and payors in managed care organizations, group purchasing organizations, and Medicare and Medicaid services.

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We face competition from a number of sources, including large pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions. We compete against all other developers of cancer treatments, including other immunotherapy treatments as well as other types of treatments for the cancer indications on which we are focused. In particular, a number of companies, some of which are large, well-established pharmaceutical companies, have development strategies similar to our current focus. These companies include, among others, Bristol Myers-Squibb, Iovance Therapeutics, Syndax, Dynavax Technologies, Checkmate and Idera Pharmaceuticals. In addition, we also compete with other clinical-stage biotechnology companies for funding and support from healthcare and other investors and potential collaboration relationships with larger pharmaceutical or other companies, as well as for personnel with expertise in our industry. We are smaller, less experienced and less well-funded than many of our competitors, and we have a shorter and less proven operating history and a less recognizable and established brand name than many of our competitors. In addition, some of our competitors have commercially available products, which provide them with operating revenue and other competitive advantages. Furthermore, recent trends in the biotechnology industry are for large drug companies to acquire smaller outfits and consolidate into a smaller number of very large entities, which further concentrates financial, technical, and market strength and increases competitive pressure in the industry.

Our competitors may obtain regulatory approval of their product candidates more rapidly than we can or may obtain more robust patent protection or other intellectual property rights to protect their product candidates and technologies, which could limit or prevent us from developing or commercializing our product candidates. If we are able to obtain regulatory approval of one or more of our product candidates, we would face competition from approved products or products under development by larger companies that may address our targeted indications. If we directly compete with these very large entities for the same markets and/or customers, their greater resources, brand recognition, sales and marketing experience and financial strength could prevent us from capturing a share of these markets or customers. Our competitors may also develop products that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed, less costly or more widely accepted for other reasons than any of our products that might obtain regulatory approvals, and our competitors may also be more successful than us in manufacturing, distributing and otherwise marketing their products.

We expect our product candidates, if approved and commercialized, to compete on the basis of, among other things, product efficacy and safety, time to market, price, coverage and reimbursement by third-party payors, extent of adverse side effects and convenience of treatment procedures. We may not be able to effectively compete in any of these areas, or we may be prevented from being able to compete at all in these areas due to the performance of our products during clinical trials and/or the circumstances of an approval. Presently, we compete with other biotechnology companies for funding and support on the basis of our technology platforms and the potential value of our product candidates based on the factors described above.

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

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

The FDA provides guidelines regarding appropriate presentation of product information and continuing medical and health education activities. Even though we do not have any FDA approved products, these guidelines apply to our current activities with respect to disclosures, presentations or other communications about our product candidates and technologies at healthcare conferences or in other forums. Although we endeavor to follow these guidelines, the FDA, the Office of the Inspector General of the U.S. Department of Health and Human Services, or the Department of Justice could disagree, in which case we could be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted and our reputation could be damaged, any of which could materially harm our business and prospects.

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

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

The manufacture of our systems and product supplies requires significant expertise and capital investment, including the use of advanced manufacturing techniques and process controls. Manufacturers often encounter difficulties in production, particularly in scaling up for commercial production if regulatory approvals are obtained. These difficulties include, among others: problems with production costs and yields; quality control issues, including qualification of the equipment, stability of product candidates and compliance with testing requirements; shortages of qualified personnel; and compliance with strictly enforced federal, state and foreign regulations. If we or our manufacturers were to encounter any of these difficulties or our manufacturers otherwise fail to comply with their contractual obligations to us, our ability to provide our electroporation equipment to our partners and product candidates to patients enrolled in our clinical trials, or to commercially launch a product if regulatory approvals are obtained, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs, and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the development program completely.

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In addition, all manufacturers of our products must comply with current good manufacturing practices, which are regulated by the FDA through its facilities inspection programs. These practices include requirements regarding, among other things, quality control, quality assurance and the generation and maintenance of records and documentation. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party manufacturers, we have limited direct control over our manufacturers' compliance with these regulations and standards. Any failure by our manufacturers, including our non-U.S. contract manufacturers, to comply with these requirements could potentially result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. Additionally, if the safety of any product candidate or approved product is compromised due to our or our manufacturers' failure to adhere to applicable regulatory requirements or for other reasons, we may not be able to obtain or maintain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result of the failure. Any of these factors could cause delays in clinical trials, regulatory submissions or approvals, entail significant costs or hinder our ability to effectively commercialize our product candidates. Furthermore, assuming we are successful in receiving approval for and commercializing one or more of our product candidates, if our manufacturers fail to deliver the required commercial quantities on a timely basis, pursuant to provided specifications and at commercially reasonable prices, we may be unable to meet demand for our products and we could lose potential revenue.

Our business and operations could suffer in the event of cyber-attacks or system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause material disruptions to our commercialization activities, clinical and other development programs, financial and disclosure controls and other reporting functions and the administrative aspects of our business, in addition to possibly requiring substantial expenditures of capital and other resources to remedy. Further, any loss of clinical trial data from completed or future clinical trials as a result of such a disruption could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. Moreover, to the extent any such disruption results in the loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur significant liabilities. The occurrence of any of these circumstances could cause our operations and our performance to suffer.

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

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

including difficulties related to:

identifying new potential product candidates or promising technologies;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- we could be subject to intense competition in seeking appropriate collaborators;
- collaboration arrangements are complex, costly and time-consuming to negotiate, document and implement, and they could require our payment to the collaborator of cash or other consideration, including issuances of equity or debt securities, in order to establish the relationship;
- we may be unsuccessful in establishing and implementing any collaboration we desire to pursue, or the terms of the arrangement may not be favorable to us;
- collaborations often would require that we relinquish some or all of the control over the future success of the product candidate to the third-party collaborator;
- the success of any collaboration arrangements we may establish would depend heavily on the efforts and activities of our collaborators, who would likely have significant discretion in determining the efforts and resources they would apply to these collaborations;
- disagreements between collaborators regarding clinical development and commercialization matters can be difficult to resolve and can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, termination of the arrangement; and
- any termination of a collaboration arrangement that we are able to establish could adversely affect our performance, particularly to the extent we become reliant upon the collaboration for revenue or important commercialization processes or efforts.

In addition, collaboration arrangements may also include our pursuit of combination trials to develop and commercialize our product candidates as combination products, such as our PISCES/KEYNOTE-695 and OMS-141/KEYNOTE-890 studies with Merck's KEYTRUDA®. To the extent we continue to pursue these or any other similar collaborative arrangement, we will face certain additional risks and uncertainties in development, as drug/device combination products are particularly complex, expensive and time-consuming to develop due to the number of variables involved in the final product design, including ease of patient and doctor use, establishing clinical efficacy, reliability and cost of manufacturing, regulatory approval requirements and standards and other important factors. Additionally, combination products face continued risk and uncertainty post-development in connection with manufacturing and supply regarding the establishment of a reliable commercial supply chain.

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

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the US and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the US mortgage market and residential real estate market in the US have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

The United Kingdom's announced withdrawal from the EU could have a negative effect on global economic conditions and financial markets, EU regulatory procedures and our business.

In June 2016, a majority of voters in the United Kingdom, or the UK, elected in a national referendum to withdraw from the EU. In March 2017, the UK government formally initiated the withdrawal process. That pending withdrawal, currently scheduled to occur in or before March 2019, has created significant uncertainty about the future relationship between the UK and the EU, including with respect to the laws and regulations that will apply as the UK determines which EU laws to replace or replicate upon withdrawal. The pending withdrawal has also given rise to calls for the governments of other EU member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict access to capital, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The UK's withdrawal from the EU also means that the EMA, from which we must obtain approval to sell any product in the EU, must relocate from its current headquarters in the UK to a new location within the EU. This relocation of the EMA could significantly disrupt its operations, which could cause delays in the EMA's review and approval of marketing authorization applications. Such a disruption could impact any future applications for EMA approval of our drug candidates, which could have a material adverse effect on our business, financial condition and results of operations and growth prospects.

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

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

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

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

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

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the prevalence and severity of adverse effects;
- limitations or warnings contained in a product's FDA-approved or other regulator-approved labeling;
- the clinical indications for which the product is approved;
- the availability and perceived advantages of alternative treatments;
- any negative publicity related to the product or any competing product;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness;
- our ability to obtain adequate third-party payor coverage or reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of adequate third-party payor coverage and reimbursement.

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

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

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

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

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

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

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

- difficulties complying with the U.S. Foreign Corrupt Practices Act and other applicable anti-bribery laws;
- difficulties maintaining compliance with the varied laws and regulations of multiple jurisdictions that may be applicable to our business, many of which may be unfamiliar to us;
- more complexity in our regulatory and accounting compliance;
- differing or changing obligations regarding taxes, duties or other fees;
- limited intellectual property protection in some jurisdictions;
- risks associated with currency exchange and convertibility, including vulnerability to appreciation and depreciation of foreign currencies against the U.S. dollar;

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

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

changes in applicable laws or policies;

the impact of and response to natural disasters; and

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

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

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

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

Additionally, although we have employment agreements with each of our executive officers, these agreements are terminable by them at will. The loss of the services of any one or more members of our current senior management team could, among other things, disrupt or divert our focus from pursuing our business plans while we seek to recruit other executives, impact the perceptions of our existing and prospective employees, partners and investors regarding our business and prospects, cause us to incur substantial costs in connection with managing transitions and recruiting suitable replacements and, if the departing personnel are crucial to any of our clinical or other development programs, delay or prevent the development and commercialization of the affected product candidates. These risks would be amplified if we are not able to recruit suitable replacements for any departing personnel on acceptable terms and in a timely manner. The occurrence of any of these or other potential consequences could cause significant harm to our business.

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

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

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

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

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

regulatory compliance, we may not be permitted to market any of our product candidates, which would materially adversely affect our prospects to generate revenue.

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

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

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

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

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

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

HIPAA and HITECH, which, in general and among other things, establish comprehensive federal standards with respect to the privacy, security and transmission of individually identifiable health information and impose requirements for the use of standardized electronic transactions with respect to transmission of such information;

the FCPA and other applicable anti-bribery laws;

state law equivalents of each of these federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by applicable federal laws, thus complicating compliance efforts.

Additionally, the healthcare compliance environment is continuously changing, with proposed revisions to or replacement of the Affordable Care Act at the federal level and with some states mandating implementation of compliance programs, compliance with industry ethics codes, registration requirements for sales personnel, spending limits and reporting to state governments of gifts, compensation and other remuneration to physicians. This shifting regulatory environment, as well as our obligation to comply with different reporting and other compliance requirements, in multiple jurisdictions, including foreign laws and regulations comparable to the U.S. laws and regulations described above, to the extent we continue to pursue operations in foreign countries, such as our clinical activities in Australia, or if we seek to sell any product that obtains regulatory approval in a foreign country, increases the possibility that we may violate one or more of these laws. In addition, these conditions may also adversely affect our ability to obtain regulatory approval for any of our product candidates, the availability of capital, our ability to generate meaningful or any revenue and, if any of our product candidates achieve regulatory approval, our ability to establish a price we believe is fair for the approved product. Further, even though we do not and will not control referrals of healthcare services or bill directly to third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights would be applicable to our business, if any of our product candidates obtain regulatory approval and become commercially available.

All of these laws impose penalties or other consequences for non-compliance, some of which may be severe. If we or our operations are found to be in violation of any of these laws or any other governmental regulations that apply to us, the consequences could include, but are not limited to, fines or other monetary damages, orders forcing us to curtail or restructure our operations, injunctions and civil or criminal prosecution. Any such penalties could adversely affect our ability to operate our business and pursue our strategic plans. Additionally, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with the various U.S. federal and state and foreign laws and regulations that apply to our business could prove costly. The occurrence of any of these risks could cause our performance and financial condition to materially suffer.

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with products, when and if any of them is approved.

Any product for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping, and requirements regarding company presentations and interactions with healthcare professionals. Even if we obtain regulatory approval of a product, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. We also may be subject to state laws and registration requirements covering the distribution of products. Later discovery of previously unknown problems with products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

restrictions on product manufacturing, distribution or use;

restrictions on the labeling or marketing of a product;

requirements to conduct post-marketing studies or clinical trials;

warning letters;

withdrawal of the products from the market;

refusal to approve pending applications or supplements to approved applications that we submit;

voluntary or mandatory recall;

fines;

suspension or withdrawal of marketing or regulatory approvals;

refusal to permit the import or export of products;

product seizure or detentions;

injunctions or the imposition of civil or criminal penalties; and

adverse publicity.

If we or our respective suppliers, third-party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we or our respective collaborators may lose marketing approval for products when and if any of them are approved, resulting in decreased revenue from milestones, product sales or royalties.

Our employees, consultants, or third-party partners may engage in misconduct or other improper activities, including but not necessarily limited to noncompliance with regulatory standards and requirements or internal procedures, policies or agreements to which such employees, consultants and partners are subject, any of which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants, or third party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, comply with internal procedures, policies or agreements to which such employees, consultants or partners are subject, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee, consultant, or third-party misconduct could also

involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We receive a large amount of proprietary information from potential or existing licensors of intellectual property and potential acquisition target companies, all pursuant to confidentiality agreements. The confidentiality and proprietary invention assignment agreements that we have in place with each of our employees and consultants prohibit the unauthorized disclosure of such information, but such employees or consultants may nonetheless disclose such information through negligence or willful misconduct. Any such unauthorized disclosures could subject us to monetary damages and/or injunctive or equitable relief. The notes, analyses and memoranda that we have generated based off such information are also valuable to our businesses, and the unauthorized disclosure or misappropriation of such materials by our employees and consultants could significantly harm our strategic initiatives — especially if such disclosures are made to our competitor companies.

We may use biological materials and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

We may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations may also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our respective resources, and clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not have insurance for environmental liability or toxic tort claims that may be asserted in connection with the storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

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

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

We believe our success and ability to compete depends in large part on obtaining and maintaining patent, trademark and trade secret protection of our product candidates and their respective components and underlying technologies, including devices, formulations, manufacturing methods and methods of treatment, as well as successfully defending our intellectual property rights against third-party challenges. Our ability to stop third parties from making, using or selling products that infringe on our intellectual property rights depends on the extent to which we have secured and properly safeguarded these rights under valid and enforceable patents or trade secrets.

Although we previously owned patents protecting our ImmunoPulse® clinical device, our primary U.S. patents providing such protection expired in 2017, the majority of our foreign patents expired in July 2018, and the final foreign patent expires in 2019. As a result, we may have limited ability to enforce these rights against third parties to prevent them from making or selling competing products that rely upon the protected technology, which could harm our competitive position and prospects. In addition to these proprietary rights that are expired or are expiring between 2017 and 2019, we have also exclusively licensed certain patents that cover our ImmunoPulse® clinical methods. These patents will expire between 2025 and 2027. These method patents protect the use of a product for a specified method under certain defined parameters. This type of patent does not prevent a competitor from making and marketing a product that is identical or similar to the protected product under parameters that are outside the scope of the patented method claims. Moreover, even if competitors do not actively promote such a product for the indications protected by the method patent, physicians could prescribe the products for these methods on an off-label basis. Although such off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to detect, prevent or prosecute. Furthermore, our licensed patents expiring between 2025 and 2027 may not have as broad a scope as our patents that are expiring or expired between 2017 and 2019, which in turn may limit our remedies against competitors making and marketing a product that is identical or similar to ours.

To the extent our existing patents or pending or planned patent applications expire before we are able to commercialize product depending on the technology or do not otherwise provide sufficient protection, we could be subject to substantially increased competition and our business and ability to commercialize or license our technology or product candidates could be materially adversely affected.

Even if we secure patents that cover our proprietary technology, our efforts to protect our intellectual property rights with patents may prove inadequate. For instance, the breadth of claims in a patent application is often restricted during patent prosecution, resulting in granted claims with a more limited scope than the claims in the original application. Additionally, pending or future patent applications may not result in issued patents. Laws and regulations for the prosecution of patents are continuously evolving, and the U.S. Supreme Court has recently revised certain tests regarding both the grant and review of patents that could make it more difficult to obtain issued patents. Also, any patents that are granted could be subject to post-grant proceedings that could limit their scope or enforceability, and claims that are amended during post-grant proceedings may not be broad enough to provide meaningful protection. Moreover, any patents that are issued to us or any future collaborators may be circumvented or invalidated by third-party efforts, may expire before or shortly after obtaining necessary regulatory approvals, or may not provide sufficient proprietary protection or competitive advantage for other reasons. Such challenges could include third-party pre-issuance submissions of prior art to the PTO, or opposition, derivation, reexamination, inter parties review, or post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The cost of these proceedings could be substantial and it is possible that our efforts to establish priority or validity of the invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Further, obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by

government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. These risks may be amplified in some foreign jurisdictions, where patent protection may not be as strong or as effective as it is in the United States.

Our reliance on unpatented proprietary rights, including trade secrets and know-how, may also pose significant risks. For instance, it can be difficult to protect these rights and they may lose their value if they are independently developed by a third party or if their secrecy is lost. Although we have taken measures to protect these rights, including establishing confidentiality agreements with employees, consultants and other third parties, these measures may not sufficiently safeguard our unpatented proprietary rights and may not provide adequate remedies in the event of unauthorized use or disclosure of the confidential information. Despite these efforts, any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Although management has determined that our internal control over financial reporting was effective as of July 31, 2018, our controls over financial processes and reporting may not continue to be effective, or we may identify significant deficiencies or material weaknesses in our internal controls in the future. Any failure to maintain effective internal control over financial reporting, including failures to implement new or improved controls as needed in a timely and effective manner or remediate any significant deficiency or material weakness that is identified in the future, could cause noncompliance with our public reporting obligations, an inability to produce reliable financial reports or material misstatements in our financial statements or other public disclosures. If any of these circumstances were to occur, investors could lose confidence in our financial and other reported information, our reputation could otherwise be harmed, the investment of our stockholders in our company could be negatively affected and the costs to us of raising additional capital could materially increase, any of which could harm our business and prospects.

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

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

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

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

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

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

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Our tax position could be affected by recent changes in United States federal income tax laws.

On December 22, 2017, legislation commonly referred to as the "Tax Cuts and Jobs Act" was signed into law and is generally effective after December 31, 2017. The Tax Cuts and Jobs Act makes significant changes to the United States federal income tax rules for taxation of individuals and business entities. Most of the changes applicable to individuals are temporary and apply only to taxable years beginning after December 31, 2017 and before January 1, 2026. For corporations, the Tax Cuts and Jobs Act reduces the top corporate income tax rate to 21% and repeals the corporate alternative minimum tax, limits the deduction for net interest expense, limits the deduction for net operating losses and eliminates net operating loss carrybacks, modifies or repeals many business deductions and credits, shifts the United States toward a more territorial tax system, and imposes new taxes to combat erosion of the United States federal income tax base. The Tax Cuts and Jobs Act makes numerous other large and small changes to the federal income tax rules that may affect potential investors and may directly or indirectly affect us. We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the Tax Cuts and Jobs Act on us and our affiliates, whether adverse or favorable, is uncertain, and may not become evident for some period of time. This document does not discuss such legislation or the manner in which it might affect us or purchasers of our common stock. Prospective investors are urged to consult with their legal and tax advisors with respect to the Tax Cuts and Jobs Act and any other regulatory or administrative developments and proposals, and their potential effects on them based on their unique circumstances.

Risks Related to our Growth Strategy

If we acquire, enter into joint ventures with or obtain a controlling interest in companies in the future, it could adversely affect our operating results and the value of our Common Stock thereby diluting stockholder value and disrupting our business.

As part of our growth strategy, we might acquire, enter into joint ventures with, or obtain a significant ownership stake in other companies. Acquisitions of, joint ventures with and investments in other companies involve numerous risks, including, but not necessarily limited to:

- risk of entering new markets in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- successfully negotiating a proposed acquisition or investment timely and at a price or on terms and conditions favorable to us;
- the impact of regulatory reviews on a proposed acquisition or investment;

the outcome of any legal proceedings that may be instituted with respect to the proposed acquisitions or investment;

with respect to an acquisition, difficulties in integrating operations, technologies, services and personnel; and

potential inability to maintain relationships with customers of the companies we may acquire or invest in.

If we fail to properly evaluate potential acquisitions, joint ventures or investments, we might not achieve the anticipated benefits of any such transaction, we might incur costs in excess of what we anticipate, and management resources and attention might be diverted from other necessary or valuable activities.

If we cannot continue to fund our research and development programs, we may be required to reduce product development, which will adversely impact our growth strategy.

Our research and development ("R&D") programs will require substantial additional capital to conduct research, preclinical testing and human studies, establish pilot scale and commercial scale manufacturing processes and facilities, and establish and develop quality control, regulatory, marketing, sales and administrative capabilities to support these programs. We expect to fund our R&D activities from a combination of cash generated from royalties and milestones from our partners in various past, ongoing and future collaborations and additional equity or debt financings from third parties. These financings could depress our stock price. If additional funds are required to support our operations and such funds cannot be obtained on favorable terms, we may not be able to develop products, which will adversely impact our growth strategy.

Risks Related to Our Common Stock

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

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

- adverse research and development or clinical trial results;
- our liquidity and ability to obtain additional capital, including the market's reaction to any capital-raising transaction we may pursue;
- declining working capital to fund operations, or other signs of financial uncertainty;
- any negative announcement by the FDA or comparable regulatory bodies outside the United States, including that it has denied any request to approve any of our product candidates for commercialization;

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

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

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

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

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

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

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

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

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

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

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

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

Our articles of incorporation authorize the issuance of up to 160,000,000 shares of our common stock. In addition to capital-raising activities, on which we have historically relied for cash to fund our operations, including with our recent October 2017 offerings, November 2017 warrant exercise inducement offering, February 2018 offering and October 2018 offering, other possible business and financial uses for our authorized common stock include, among others, stock splits, acquiring other businesses or assets in exchange for shares of our common stock, issuing shares of our common stock to collaborators in connection with strategic alliances, issuing common stock to vendors for services performed, attracting and retaining employees with equity compensation or other transactions and corporate purposes that our Board of Directors deems to be in the best interest of our Company. Additionally, issuances of common stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of our Company. Any future issuances of our common stock may be consummated on terms that are not favorable, may not enhance stockholder value and may adversely affect the trading price of our common stock. Further, any such issuance will reduce the book value per share of our common stock and reduce the proportionate ownership and voting power of our existing stockholders.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of your stock.

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our stock if you require dividend income. Further, you will only realize income on an investment in our stock in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

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

As of July 31, 2018, we had outstanding (i) options to purchase 8.9 million shares of our common stock, (ii) warrants to purchase 9.0 million shares of our common stock, and (iii) 0.6 million restricted stock units. In addition, as of July 31, 2018, there were 1.2 million shares reserved for future issuance under our stock incentive and stock purchase plans. The exercise of options and warrants, the vesting and settlement of restricted stock units or the issuance of additional equity awards under our stock incentive and stock purchase plans could have an adverse effect on the market for our common stock, including the price that any stockholder could obtain for its shares. Further, our existing stockholders could experience significant dilution in the net tangible book value of their investment upon the issuance of additional shares of our common stock through the exercise of derivative securities that are currently outstanding or that we may issue in the future.

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

The market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, our existing stockholders. Since March 2011, we have completed a number of offerings of our common stock and warrants. Future sales of common stock by significant stockholders, including by those who acquired their shares in our prior equity offerings, or the perception that such sales may occur, could depress the price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

On February 14, 2018, the Company entered into a lease agreement for approximately 3,100 rentable square feet located at 24 N. Main Street, Pennington, New Jersey, 08534, which serves as the Company's New Jersey corporate headquarters. The term of the lease commenced on March 1, 2018 and expires on April 30, 2020. Base rent under the lease agreement is $3,079 per month for each of the first five months, $6,158 per month for each of the sixth through twelfth months and $6,286 per month for each of the thirteenth through twenty-sixth months. The lease agreement also requires the Company to share in certain monthly operating expenses of the premises, and required the Company to pay a security deposit of $12,316 in February 2018 upon entering into the lease agreement.

In March 2018, we entered into a lease assignment agreement (the "Lease Assignment Agreement") with Vividion Therapeutics, Inc. ("Vividion") for a 34,054 square foot location at 5820 Nancy Ridge Drive, San Diego, California, 92121 (the "NR Premises"), whereby we assigned the lease agreement with ARE-SD Region No. 18, LLC (the "Landlord") to Vividion. Under the Lease Assignment Agreement, Vividion pays directly to Landlord the base rent of $101,500 per month (based upon $2.98 per rentable square foot of the NR Premises) plus operating expenses and property management fees attributable to the NR Premises currently estimated at $43,500 per month (including an estimate for utilities) during the term of the Lease Assignment Agreement, which is the remaining term of the lease through October 2025.

While the lease and all of the related obligations were assigned to Vividion, we could ultimately have an obligation on the Lease Assignment Agreement if Vividion defaulted on their obligation to the Landlord after all remedies were exhausted by the Landlord with regard to Vividion's obligations. Such an event is not considered probable and no obligation has been recorded at July 31, 2018.

In conjunction with the Lease Assignment Agreement, we also entered into a sublease (the "Sublease") with Vividion, for a 12,442 square-foot location at 3565 General Atomics Court, Suite 100, San Diego, CA, 92121, leased by Vividion from Landlord which serves as the Company's California office (the "Sublease Premise"). Under the Sublease, we are obligated to pay Vividion base rent of $49,768 per month, subject to an annual 3% increase, (based upon $4.00 per rentable square foot of the Sublease Premises) plus operating expenses and property management fees attributable to the Sublease Premises currently estimated at $30,400 per month during the term of the Sublease, which extends through September 2020. We moved to the new location in April 2018.

At the time of the lease agreements noted above, we had a deferred rent liability recorded on the consolidated balance sheet of $1.1 million, is currently being amortized on a straight-line basis over the term of the Sublease.

We have also entered into lease arrangements for vivarium space in San Diego, California to support our research and development department.

We believe our current facilities are adequate to meet our current operating needs and will remain adequate for the foreseeable future. Should we need additional space, we currently do not foresee significant difficulties in obtaining additional facilities.

ITEM 3. LEGAL PROCEEDINGS

In the ordinary course of business, we may become a party to lawsuits involving various matters. The impact and outcome of litigation, if any, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are not currently a party, and our properties are not currently subject, to any legal proceedings that, in the opinion of management, are expected to have a material adverse effect on our business, financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Trading Information

Our common stock began trading on the NASDAQ Capital Market tier under the symbol "ONCS" since May 29, 2015. Prior to that, our common stock was quoted on the OTC Market Group, Inc.'s OTCQB tier.

The following table sets forth the range of reported high and low sales prices for our common stock for the fiscal quarters indicated, as reported on the NASDAQ:

	High	Low
Fiscal Year Ended July 31, 2017		
First Quarter ended October 31, 2016	$2.08	$1.65
Second Quarter ended January 31, 2017	$2.04	$1.11
Third Quarter ended April 30, 2017	$1.69	$1.03
Fourth Quarter ended July 31, 2017	$1.36	$0.88
Fiscal Year Ended July 31, 2018		
First Quarter ended October 31, 2017	$1.54	$0.88
Second Quarter ended January 31, 2018	$2.95	$1.15
Third Quarter ended April 30, 2018	$2.21	$1.45
Fourth Quarter ended July 31, 2018	$1.80	$1.21

Holders

As of October 1, 2018, there were 45 holders of record of our common stock, plus an indeterminate number of additional stockholders whose shares of our common stock are held on their behalf by brokerage firms or other agents.

Dividends

We have never declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain future earnings, if any, to support operations and to finance expansion and therefore we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

The information included under Item 12 of Part III of this report, “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters,” is hereby incorporated by reference into this Item 5 of Part II of this report.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other portions of this report contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, product demand, market acceptance and other factors discussed in this report under the heading "Risk Factors". This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our financial statements and the related notes included elsewhere in this report.

Overview

We are a biotechnology company focused on designing, developing and commercializing innovative therapies and proprietary medical approaches to stimulate and to guide an anti-tumor immune response for the treatment of cancer. Our core platform technology, ImmunoPulse®, is a drug-device therapeutic modality comprised of a proprietary intratumoral electroporation delivery device. The ImmunoPulse® platform is designed to deliver plasmid DNA-encoded drugs directly into a solid tumor and promote an immunological 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. Our lead product candidate, ImmunoPulse® IL-12, uses our 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. The activation of the appropriate inflammatory response can drive a systemic anti-tumor response against untreated tumors in other parts of the body. In February 2017, we received Fast Track designation from the U.S. Food and Drug Administration ("FDA") for TAVO in metastatic melanoma, which could qualify TAVO for expedited FDA review, a rolling Biologics License Application review and certain other benefits.

We have ongoing development of TAVO in both monotherapy and combination programs and intend to continue to pursue other ongoing or potential new trials and studies related to TAVO, in various tumor types including melanoma, TNBC and Head and Neck cancers. In addition, we are also developing our next-generation electroporation device and applicator, and pursuing discovery research to identify other product candidates that, in addition to IL-12, can be encoded into propriety plasmid-DNA, delivered intratumorally using electroporation.

Results of Operations for the Year Ended July 31, 2018 Compared to the Year Ended July 31, 2017

The unaudited financial data for the year ended July 31, 2018 and July 31, 2017 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	July 31, 2018	July 31, 2017	Increase/(Decrease)	Increase/(Decrease) %
Revenue	$-	$-	$ -	-
Expenses				
Research and development	17,415,520	11,952,748	5,462,772	46
General and administrative	18,689,839	9,669,481	9,020,358	93
Loss from operations	(36,105,359)	(21,622,229)	14,483,130	67
Other income (expense), net	310,167	173,822	136,345	78
Loss on disposal of property and equipment	(875,098)	-	875,098	100
Warrant inducement expense	(2,465,396)	-	2,465,396	100
Net loss before income taxes	(39,135,686)	(21,448,407)	17,687,279	82
Provision for income taxes	680	1,391	(711)	(51)
Net loss	$(39,136,366)	$(21,449,798)	$ 17,686,568	82

Revenue

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

Research and Development Expenses

Our research and development expenses increased by $5.4 million, from $12.0 million in the year ended July 31, 2017 to $17.4 million in the year ended July 31, 2018. This increase was largely due to increases of: (i) $3.4 million in outside services costs related to the development of our next-generation electroporation device, clinical research organization costs, as well as clinical consulting costs to primarily support our PISCES/KEYNOTE-695 study; (ii) $2.3 million increase in plasmid manufacturing costs to support clinical trial supply readiness, and, (iii) $0.4 million in patient-related treatment costs; these increases were net of (iv) $0.7 million in a research and development tax credit against our clinical trial costs incurred in Australia. We expect research and development to continue to account for a significant portion of our total expenses in the future as we continue to develop our pipeline of product candidates and electroporation devices. [Note: The research and development tax credit relates to a tax credit from Australian government based on research and development expenses incurred by our wholly-owned subsidiary in Australia. 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.]

General and Administrative

Our general and administrative expenses increased by $9.0 million, from $9.7 million in the year ended July 31, 2017 to $18.7 million in the year ended July 31, 2018. This increase was largely due to increases of: (i) $4.1 million in stock-based compensation expense primarily related to option and RSU grants to our current directors and executives, as well as acceleration of the vesting of stock based compensation to previous executives; (ii) $2.5 million in cash for services and non-cash stock options granted to third-party firms to provide certain investor relations and advisory consulting services; (iii) $2.3 million in compensation costs, including severance expense for former executives; and, (iv) $0.2 million in other general and administrative-related costs.

Other Income (Expense), Net

Other income (expense), net, increased by $0.1 million, from other income net of $0.2 million in the year ended July 31, 2017 to other income net of $0.3 million in the year ended July 31, 2018. This increase was primarily due to interest-bearing cash and marketable securities investment accounts.

Loss on Disposal of Property and Equipment

Loss on disposal of property and equipment increased by $0.9 million, from $0 in the year ended July 31, 2017 to $0.9 million in the year ended July 31, 2018. This increase was due to the loss on disposal of property and equipment related to our move to a smaller facility in San Diego, California.

Warrant Inducement Expense

The warrants issued in connection with our November 2017 warrant exercise inducement offering were considered inducement warrants and the fair value of the inducement warrants of $2.5 million is classified as equity and expensed as warrant inducement expense. (See Note 6).

Provision for Income Taxes

We recorded an income tax provision of $680 and $1,391 in the year ended July 31, 2018 and 2017, respectively, comprised solely of minimum state taxes because of a net tax loss in both periods.

Liquidity and Capital Resources

Working Capital

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

	At July 31, 2018	At July 31, 2017
Current assets	$28,621,823	$12,513,623
Current liabilities	5,849,636	3,395,974
Working capital	$22,772,187	$9,117,649

Current Assets

Current assets as of July 31, 2018 increased to $28.6 million, from $12.5 million as of July 31, 2017. This increase was primarily due to an increase in cash, cash equivalents and short-term investment securities from $11.4 million as of July 31, 2017 to $27.0 million as of July 31, 2018, which is attributable to the net proceeds received from our October 2017 offerings, November 2017 warrant exercise inducement offering and February 2018 offering (see "Sources of Capital" below).

Current Liabilities

Current liabilities as of July 31, 2018 increased to $5.8 million, from $3.4 million as of July 31, 2017. This increase was primarily due to an increase in accrued clinical and R&D related costs and an increase in accrued compensation.

Cash Flow

Cash Used in Operating Activities

Net cash used in operating activities for the year ended July 31, 2018 was $23.2 million, as compared to $17.3 million for the year ended July 31, 2017. The $5.9 million increase in cash used in operating activities was primarily attributable to an increase in cash used to support our operating activities, including but not limited to, our clinical trials, an increase in R&D activities and general working capital requirements.

Cash Used in Investing Activities

Net cash used in investing activities for the year ended July 31, 2018 was $23.3 million, as compared to $22,000 for the year ended July 31, 2017. The increase was related to our movement of cash from a bank interest-earning account to two short-term investment accounts. We have an investment policy which is administered by management and reviewed by the Board of Directors. We believe our investment policy is conservative and maximizes returns, while minimizes risk, since we rely on the cash to fund operations.

Cash Provided by Financing Activities

Net cash provided by financing activities was $38.9 million for the year ended July 31, 2018, as compared to $64,000 for the year ended July 31, 2017. The increase was primarily attributable to the net proceeds received from our October 2017 offerings, November 2017 warrant exercise inducement offering, February 2018 offering and the exercise of certain stock options and warrants (see “Sources of Capital” below).

Uses of Cash and Cash Requirements

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

Our primary objectives for the next 12 months are to continue the advancement of our PISCES/KEYNOTE-695 and OMS-141/KEYNOTE-890 studies and, to a lesser extent, our other ongoing clinical trials and studies, and to continue our research and development activities for our next-generation electroporation device and drug discovery efforts. In addition, we expect to pursue capital-raising transactions, which could include equity or debt financings, in the near term to fund our existing and planned operations and acquire and develop additional assets and technology consistent with our business objectives as opportunities arise.

We currently estimate our monthly working capital requirements to be approximately $2.0 million, although we may modify or deviate from this estimate and it is likely that our actual operating expenses and working capital requirements will vary from our estimate. Based on these expectations regarding future expenses, rate of consumption, as well as our current cash levels, inclusive of $8.0 million in gross proceeds received from the first tranche of Alpha Holding equity offering in October 2018, we believe our cash resources are sufficient to meet our anticipated needs for more than the 12 months following the issuance of this report. We will continue to assess our cash resources and anticipated needs on a quarterly basis.

Sources of Capital

We have not generated any revenue since our inception, and we do not anticipate generating meaningful, or any, revenue in the near term. Historically, we have raised the majority of the funding for our business through offerings of our common stock and warrants to purchase our common stock. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders would experience further dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur debt, our fixed payment obligations, liabilities and leverage relative to our equity capitalization would increase, which could increase the cost of future capital. Further, the terms of any debt securities we issue or borrowings we incur, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity or other operating restrictions that could adversely affect our ability to conduct our business, and any such debt could be secured by any or all of our assets pledged as collateral. Additionally, we may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other costs.

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

February 2018 Offering

On February 6, 2018, the Company completed a follow-on public offering, selling 13,333,334 shares at an offering price of $1.50 per share. Additionally, the underwriters exercised in full their over-allotment option to purchase an additional 2,000,000 shares at an offering price of $1.50 per share. Aggregate gross proceeds from this follow-on public offering, including the exercise of the over-allotment option, were approximately $23 million, and net proceeds received, after underwriting fees of approximately $1.7 million and offering expenses of approximately $0.5 million, were approximately $20.8 million.

November 2017 Warrant Exercise Inducement Offering

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

The warrants issued in connection with the Exercise Agreement were considered inducement warrants and are classified in equity. The fair value of the inducement warrants of $2.5 million was expensed as warrant inducement expense in the accompanying consolidated statement of operations for the year ended July 31, 2018.

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October 2017 Offerings

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

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

ATM Program

On July 25, 2017, we entered into an equity distribution agreement with Oppenheimer & Co. Inc., or Oppenheimer, to commence an "at the market" offering program, or the ATM Program, under which we were permitted to offer and sell, from time to time through or to Oppenheimer, acting as sales agent or principal, shares of our common stock having an aggregate gross sales price of up to $8.4 million. An aggregate of 897,311 shares of our common stock were sold in the ATM Program during the year ended July 31, 2018, for net proceeds to us, after deducting Oppenheimer's commissions and other expenses paid or payable by us, of $1.1 million. Effective as of October 22, 2017, we terminated the ATM Program. As a result of such termination, no further offers or sales of our common stock will be made in the ATM Program.

Warrant Exercises

During the year ended July 31, 2018, we received gross proceeds of $10.0 million related to the November 2017 Warrant Exercise Inducement Offering as well as an additional $0.7 million from other warrant exercises. If the holders of all our warrants that are outstanding as of the issuance of this report were to exercise all such warrants in full on a cash basis, we would receive an aggregate of approximately $26.4 million in net proceeds. However, the holders of these warrants may choose to exercise only a portion of the warrants they hold, may choose not to exercise any of the warrants they hold, or may choose to “net” exercise their warrants on a cashless basis to the extent permitted by the warrants. As a result, we may never receive meaningful, or any, proceeds from the exercise of these warrants.

Alpha Holdings

On August 31, 2018, the Company entered into a stock purchase agreement with Alpha Holdings, Inc. (“Alpha Holdings”), pursuant to which the Company agreed to issue and sell to Alpha Holdings shares of its common stock equal to an aggregate amount of up to $15.0 million at a market purchase price of $1.50 per share, which was the closing price of the Company’s common stock the day immediately before the agreement was executed by the parties.

On October 9, 2018, the Company received total proceeds, before expenses, of $8.0 million in cash from the offering and issued Alpha Holdings 5,333,333 shares of common stock. There were no underwriting or placement agent fees associated with the offering. The second closing of 4,666,667 shares of Common Stock is expected to occur on or before December 15, 2018.

Critical Accounting Policies

Investment Securities

Securities available for sale are recorded at fair value and unrealized gains and losses are reported, net of taxes, in accumulated other comprehensive income (loss) included in stockholders’ equity. Securities held to maturity are recorded at amortized cost based on the Company’s positive intent and ability to hold these securities to maturity. Realized gains and losses from sales of securities available for sale are determined on a specific identification basis and are included in other revenue – net.

Management evaluates whether securities available for sale and securities held to maturity are other-than-temporarily impaired (“OTTI”) on a quarterly basis. Debt securities with unrealized losses are considered OTTI if the Company intends to sell the security or if it is more likely than not that the Company will be required to sell such security prior to any anticipated recovery. If management determines that a security is OTTI under these circumstances, the impairment recognized in earnings is measured as the entire difference between the amortized cost and the then-current fair value.

Accounting for Long-Lived Assets

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

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

Equity-Based Awards

The Company grants equity-based awards (typically stock options or restricted stock units) under our stock-based compensation plan and outside of our stock-based compensation plan, with terms generally similar to the terms under our stock-based compensation plan. The Company estimates the fair value of stock option awards using the Black-Scholes option valuation model. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. 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. The Company estimates the fair value of restricted stock unit awards based on the closing price of the Company's common stock on the date of issuance. Changes in assumptions used under the Black-Scholes option valuation model could materially affect the Company's net loss and net loss per share.

Employee Stock Purchase Plan

Employees may elect to participate in our stockholder approved employee stock purchase plan. The stock purchase plan allows for the purchase of our common stock at not less than 85% of the lesser of (i) the fair market value of a share of stock on the beginning date of the offering period or (ii) the fair market value of a share of stock on the purchase date of the offering period, subject to a share and dollar limit as defined in the plan and subject to the applicable legal requirements. There are two 6-month offering periods during each fiscal year, ending on January 31 and July 31. In accordance with applicable accounting guidance, the fair value of awards under the stock purchase plan is calculated at the beginning of each offering period. We estimate the fair value of the awards using the Black-Scholes option valuation model. The Black-Scholes option valuation model requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and the offering period. This fair value is then amortized at the beginning of the offering period. Stock-based compensation expense is based on awards expected to be purchased at the beginning of the offering period, and therefore is reduced when participants withdraw during the offering period.

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Australia Research and Development Tax Credit

Our Australian, wholly-owned, subsidiary incurs research and development expenses, primarily in the course of conducting clinical trials. The 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 our 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 in the Consolidated Statements of Operations.

Tax Reform

The Tax Cuts and Jobs Act was signed into law in December 2017, impacting federal corporate tax rates. While the Act will impact certain aspects in the calculation of our tax provision, we maintain a full valuation allowance and do not anticipate any net impact to our financial statements in 2018.

Recent Accounting Pronouncements

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

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditure or capital resources that is material to investors.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item 8 is incorporated by reference to our consolidated financial statements and the related notes and the report of our independent registered public accounting firm beginning at page F-1 of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures reflects the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of July 31, 2018. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of July 31, 2018, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. With the participation of our Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of July 31, 2018. In conducting such evaluation, management used the criteria set forth in the report entitled "*Internal Control — Integrated Framework*" published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) to evaluate the effectiveness of our internal control over financial reporting. Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of July 31, 2018, based on those criteria.

This report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting, in accordance with applicable SEC rules that permit us to provide only management's report in this report.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended July 31, 2018, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

ITEM 9B. OTHER INFORMATION

None

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Director independence and other information required by this Item 13 is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) The following financial statements of OncoSec Medical Incorporated are filed as part of this report under Item 8 — Financial Statements and Supplementary Data:

(a)(2) All financial statement schedules are omitted because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto included in this report.

(a)(3) The exhibits listed in the Exhibit Index, which appears immediately following the last page of this report and is incorporated herein by reference, are filed or incorporated by reference as part of this report.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and

Stockholders of OncoSec Medical Incorporated

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of OncoSec Medical Incorporated (the "Company") as of July 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended July 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of July 31, 2018 and 2017, and the results of their operations and their cash flows for each of the years in the two-year period ended July 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also

included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Mayer Hoffman McCann P.C.
We have served as the Company's auditor since 2011.
San Diego, California

October 19, 2018

OncoSec Medical Incorporated

Consolidated Balance Sheets

	July 31, 2018	July 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$3,803,627	$11,444,676
Prepaid expenses and other current assets	1,643,749	1,068,947
Investment securities	23,174,447	-
Total Current Assets	28,621,823	12,513,623
Property and equipment, net	1,265,662	2,410,099
Other long-term assets	358,987	309,187
Total Assets	$30,246,472	$15,232,909
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	$4,778,892	$3,281,133
Accrued compensation related	1,070,744	114,841
Total Current Liabilities	5,849,636	3,395,974
Other long-term liabilities	1,472,630	1,140,953
Total Liabilities	7,322,266	4,536,927
Commitments and Contingencies (Note 9)		
Stockholders' Equity		
Common stock authorized - 160,000,000 common shares with a par value of $0.0001, common stock issued and outstanding — 53,511,626 and 21,618,194 common shares as of July 31, 2018 and July 31, 2017, respectively	5,351	2,162
Additional paid-in capital	145,744,373	93,866,088
Warrants issued and outstanding - 8,958,059 and 9,044,740 warrants as of July 31, 2018 and July 31, 2017, respectively	11,271,327	11,775,807
Accumulated other comprehensive loss	(16,024)	(3,620)
Accumulated deficit	(134,080,821)	(94,944,455)
Total Stockholders' Equity	22,924,206	10,695,982
Total Liabilities and Stockholders' Equity	$30,246,472	$15,232,909

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

OncoSec Medical Incorporated

Consolidated Statements of Operations

	Year Ended July 31, 2018	Year Ended July 31, 2017
Revenue	$-	$-
Expenses:		
Research and development	17,415,520	11,952,748
General and administrative	18,689,839	9,669,481
Loss from operations	(36,105,359)	(21,622,229)
Other income (expense), net	310,167	173,822
Loss on disposal of property and equipment	(875,098)	-
Warrant inducement expense	(2,465,396)	-
Loss before income taxes	(39,135,686)	(21,448,407)
Provision for income taxes	680	1,391
Net loss	$(39,136,366)	$(21,449,798)
Basic and diluted net loss per common share	$(0.98)	$(1.06)
Weighted average shares used in computing basic and diluted net loss per common share	40,123,371	20,189,678

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

OncoSec Medical Incorporated

Consolidated Statements of Comprehensive Loss

	Year Ended July 31, 2018	Year Ended July 31, 2017
Net Loss	$(39,136,366)	$(21,449,798)
Foreign currency translation adjustments	(12,404)	(3,620)
Comprehensive Loss	$(39,148,770)	$(21,453,418)

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

Oncosec Medical Incorporated

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-In	Warrants		Accumulated Other Comprehensive	Accumulated	Total Stockholders
	Shares	Amount	Capital	Shares	Amount	Loss	Deficit	Equity
Balance, July 31, 2016	18,036,263	$1,804	$88,257,430	12,859,286	$13,288,527	$—	$(73,494,657)	$28,053,104
Exercise of common stock warrants	3,544,593	354	68,537	(3,344,593)	(33,446)	—	—	35,445
Exercise of common stock options	918	—	—	—	—	—	—	—
Common stock issued for employee stock purchase plan	36,420	4	44,057	—	—	—	—	44,061
Cancellation of expired warrants	—	—	1,479,274	(469,953)	(1,479,274)	—	—	—
Stock-based compensation expense	—	—	4,016,790	—	—	—	—	4,016,790
Net loss and comprehensive loss	—	—	—	—	—	(3,620)	(21,449,798)	(21,453,418
Balance, July 31, 2017	21,618,194	2,162	93,866,088	9,044,740	11,775,807	(3,620)	(94,944,455)	10,695,982
Exercise of common stock warrants	6,953,392	695	14,704,596	(6,953,392)	(4,705,307)	—	—	9,999,984
Exercise of common stock options	252,270	25	321,120	—	—	—	—	321,145
Common stock issued for employee stock purchase plan	40,606	4	35,805	—	—	—	—	35,809
Stock-based compensation expense	1,277,015	128	8,252,387	—	—	—	—	8,252,515
	—	—	(181,550)	—	—	—	—	(181,550

Tax withholdings paid related to net share settlement of equity awards								
At-the-market offering program, net of issuance costs of $299,963	897,311	90	825,573	—	—	—	—	825,663
Public offering on October 25, 2017, net of issuance costs of $901,137	6,070,934	607	4,319,900	4,917,457	2,936,173	—	—	7,256,680
Warrant Exercise Inducement Offering on November 13, 2017	—	—	(195,431)	2,515,711	2,465,396	—	—	2,269,965
Public offering in February 2018, net of issuance costs of $2,249,169	15,333,334	1,533	20,749,299	—	—	—	—	20,750,832
Cancellation of expired warrants	—	—	1,200,742	(566,457)	(1,200,742)	—	—	—
Common stock issued for services	1,068,570	107	1,845,844	—	—	—	—	1,845,951
Net loss and comprehensive loss	—	—	—	—	—	(12,404)	(39,136,366)	(39,148,770)
Balance, July 31, 2018	53,511,626	$5,351	$145,744,373	8,958,059	$11,271,327	$(16,024)	$(134,080,821)	$22,924,206

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

OncoSec Medical Incorporated

Consolidated Statements of Cash Flows

	Year Ended July 31, 2018	Year Ended July 31, 2017
Operating activities		
Net loss	$(39,136,366)	$(21,449,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	334,494	379,988
Loss on disposal of property and equipment	875,098	-
Warrant inducement expense	2,465,396	-
Amortization of discount on investments	(28,948)	-
Stock-based compensation	8,252,515	4,016,790
Common stock issued for services	1,845,951	-
Changes in operating assets and liabilities:		
Prepaid expenses	97,535	(130,926)
Other current assets	(593,141)	14,750
Other long-term assets	(49,800)	(88,473)
Accounts payable and accrued liabilities	1,427,760	(208,281)
Accrued compensation	955,903	(128,083)
Other long-term liabilities	331,677	253,661
Net cash used in operating activities	(23,221,926)	(17,340,372)
Investing activities		
Purchases of property and equipment	(65,156)	(21,562)
Purchase of investment securities	(25,474,695)	-
Maturity of investment securities	2,250,000	-
Net cash used in investing activities	(23,289,851)	(21,562)
Financing activities		
Proceeds from issuance of common stock through ESPP	35,809	-
Proceeds from issuance of common stock and warrants	32,283,444	-
Payment of financing and offering costs	(3,575,699)	(15,500)
Proceeds from exercise of options	321,145	79,506
Tax withholdings paid related to net share settlement of equity awards	(181,550)	-
Proceeds from exercise of inducement warrants	9,999,983	-
Net cash provided by financing activities	38,883,132	64,006
Effect of exchange rate changes on cash	(12,404)	(3,620)
Net decrease in cash	(7,641,049)	(17,301,548)
Cash and cash equivalents, at beginning of year	11,444,676	28,746,224
Cash and cash equivalents, at end of year	$3,803,627	$11,444,676
Supplemental disclosure for cash flow information:		
Cash paid during the period for:		
Interest	$-	$-
Income taxes	$680	$1,391
Noncash investing and financing transactions:		

Expiration of warrants	$1,200,742	$1,479,274
Amounts accrued for offering costs	$45,000	$256,296

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

OncoSec Medical Incorporated

Notes to Consolidated Financial Statements

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 to 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 plasmid DNA-encoded drugs directly into a solid tumor and promote an immunological 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. Its lead product candidate, ImmunoPulse® IL-12, uses our 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. The activation of the appropriate inflammatory response can drive 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 TAVO in metastatic melanoma, which could qualify TAVO for expedited FDA review, a rolling Biologics License Application review and certain other benefits.

The Company's current focus is to pursue its study of TAVO in combination with KEYTRUDA® (pembrolizumab) for melanoma patients who are definitive anti-PD-1 non-responders. The trial is referred to as the PISCES/KEYNOTE-695. 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. Pursuant to the terms of the agreement, both companies will bear their own costs related to manufacturing and supply of their product, as well as be responsible for their own internal costs. The Company will sponsor the study and be responsible for external costs. The PISCES/KEYNOTE-695 study is currently enrolling patients and the Company plans to provide a topline preliminary data update at The Society for Immunotherapy of Cancer ("SITC") 2018. This study is a registrational-directed, Phase 2b open-label, single-arm, multicenter study in the United States, Canada and Australia.

The Company is also pursing development in triple negative breast cancer ("TNBC"). On May 8, 2018, the Company entered into a second clinical trial collaboration and supply agreement with Merck with respect to a Phase 2 study of TAVO in combination with KEYTRUDA® to evaluate the safety and efficacy of the combination in patients with inoperable locally advanced or metastatic TNBC, who have previously failed at least one systemic chemotherapy or immunotherapy. This study is referred to as KEYNOTE-890. Pursuant to the terms of the agreement, both companies will bear their own costs related to manufacturing and supply of their product, as well as be responsible for their own internal costs. The Company will sponsor the study and be responsible for external costs. The KEYNOTE-890 study is opened for enrollment. The study is a Phase 2 open-label, single-arm, multicenter study in the United States and Australia.

The Company intends to continue to pursue other ongoing or potential new trials and studies related to TAVO, in various tumor types including melanoma, TNBC and head and neck cancers. In addition, the Company is also developing its next-generation electroporation device and applicator, including advancements toward prototypes, pursuing discovery research to identify other product candidates that, in addition to IL-12, can be encoded into propriety plasmid-DNA, delivered intratumorally using electroporation. Using the Company's next-generation technology, its goal is to reverse the immunosuppressive mechanisms of a tumor, as well as to expand its ImmunoPulse® pipeline. The Company believes that the flexibility of its propriety plasmid-DNA technology allows it to deliver other immunologically relevant molecules into the tumor microenvironment in addition to the delivery of plasmid-DNA encoding for IL-12. These other immunologically relevant molecules may compliment IL-12's activity by limiting or enhancing 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, in the opinion of management, reflect all adjustments necessary to state fairly the Company's financial position, results of operations and cash flows in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All intercompany accounts and transactions have been eliminated in consolidation.

Reclassifications

Certain amounts in the accompanying consolidated balance sheet for the year ended July 31, 2017 have been reclassified to conform to the year ended July 31, 2018 presentation, but there was no effect on net loss for the year ended July 31, 2017.

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Note 2—Significant Accounting Policies

Use of Estimates

The accompanying 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.

Cash and Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash and have an original maturity of three months or less at the time of purchase to be cash equivalents.

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.

Investment Securities

Securities available for sale are recorded at fair value and unrealized gains and losses are reported, net of taxes, in accumulated other comprehensive income (loss) included in stockholders' equity. Securities held to maturity are recorded at amortized cost based on the Company's positive intent and ability to hold these securities to maturity. Realized gains and losses from sales of securities available for sale are determined on a specific identification basis and are included in other revenue – net.

Management evaluates whether securities available for sale and securities held to maturity are other-than-temporarily impaired ("OTTI") on a quarterly basis. Debt securities with unrealized losses are considered OTTI if the Company intends to sell the security or if it is more likely than not that the Company will be required to sell such security prior to any anticipated recovery. If management determines that a security is OTTI under these circumstances, the impairment recognized in earnings is measured as the entire difference between the amortized cost and the then-current fair value.

Property and Equipment

The Company's capitalization threshold is $5,000 for property and equipment. The cost of property and equipment is depreciated on a straight-line basis over the estimated useful lives of the related assets. The useful lives of property and equipment for the purpose of computing depreciation are as follows:

Computers and equipment:	3 to 10 years
Computer software:	1 to 3 years
Leasehold improvements:	Shorter of lease period or useful life

Impairment of Long-Lived Assets

The Company periodically assesses the carrying value of intangible and other long-lived assets, and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. The assets are considered to be impaired if the Company determines that the carrying value may not be recoverable based upon its assessment, which includes consideration of the following events or changes in circumstances:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to the asset;
- significant changes in the Company's strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by the application of discounted cash flow models to project cash flows from the asset. In addition, the Company bases estimates of the useful lives and related amortization or depreciation expense on its subjective estimate of the period the assets will generate revenue or otherwise be used by it. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less selling costs. The Company also periodically reviews the lives assigned to long-lived assets to ensure that the initial estimates do not exceed any revised estimated periods from which the Company expects to realize cash flows from its assets.

Fair Value of Financial Instruments

The carrying amounts for cash, prepaid expenses, accounts payable and accrued expenses approximate fair value due to the short-term nature of these instruments. It is management's opinion that the Company is not exposed to significant interest, currency, or credit risks arising from its other financial instruments and that their fair values approximate their carrying values except where expressly disclosed.

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value.

The three tiers are defined as follows:

Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets at the measurement date. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment. The Company's Level 1 assets consist of bank deposits and money market funds.

Level 2—Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities. The Company's Level 2 assets consist of U.S. government sponsored securities.

Level 3— Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The development and determination of the unobservable inputs for Level 3 fair value measurements and fair value calculations are the responsibility of the Company's Chief Financial Officer.

Changes in fair value measurements categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded as appropriate.

No such items existed as of July 31, 2018 and 2017.

Financial instruments not recorded at fair value

Descriptions of the valuation methodologies and assumptions used to estimate the fair value of financial instruments not recorded at fair value are described below. The Company's financial instruments not recorded at fair value but for which fair value can be approximated and disclosed include:

Securities held to maturity – The fair values of securities held to maturity are obtained using an independent third-party financial institution.

Warrants

The Company assesses its warrants as either equity or a liability based upon the characteristics and provisions of each instrument. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's balance sheet and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's balance sheet at their fair value on the date of issuance and are re-measured on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or other instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield and risk-free interest rate. As of July 31, 2018 and 2017, all outstanding warrants issued by the Company were classified as equity.

Net Loss Per Share

The Company computes basic net loss per common share by dividing the applicable net loss by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing the applicable net loss by the weighted-average number of common shares outstanding during the period plus additional shares to account for the dilutive effect of potential future issuances of common stock relating to stock options and other potentially dilutive securities using the treasury stock method.

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

	July 31, 2018	July 31, 2017
Stock options	8,912,720	3,653,641
Restricted stock units	647,500	1,100,000
Warrants	8,958,059	9,044,740
Total	18,518,279	13,798,381

Stock-Based Compensation

The Company grants equity-based awards (typically stock options or restricted stock units) under our stock-based compensation plan and outside of our stock-based compensation plan, with terms generally similar to the terms under our stock-based compensation plan. The Company estimates the fair value of stock option awards using the Black-Scholes option valuation model. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally re-measured on vesting dates and interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. 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. The Company estimates the fair value of restricted stock unit awards based on the closing price of the Company’s common stock on the date of issuance. Changes in assumptions used under the Black-Scholes option valuation model could materially affect the Company’s net loss and net loss per share.

Employee Stock Purchase Plan

Employees may elect to participate in the Company's stockholder approved employee stock purchase plan. The stock purchase plan allows for the purchase of the Company's common stock at not less than 85% of the lesser of (i) the fair market value of a share of common stock on the beginning date of the offering period or (ii) the fair market value of a share of common stock on the purchase date of the offering period, subject to a share and dollar limit as defined in the plan and subject to the applicable legal requirements. There are two six-month offering periods during each fiscal year, ending on January 31 and July 31.

In accordance with applicable accounting guidance, the fair value of awards under the stock purchase plan is calculated at the beginning of each offering period. The Company estimates the fair value of the awards using the Black-Scholes option valuation model. The Black-Scholes option valuation model requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and the offering period. This fair value is then amortized at the beginning of the offering period. Stock-based compensation expense is based on awards expected to be purchased at the beginning of the offering period, and therefore is reduced when participants withdraw during the offering period.

Deferred Rent

Rent expense from leases is recorded on a straight-line basis over the lease period. The net excess of rent expense over the actual cash paid is recorded as deferred rent.

Accumulated and Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) includes foreign currency translation adjustments related to the Company's subsidiary in Australia and is excluded from the accompanying consolidated statements of operations.

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 enacted in December 2017. Among other things, the Act reduced the U.S. federal corporate tax rate from 34 percent to 21 percent as of January 1, 2018 and eliminated the alternative minimum tax ("AMT") for corporations. Since the deferred tax assets are expected to reverse in a future year, it has been tax effected using the 21% federal corporate tax rate. As a result of the reduction in the corporate tax rate, the Company decreased its gross deferred tax assets by approximately $12.4 million which was offset by a corresponding decrease to the valuation allowance as of July 31, 2018, which has no impact on the Company's consolidated financial statements for the year ended July 31, 2018.

On December 22, 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin 118, which allows a measurement period, not to exceed one year, to finalize the accounting for the income tax effects of the Act. Until the accounting for the income tax effects of the Act is complete, the reported amounts are based on reasonable estimates, are disclosed as provisional and reflect any adjustments in subsequent periods as estimates are refined or the accounting of the tax effects are completed.

Recent Accounting Pronouncements

The following discussion includes recent accounting pronouncements that are anticipated to have an impact on or are otherwise related to the Company's financial condition, results of operations or related disclosures. Recent accounting 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 Accounting Standards Update No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 establishes a right-of-use model that requires a lessee to record an asset and liability on the balance sheet for all leases with terms longer than 12 months. ASU 2016-02 is effective for fiscal years and interim periods beginning after December 15, 2018. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements. In issuing ASU No. 2018-11, the FASB decided to provide another transition method in addition to the existing transition method by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently evaluating the impact that ASU 2016-02 and ASU 2018-11 will have on its consolidated 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: (i) income tax consequences; (ii) classification of awards as either equity or liabilities; and (iii) 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. The Company adopted this guidance for the annual period ended July 31, 2018. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718) ("ASU 2017-09"),* which provides further guidance as to what constitutes a modification to the terms of share-based compensation, in order to create consistency in practice among all entities. ASU 2017-09 becomes effective for annual reporting periods beginning after December 15, 2017, including interim periods thereafter; early adoption is permitted, including adoption in an interim period. The Company intends to adopt this standard as of August 1, 2018, and does not anticipate this standard will have a material impact on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows ("ASU 2016-15"), to reduce diversity in practice of how certain transactions are classified in the statement of cash flows. The effective date for ASU 2016-15 is for annual periods beginning after December 15, 2017, and interim periods within those fiscal years. The Company intends to adopt this standard as of August 1, 2018, and does not anticipate this standard will have a material impact on its consolidated financial statements.

In January 2017, the FASB issued guidance codified in ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"). Under this guidance, an entity will no longer determine goodwill impairment by calculating the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. Instead, an entity will compare the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods therein, with early adoption permitted. The Company will evaluate the impact of this guidance and expects to adopt the standard in the first calendar quarter of 2019. The Company does not currently have any intangible or goodwill balances.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Equity from Liabilities (Topic 480) and Derivatives and Hedging (Topic 815) ("ASU 2017-11"),* which addresses the complexity of accounting for certain financial instruments with down-round features and finalizes pending guidance related to mandatorily redeemable noncontrolling interests. Under ASU 2017-11, when determining whether certain financial instruments should be classified as liabilities or equity instruments, a down-round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. ASU 2017-11 becomes effective for annual reporting periods beginning after December 15, 2018, including interim periods thereafter; early adoption is permitted, including adoption in an interim period. As the Company currently does not hold this type of financing instrument, the Company does not anticipate the standard will have a material impact on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, "Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting", which expands the scope of Topic 718 to include all share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which the grantor acquires goods and services to be used or consumed in its own operations by issuing share-based payment awards. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under ASC 606. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted, but no earlier than our adoption of ASC 606. The Company is currently evaluating the impact the adoption of the new standard will have on its consolidated financial statements.

On February 14, 2018 the FASB issued ASU 2018-02, “Income Statement—Reporting Comprehensive Income” (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income”. This update allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Job Acts. Because the amendments only relate to the reclassification of the income tax effects of the Tax Cuts and Jobs Act, the underlying guidance that requires that the effect of a change in tax laws or rates be included in income from continuing operations is not affected. ASU 2018-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect this standard will have on its consolidated financial statements.

Note 3—Liquidity and Financial Condition

The Company has sustained losses in all reporting periods since inception, with an inception-to date-loss of $134.1 million as of July 31, 2018 which raises substantial doubt. Further, the Company has never generated any cash from its operations and does not expect to generate such cash in the near term. 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.

As of July 31, 2018, the Company had a cash, cash equivalents and total investment securities balance of $27.0 million. The Company had cash of $3.2 million and cash equivalents of $0.6 million for a total cash and cash equivalent balance of $3.8 million. In addition, the Company had short-term investment securities of $23.2 million. Cash flows from financing activities continued to provide the primary source of our liquidity. Net cash provided by financing activities was $38.9 million during the year ended July 31, 2018 which was primarily attributable to the net proceeds received from our October 2017 offerings, November 2017 warrant exercise inducement offering, February 2018 offering and the exercise of certain stock options and warrants (See Note 7).

Additionally, subsequent to July 31, 2018, the Company received additional gross proceeds of $8.0 million from the funding of the first tranche in the Alpha Holdings agreement (see Note 12). As of October 12, 2018, the Company had cash, cash equivalents and investment securities of approximately $28.9 million. The Company is anticipating raising additional capital but there can be no assurance that it will be able to do so or if the terms will be favorable.

The above financing activities substantially increased the Company’s cash position. As a result, as of the date of the issuance of these consolidated financial statements, the Company believes its current cash position as a result of the Company’s financing activities during the year ended July 31, 2018 and October 2018 has alleviated substantial doubt about its ability to sustain operations through at least the next 12 months from the issuance date of the consolidated financial statements.

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Note 4—Investment Securities

The amortized cost, gross unrealized gains and losses, and fair value of securities held to maturity are as follows as of July 31, 2018:

Description	Amortized Cost	Gross Unrealized Gain/(Loss)	Fair Value
Investment securities			
U.S. treasury securities with maturities of one year or less	$23,174,447	$ (20,212)	$23,154,235
Total	$23,174,447	$ (20,212)	$23,154,235

The fair values of held to maturity securities, excluding U.S. treasury securities, were obtained using an independent third-party financial institution. Management made no adjustments to the fair value quotes that were provided by the third-party financial institution. The fair values of U.S. treasury securities were determined using quoted, active market prices for identical securities.

Note 5—Balance Sheet Details

Property and Equipment

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

	July 31, 2018	July 31, 2017
Equipment and furniture	$1,873,880	$2,861,632
Computer software	109,242	292,034
Leasehold improvements	12,054	80,102
Property and equipment, gross	1,995,176	3,233,768
Accumulated depreciation and amortization	(729,514)	(823,669)
	$1,265,662	$2,410,099

Depreciation and amortization expense recorded for the years ended July 31, 2018 and 2017 was approximately $334,000 and $380,000, respectively. In conjunction with the move to a new facility, the Company wrote down $860,000 in property and equipment.

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities are comprised of the following:

	July 31, 2018	July 31, 2017
Research and development costs	$3,801,211	$1,537,892
Professional services fees	770,853	1,584,899
Other	206,828	158,342
	$4,778,892	$3,281,133

Accrued Compensation

Accrued compensation is comprised of the following:

	July 31, 2018	July 31, 2017
Separation costs	$840,320	$-
Accrued payroll	215,937	100,295
401K payable	14,487	14,222
Other	-	324
Total	$1,070,744	$114,841

Other Long-Term Liabilities

Other long-term liabilities are comprised of the following:

	July 31, 2018	July 31, 2017
Deferred rent	$1,101,222	$1,140,953
Separation costs	371,408	-
Total	$1,472,630	$1,140,953

Note 6—Stockholders' Equity

February 2018 Offering

On February 6, 2018, the Company completed a follow-on public offering, selling 13,333,334 shares at an offering price of $1.50 per share. Additionally, the underwriters exercised in full their over-allotment option to purchase an additional 2,000,000 shares at an offering price of $1.50 per share. Aggregate gross proceeds from this follow-on public offering, including the exercise of the over-allotment option, were approximately $23 million, and net proceeds received, after underwriting fees of approximately $1.7 million and offering expenses of approximately $0.5 million, were approximately $20.8 million.

November 2017 Warrant Exercise Inducement Offering

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

Pursuant to the terms of the warrant exercise agreement, and in order to induce each holder to exercise its Original Warrants, the Company issued 1,377,411 new warrants to purchase a number of shares of its common stock which is equal to 25% of the number of shares of common stock received by such holders upon the cash exercise of its Original Warrants. The terms of the inducement warrants are substantially similar to the terms of the Original Warrants, except that the inducement warrants: (i) have an initial exercise price of $2.26 per share; (ii) become exercisable on May 13, 2018 and expire on November 13, 2019; and, (iii) contain certain additional transfer restrictions and limitations due to their offer and sale in a private placement offering.

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

The warrants issued in connection with the warrant exercise agreement were considered inducement warrants and are classified in equity. The fair value of the warrants issued was approximately $2.5 million (based on the Black-Scholes option valuation model assuming no dividend yield, a 2.0-year life, volatility of 73.12% and a risk-free interest rate of 1.7%). The fair value of the inducement warrants of $2.5 million was expensed as warrant inducement expense in the accompanying consolidated statements of operations for the year ended July 31, 2018.

First October 2017 Offerings

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

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

Second October 2017 Offering

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

The fair value of the warrants issued to the purchasers in the offering, based on their fair value relative to the common stock issued, was approximately $0.4 million (based on the Black-Scholes option valuation model assuming no

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

ATM Program

On July 25, 2017, the Company entered into an equity distribution agreement with Oppenheimer & Co. Inc. ("Oppenheimer") to commence an "at the market" offering program (the "ATM Program"), under which the Company was permitted to offer and sell, from time to time through or to Oppenheimer, acting as sales agent or principal, shares of the Company's common stock having an aggregate gross sales price of up to $8.4 million. An aggregate of 897,311 shares of the Company's common stock were sold in the ATM Program during the year ended July 31, 2018, for net proceeds to the Company, after deducting Oppenheimer's commissions and other expenses paid or payable by the Company, of $1.1 million. Effective as of October 22, 2017, the Company terminated the ATM Program. As a result of such termination, no further offers or sales of the Company's common stock will be made in the ATM Program.

Outstanding Warrants

At July 31, 2018, the Company had outstanding warrants to purchase 8,958,059 shares of its common stock, with exercise prices ranging from $1.64 to $16.10, all of which were classified as equity instruments. These warrants expire at various dates between September 2018 and May 2025.

Note 7—Stock-Based Compensation

2011 Plan

The OncoSec Medical Incorporated 2011 Stock Incentive Plan (as amended and approved by the Company's stockholders (the "2011 Plan"), authorizes the Company's Board of Directors to grant equity awards, including stock options and restricted stock units, to employees, directors and consultants. The 2011 Plan authorizes a total of 7,500,000 for issuance thereunder, and includes an automatic increase of the number of shares of common stock reserved thereunder on the first business day of each calendar year by the lesser of: (i) 3% of the shares of the Company's common stock outstanding as of the last day of the immediately preceding calendar year; (ii) 1,000,000 shares; or (iii) such lesser number of shares as determined by the Company's Board of Directors. As of July 31, 2018, there were an aggregate of 8,500,000 shares of the Company's common stock authorized for issuance pursuant to awards granted under the 2011 Plan. The 2011 Plan allows for an annual fiscal year per individual grant of up to 500,000 shares of its common stock. Under the 2011 Plan, incentive stock options are to be granted at a price that is no less than 100% of the fair value of the Company's common stock at the date of grant. Stock options vest over a period specified in the individual option agreements entered into with grantees, and are exercisable for a maximum period of 10 years after the date of grant. Stock options granted to stockholders who own more than 10% of the outstanding stock of the Company at the time of grant must be issued at an exercise price of no less than 110% of the fair value of the Company's common stock on the date of grant.

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Stock Options

During the fiscal year ended July 31, 2018, the Company granted options to purchase 5,281,500, 300,000 and 705,000 shares of its common stock to employees, directors and consultants under the 2011 Plan, respectively. The stock options issued to employees have a ten-year term, vest over three years, and have exercise prices ranging from $0.92 to $1.86. The stock options issued to directors have a ten-year term, vest monthly in equal increments over one year and have exercise prices ranging from $0.979 to $1.94. The stock options issued to consultants have ten-year terms, vest in accordance with the terms of the applicable consulting agreement, and have exercise prices ranging from $1.00 to $1.88.

During the year ended July 31, 2018, the Company granted its President and Chief Executive Officer, Mr. Daniel J. O'Connor, options to purchase 2,500,000 shares of the Company's common stock outside of the 2011 Plan. This grant was approved by stockholders at the Company's annual meeting on January 12, 2018. Of the total grant, options on 1,000,000 shares vested upon stockholder approval and options on 1,000,000 shares will vest over a two-year period from the date of grant. Mr. O'Connor also received a performance stock option award to purchase up to 500,000 shares of the Company's common stock, which is subject to vesting as to options on 250,000 shares on the date of the Company's achievement of 100% enrollment in the first cohort of its PISCES/KEYNOTE-695 study and as to the remaining options on 250,000 shares in one installment on the one-year anniversary of the date of achievement of such enrollment.

During the fiscal year ended July 31, 2017, the Company granted options to purchase 1,841,037, 355,416 and 832,083 shares of its common stock to employees, directors and consultants under the 2011 Plan, respectively. The stock options issued to employees have a ten-year term, vest over three years, and have exercise prices ranging from $1.11 to $1.94. The stock options issued to directors have a ten-year term, vest monthly in equal increments over one year and have exercise prices ranging from $1.29 to $1.34. The stock options issued to consultants have three-year terms, vest in accordance with the terms of the applicable consulting agreement, and have exercise prices ranging from $1.29 to $2.00.

On December 14, 2016, the Company completed an offer (the "Exchange Offer") to exchange certain stock options to purchase shares of its common stock for a lesser number of new stock options with a lower exercise price. Stock options with an exercise price greater than or equal to $3.00 and held by employees, directors, and consultants in continuous service for the Company through the completion of the Exchange Offer were eligible for exchange. In the Exchange Offer, an exchange rate of 2-for-1 applied to stock options with an exercise price from $3.00 to $9.99, and an exchange rate of 3-for-1 applied to stock options with an exercise price of $10.00 or more. Each new stock option granted in the Exchange Offer was granted pursuant to the 2011 Plan on the date the Exchange Offer closed and has an exercise price equal to the market price of the Company's common stock on that date. At the closing of the Exchange Offer, 29 eligible participants had exchanged stock options to purchase 2,214,500 shares of the Company's common stock for new stock options to purchase 1,070,536 shares of the Company's common stock.

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Stock-based compensation expense recognized in the accompanying consolidated statements of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. The service period is generally the vesting period, with the exception of stock options granted pursuant to a consulting agreement, in which case the stock option vesting period and the service period are defined pursuant to the terms of the consulting agreement. Stock-based compensation expense related to stock options granted to consultants in which the options are not entirely vested at the grant date are generally re-measured each month.

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

	Year Ended July 31, 2018		Year Ended July 31, 2017	
Expected term (years)	5.00 – 6.50 years	%	2.08 – 10 years	%
Risk-free interest rate	1.66 - 2.90	%	0.82 – 2.52	%
Volatility	73.24 – 91.99	%	71.9 –124.5	%
Dividend yield	0	%	0	%

The Company’s expected volatility is derived from the historical daily change in the market price of its common stock since its stock became available for trading, as well as the historical daily changes in the market price of its peer group, based on weighting, as determined by the Company. The Company uses the simplified method to calculate the expected term of options issued to employees and directors, and the Company’s estimation of the expected term for stock options granted to parties other than employees or directors is the contractual term of the option award. The risk-free interest rate used in the Black-Scholes calculation is based on the prevailing U.S. Treasury yield in effect at the time of grant, commensurate with the expected term. For the expected dividend yield used in the Black-Scholes calculation, the Company has never paid any dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future.

The following is a summary of the Company’s 2011 Plan and non-Plan stock option activity for the years ended July 31, 2018 and 2017:

	Options	Weighted Average Exercise Price
Outstanding - July 31, 2016	3,263,460	$ 5.88
Granted	3,028,536	$ 1.41
Exercised	(7,500)	$ 1.29
Forfeited/Cancelled/Expired	(2,644,883)	$ 6.21

Outstanding - July 31, 2017	3,639,613	$ 1.94
Granted	6,286,500	$ 1.38
Exercised	(252,270)	$ 1.27
Forfeited/Cancelled	(761,123)	$ 2.66
Outstanding – July 31, 2018	8,912,720	$ 1.50
Exercisable – July 31, 2018	5,674,496	$ 1.55

As of July 31, 2018, the total intrinsic value of options outstanding and exercisable was approximately $65,500 and $37,000, respectively. As of July 31, 2018, the Company has approximately $3.9 million in unrecognized stock-based compensation expense attributable to the outstanding options, which will be amortized over a period of approximately1.59 years.

Stock-based compensation expense recorded in the Company's consolidated statements of operations for the year ended July 31, 2018 resulting from stock options awarded to the Company's employees, directors and consultants was approximately $6.2 million. Of this balance, $1.0 million was recorded to research and development and $5.2 million was recorded in general and administrative in the Company's consolidated statements of operations for the year ended July 31, 2018.

Stock-based compensation expense recorded in the Company's consolidated statements of operations for the year ended July 31, 2017 resulting from stock options awarded to the Company's employees, directors and consultants was approximately $3.6 million. Of this balance, $1.1 million was recorded to research and development and $2.5 million was recorded in general and administrative in the Company's consolidated statement of operations for the year ended July 31, 2017.

The weighted-average grant date fair value of stock options granted during the year ended July 31, 2018 was $1.24. The weighted-average grant date fair value of stock options granted during the year ended July 31, 2017 was $0.69.

Restricted Stock Units

In February 2018, the Company granted an aggregate of 300,000 restricted stock unit awards ("RSUs") to two employees under the 2011 Plan. All RSUs vest in full three years following the date of grant. The closing price of the Company's common stock on the date of grant was $1.64 per share, which is the fair market value per unit of the RSUs.

On February 8, 2018, the Company's Board of Directors approved the accelerated vesting of outstanding restricted stock units (RSUs) held by certain executives and board members. The RSUs, the majority of which vested on the third anniversary of the grant date, were accelerated to vest on June 15, 2018, resulting in stock compensation expense of $1.1 million for the year ended July 31, 2018.

In May 2018, the Company granted 35,000 restricted stock unit awards ("RSUs") to an employee under the 2011 Plan. All RSUs vest in full three years following the date of grant. The closing price of the Company's common stock on the

date of grant was $1.59 per share, which is the fair market value per unit of the RSUs.

In July 2018, the Company granted 625,000 restricted stock unit awards ("RSUs") to the Company's current CFO. The units vest as follows: 312,500 units vested on July 16, 2018, and the remaining 312,500 units vest in equal quarterly installments over the 24 months following the date of grant. The closing price of the Company's common stock on the date of grant was $1.34 per share, which is the fair market value per unit of the RSUs.

For the year ended July 31, 2018, the Company recorded $2.0 million in stock-based compensation related to RSUs, which is reflected in the consolidated statements of operations.

As of July 31, 2018, there were 647,500 RSUs outstanding.

In March 2017, the Company granted 525,000 restricted stock unit awards ("RSUs") to employees under the 2011 Plan. All RSUs vest in full three years following the date of grant. The closing price of the Company's common stock on the date of grant was $1.34 per share, which is the fair market value per unit of the RSUs.

For the year ended July 31, 2017, the Company recorded $462,000 in stock-based compensation related to RSUs, which is reflected in the consolidated statements of operations.

As of July 31, 2017, there were 1,100,000 RSUs outstanding.

2015 Employee Stock Purchase Plan

Under the Company's 2015 Employee Stock Purchase Plan ("ESPP"), the Company is authorized to issue 500,000 shares of the Company's common stock. The first offering period under the ESPP ended on July 31, 2016, with 17,789 shares purchased and distributed to employees. The second offering period under the ESPP ended on January 31, 2017, with 18,631 shares purchased and distributed to employees, and the third offering period under the ESPP ended on July 31, 2017, with 21,646 shares purchased and distributed to employees. The fourth offering period under the ESPP ended on January 31, 2018, with 18,960 shares purchased and distributed to employees, and the fifth offering period under the ESPP ended on July 31, 2018, with 12,071 shares purchased and distributed to employees. At July 31, 2018, there were 410,903 shares remaining available for issuance under the ESPP.

The ESPP is considered a Type B plan under FASB ASC Topic 718 because the number of shares a participant is permitted to purchase is not fixed based on the stock price at the beginning of the offering period and the expected

withholdings. The ESPP enables the participant to “buy-up” to the plan’s share limit, if the stock price is lower on the purchase date. As a result, the fair value of the awards granted under the ESPP is calculated at the beginning of each offering period as the sum of:

- 15% of the share price of an unvested share at the beginning of the offering period,
- 85% of the fair market value of a six-month call on the unvested share aforementioned, and
- 15% of the fair market value of a six-month put on the unvested share aforementioned.

The fair market value of the six-month call and six-month put are based on the Black-Scholes option valuation model. For the six-month offering period ended January 31, 2018, the following assumptions were used: six-month maturity, 1.15% risk free interest, 62.6% volatility, 0% forfeitures and $0 dividends. For the six-month offering period ended July 31, 2018, the following assumptions were used: six-month maturity, 1.64% risk free interest, 97.86% volatility, 0% forfeitures and $0 dividends.

For the six-month offering period ended January 31, 2017, the following assumptions were used: six-month maturity, 0.40% risk free interest, 96.91% volatility, 0% forfeitures and $0 dividends. For the six-month offering period ended July 31, 2017, the following assumptions were used: six-month maturity, 0.65% risk free interest, 132.68% volatility, 0% forfeitures and $0 dividends.

Approximately $16,000 and $23,000 was recorded as stock-based compensation during the years ended July 31, 2018 and 2017, respectively.

Common Stock Reserved for Future Issuance

The following table summarizes all common stock reserved for future issuance at July 31, 2018:

Common Stock options outstanding (within the 2011 Plan and outside of the terms of the 2011 Plan)	8,912,720
Common Stock reserved for restricted stock unit release	647,500
Common Stock authorized for future grant under the 2011 Plan	760,010
Common Stock reserved for warrant exercise	8,958,059
Commons Stock reserved for future ESPP issuance	410,903
Total common stock reserved for future issuance	19,689,192

Note 8—Income Taxes

The FASB Topic on Income Taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company has had no unrecognized tax benefits.

The Company recognizes interest and/or penalties related to income tax matters in income tax expense. The Company has not recognized any interest and/or penalties in the accompanying consolidated statement of operations for the year ended July 31, 2018 and 2017.

The Company is subject to taxation in the United States, various states and in Australia. The Company's tax years for 2009 and forward and 2012 and forward are subject to examination by the United States federal tax authorities and California tax authorities, respectively, due to the carry forward of unutilized net operating losses and research and development credits.

At July 31, 2018, the Company had federal and California income tax net operating loss carryforwards of approximately $103.1 million and $98.1 million, respectively. In addition, the Company has federal and California research and development tax credit carryforwards of approximately $1.2 million and $1.3 million, respectively. The Company also has California Hiring Credits of approximately $9,300. The federal net operating loss, research tax credit carryforwards and California net operating loss carryforwards will begin to expire in 2028 unless previously utilized. The California research and development credit carryforwards will carry forward indefinitely until utilized. The Company has foreign net operating loss carryforwards in Australia of $0.6 million. The Company has not completed a study to assess whether one or more ownership changes, as defined by IRC Section 382/383 of the Internal Revenue Code of 1986, as amended (the "Code"), have occurred since the Company's formation, due to the complexity and cost associated with such a study, and the fact that there may be additional such ownership changes in the future. Based on a preliminary assessment, the Company believes that ownership changes have occurred. The Company estimates that if such an ownership change had occurred, the federal and state net operating loss carry-forwards and research and development tax credits that can be utilized in the future will be significantly limited. The Company may never be able to realize the benefit of some or all of the federal and state net loss carryforwards or research and development tax credit carryforwards, either due to ongoing operating losses or due to ownership changes, which limits the usefulness of the loss carryforwards.

Significant components of the Company's deferred tax assets as of July 31, 2018 and 2017 are listed below:

	2018	2017
Net operating loss carryforwards	$28,313,000	$30,237,000
Credits	2,408,000	2,004,000
Start-up costs	24,000	46,000
Accumulated depreciation	162,000	170,000
Option and stock awards	5,703,000	4,886,000
Other	591,000	686,000
Net deferred tax assets	37,201,000	38,029,000
Valuation allowance for deferred tax assets	(37,201,000)	(38,029,000)
Net deferred taxes	$-	-

A valuation allowance of $37.2 million and $38.0 million at July 31, 2018 and 2017, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain. The valuation allowance decreased by $0.8 million and increased by $8.8 million for the years ended July 31, 2018 and 2017, respectively.

A reconciliation of incomes taxes using the statutory income tax rate, compared to the effective rate, is as follows:

	2018	2017
Federal tax benefit at the expected statutory rate	26.47 %	34.00 %
State income tax, net of federal tax benefit	0.00 %	0.00 %
Non-deductible expenses	(2.53)%	(0.94)%
Impact of federal rate change	-32.14%	- %
Impact of rate change on valuation allowance	32.14 %	- %
Change in valuation allowance	(24.72)%	(33.74)%
Other	0.78 %	0.67 %
Income tax benefit - effective rate	(0.00)%	(0.01)%

Note 9—Commitments and Contingencies

Contingencies

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

Employment Agreements

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

On November 7, 2017, the Company entered into an executive employment agreement with Daniel J. O'Connor (the "O'Connor Employment Agreement") pursuant to which Mr. O'Connor will serve as the Chief Executive Officer (the "CEO") of the Company through November 7, 2020, subject to extension as provided in the agreement. The agreement calls for an annual salary of $400,000 per annum, an annual performance bonus in the amount of 50% of Mr. O'Connor's then-current annual base salary and a living allowance of up to $4,500 per month for the first 12 months of

the agreement. In addition, pursuant to the O'Connor Employment Agreement, the Company granted to Mr. O' Connor certain stock options (See Note 7).

On May 2, 2018, the Board of Directors of the Company consolidated the roles of Chief Executive Officer and President, with Daniel J. O'Connor to serve as both. Accordingly, Punit Dhillon will no longer serve as President of the Company, but will remain as a member of the Board of Directors. The Company and Mr. Dhillon have entered into a separation agreement that triggers the compensation provisions pursuant to his Amended and Restated Executive Employment Agreement, dated November 7, 2017. As of July 31, 2018, the Company has accrued a liability of $828,403 under the agreement.

On July 16, 2018, the Company entered into an executive employment agreement with Sara M. Bonstein (the "Bonstein Employment Agreement") pursuant to which Ms. Bonstein will serve as the Chief Financial Officer (the "CFO") of the Company through July 16, 2021, subject to extension as provided in the agreement. The agreement calls for an annual salary of $350,000 per annum, a cash signing bonus in the amount of $75,000 and an annual performance bonus in the amount of 40% of Ms. Bonstein's then-current annual base salary. In addition, pursuant to the Bonstein Employment Agreement, the Company granted to Ms. Bonstein an award of 625,000 restricted stock units convertible into shares of the Company's common stock. The units vest as follows: 312,500 units vested on July 16, 2018 (date of grant), and the remaining 312,500 units vest in equal quarterly installments over the 24 months following the date of grant.

On July 16, 2018, the Company and the Company's former Chief Financial Officer entered into a separation and release agreement in connection with the former CFO's termination of employment with the Company. Pursuant to the agreement, the Company will pay the former CFO severance compensation of $300,000, less applicable withholdings, in the form of salary continuation in accordance with the Company's customary payroll practices. On July 16, 2018, the Company recorded a liability of $300,000 on its consolidated balance sheet, and the offsetting charge was recorded in general and administrative expense as salary expense. As of July 31, 2018, the Company made no payments against the liability.

Lease Agreements

On February 14, 2018, the Company entered into a lease agreement for approximately 3,100 rentable square feet located at 24 N. Main Street, Pennington, New Jersey, which serves as the Company's New Jersey corporate headquarters. The term of the lease commenced on March 1, 2018 and expires on April 30, 2020. Base rent under the lease agreement is $3,079 per month for each of the first five months, $6,158 per month for each of the sixth through twelfth months and $6,286 per month for each of the thirteenth through twenty-sixth months. The lease agreement also requires the Company to share in certain monthly operating expenses of the premises, and required the Company to pay a security deposit of $12,316 in February 2018 upon entering into the lease agreement.

On December 31, 2014, the Company entered into a lease agreement for approximately 34,000 rentable square feet located at 5820 Nancy Ridge Drive, San Diego, California, which serves as the Company's California corporate headquarters and research and development laboratory. The term of the lease commenced on October 19, 2015 and expires on October 19, 2025, although the Company has an option to extend the lease for an additional five years following this expiration date, if it provides notice of such extension within 12 months prior to such expiration date. The Company also has the right to terminate the lease after the end of the 84th month following its commencement of rent payments under the lease agreement, if it provides notice of such termination at least 12 months in advance and pays certain early termination fees. Base rent under the lease agreement is approximately $90,000 per month, although the Company received a 12-month rent abatement for its first year of occupancy, and increases by 3% annually. The lease agreement also requires the Company to share in certain monthly operating expenses of the premises, and required the Company to pay a security deposit of approximately $90,000 in December 2014 upon entering into the lease agreement. See Lease Assignment Agreement below.

In March 2018, the Company entered into a Lease Assignment Agreement with Vividion Therapeutics, Inc. (“Vividion”) for the Company’s 34,054 square foot location at 5820 Nancy Ridge Drive, San Diego, California, 92121 (“NR Premises”), whereby the Company assigned its Lease Agreement with ARE-SD Region No. 18, LLC (the “Landlord”) to Vividion. Under the Lease Assignment Agreement, Vividion pays directly to Landlord the base rent of $101,500 per month (based upon $2.98 per rentable square foot of the NR Premises) plus operating expenses and property management fees attributable to the NR Premises currently estimated at $43,500 per month (including an estimate for utilities) during the term of the Lease Assignment Agreement, which is the remaining term of the lease through October 2025.

While the lease and all of the related obligations were assigned to Vividion, the Company could ultimately have an obligation on the Lease Assignment Agreement if Vividion defaulted on their obligation to the Landlord after all remedies were exhausted by the Landlord with regard to Vividion’s obligations. Such an event is not considered probable and no obligation has been recorded at July 31, 2018.

In conjunction with the Lease Assignment Agreement, the Company and Vividion also entered into a Sublease, with respect to the 12,442 square-foot location leased by Vividion from Landlord. Under the Sublease, the Company shall pay to Vividion base rent of $49,768 per month (based upon $4.00 per rentable square foot of the Sublease Premises) plus operating expenses and property management fees attributable to the Sublease Premises currently estimated at $30,400 per month during the term of the Sublease, which extends through September 2020. The Company moved to the new location in April 2018.

At the time of the lease agreements noted above, the Company had a deferred rent liability recorded on the consolidated balance sheet of $1.1 million, which is being amortized on a straight-line basis over the term of the Sublease.

Total rent expense for the years ended July 31, 2018 and 2017 was approximately $1.4 million and $1.6 million, respectively.

At July 31, 2018, future minimum lease payments under the Company’s non-cancelable operating leases are as follows:

Year Ending July 31, 2018	Operating Lease
2019	976,721
2020	1,067,919
2021	179,620

Total minimum payments	$2,224,260

Note 10—401(k) Plan

Effective May 15, 2012, the Company adopted a defined contribution savings plan pursuant to Section 401(k) of the Code. The plan is for the benefit of all qualifying employees and permits voluntary contributions by employees of up to 100% of eligible compensation, subject to the maximum limits imposed by Internal Revenue Service. The terms of the plan allow for discretionary employer contributions and the Company currently matches 100% of its employees' contributions, up to 3% of their annual compensation. The Company's contributions are recorded as expense in the accompanying consolidated statements of operations and totaled approximately $111,000 and $87,000 for the fiscal years ended July 31, 2018 and 2017, respectively.

Note 11—Related Party Transactions

The Company has subleased a portion of its office space to another company beginning April 1, 2017 and ending March 31, 2018. The Company's former President and two other members of the Company's Board of Directors held positions as directors and/or officers of the sublessee. The Company had received payments totaling $27,900 and $15,000 related to the sublease as of July 31, 2018 and 2017, respectively.

Note 12—Subsequent Events

Alpha Holdings

On August 31, 2018, the Company entered into a stock purchase agreement with Alpha Holdings, Inc. ("Alpha Holdings"), pursuant to which the Company agreed to issue and sell to Alpha Holdings shares of its common stock equal to an aggregate amount of up to $15.0 million at a market purchase price of $1.50 per share, which was the closing price of the Company's common stock the day immediately before the agreement was executed by the parties.

On October 9, 2018, the Company received total proceeds, before expenses, of $8.0 million in cash from the offering and issued Alpha Holdings 5,333,333 shares of common stock. There were no underwriting or placement agent fees associated with the offering. The second closing of 4,666,667 shares of Common Stock is expected to occur on or before December 15, 2018.

Subsequent to July 31, 2018, shares of common stock issued to executives and employees related to vested RSU's and the Company's ESPP totaled 27,917 and 12,071, respectively.

Subsequent to July 31, 2018, shares of common stock issued to consultants for services totaled 154,000.

Subsequent to July 31, 2018, 39,063 RSU's (equal to 23,658 shares on a net basis after employee taxes) held by an executive vested. The shares have not been issued as of the date of this filing.

Subsequent to July 31, 2018, the Company issued 118,500 stock options to employees as per the terms of various employment agreements.

Subsequent to July 31, 2018, the Company issued 250,000 stock options to a consultant as per the terms of a consulting agreement.

On August 22, 2018, the Company entered into a stock option cancellation agreement with an individual. As per the terms of the agreement, 300,000 fully vested stock options were cancelled in exchange for the issuance of 175,000 shares of restricted common stock.

ITEM 16. FORM 10-K SUMMARY

We have elected not to provide summary information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ONCOSEC MEDICAL INCORPORATED

By: */s/ Daniel J. O'Connor*
Date: October 19, 2018 Daniel J. O'Connor
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

SIGNATURE	**TITLE**	**DATE**
/s/ Daniel J. O'Connor Daniel J. O'Connor, J.D.	President, Chief Executive Officer and Director	October 19, 2018
/s/ Sara M. Bonstein Sara Bonstein	Chief Financial Officer and Chief Operating Officer	October 19, 2018
/s/ Avtar Dhillon Dr. Avtar Dhillon	Chairman of the Board	October 19, 2018
/s/ James DeMesa Dr. James DeMesa	Director	October 19, 2018
/s/ Punit Dhillon Punit Dhillon	Director	October 19, 2018
/s/ Gregory Mayes Gregory Mayes	Director	October 19, 2018

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	Articles of Incorporation of OncoSec Medical Incorporated, as amended (incorporated by reference to our Annual Report on Form 10-K, filed on October 25, 2017.)
3.2	Amended and Restated Bylaws (incorporated by reference to our Current Report on Form 8-K, filed on March 6, 2012)
4.1	Form of Common Stock Purchase Warrant (incorporated by reference to our Current Report on Form 8-K, filed on December 19, 2012)
4.2	Form of Common Stock Purchase Warrant (incorporated by reference to our Current Report on Form 8-K, filed on September 19, 2013)
4.3	Form of Common Stock Purchase Warrant (incorporated by reference to our Current Report on Form 8-K, filed on June 5, 2014)
4.4	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on November 5, 2015)
4.5	Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on May 24, 2016)
4.6	Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K, filed on May 24, 2016)
4.7	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on October 24, 2017)
4.8	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on October 26, 2017)
4.9	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed on November 13, 2017)
4.10	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K, filed on November 13, 2017)
10.1†	Cross-License Agreement, dated March 24, 2011 by and between OncoSec Medical Incorporated and Inovio Pharmaceuticals, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q, filed on June 14, 2011)
10.2#	

	Employment Agreement with Punit Dhillon dated May 18, 2011 (incorporated by reference to our Quarterly Report on Form 10-Q, filed on June 14, 2011)
10.3#	Form of Indemnification Agreement (incorporated by reference to our Current Report on Form 8-K, filed on October 29, 2015)
10.4#	Executive Employment Agreement, effective July 6, 2015, by and between the Company and Richard Slansky (incorporated by reference to our Quarterly Report on Form 10-Q, filed on December 8, 2015)

Exhibit Number	Description of Exhibit
10.5	Lease Agreement, dated December 31, 2014, by and between the Company and ARE-SD Region No. 18, LLC (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on January 2, 2015)
10.6	Securities Purchase Agreement, dated as of November 3, 2015, by and among the Company and signatories thereto (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on November 5, 2015)
10.7	Placement Agency Agreement, dated as of November 3, 2015, by and between the Company and H.C. Wainright & Co., LLC (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed on November 5, 2015)
10.8	Securities Purchase Agreement, dated as of May 22, 2016, by and among the Company and signatories thereto (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on May 24, 2016)
10.9	Placement Agency Agreement, dated as of May 22, 2016, by and between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.2 our Current Report on Form 8-K, filed on May 24, 2016)
10.10†	Clinical Trial Collaboration and Supply Agreement, dated as of May 10, 2017, by and between the Company and MSD International GmbH (incorporated by reference to Exhibit 10.11 of our Current Report on Form 10-Q, filed on June 13, 2018)
10.11	Securities Purchase Agreement, dated October 22, 2017, by and between the Company and each purchaser named therein (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on October 24, 2017)
10.12	Engagement Letter, dated October 20, 2017, by and between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed on October 24, 2017)
10.13	Securities Purchase Agreement, dated October 25, 2017, by and between the Company and the purchaser named therein (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on October 26, 2017)
10.14#	Executive Employment Agreement, dated November 7, 2017, by and between the Company and Daniel J. O'Connor (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on November 9, 2017)
10.15#	Amended and Restated Executive Employment Agreement, dated November 7, 2017, by and between the Company and Punit Dhillon (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed on November 9, 2017)

10.16#	Stock Option Award Agreement, dated November 7, 2017, by and between the Company and Daniel J. O'Connor (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K, filed on November 9, 2017)
10.17#	Stock Option Award Agreement, dated November 7, 2017, by and between the Company and Daniel J. O'Connor (incorporated by reference to Exhibit 10.4 of our Current Report on Form 8-K, filed on November 9, 2017)

Exhibit Number	Description of Exhibit
10.18	Form of Warrant Exercise Agreement, dated November 13, 2017, by and between the Company and such holder named therein (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on November 13, 2017)
10.19#	OncoSec Medical Incorporated 2011 Stock Incentive Plan, as amended and restated, dated January 12, 2018 (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on January 12, 2018)
10.20	Assignment of Lease, dated March 9, 2018, by and between OncoSec Medical Incorporated and Vividion Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on March 22, 2018)
10.21	Sublease, dated March 9, 2018, by and between OncoSec Medical Incorporated and Vividion Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 of our Current Report on Form 10-Q, filed on June 13, 2018)
10.22#	Confidential Separation Agreement, dated May 2, 2018, by and between OncoSec Medical Incorporated and Punit S. Dhillon (incorporated by reference to Exhibit 10.4 of our Current Report on Form 10-Q, filed on June 13, 2018)
10.23	Clinical Trial Collaboration and Supply Agreement between OncoSec Medical Incorporated and Merck dated May 8, 2018 (incorporated by reference to Exhibit 10.5 of our Current Report on Form 10-Q, filed on June 13, 2018)
10.24#	Executive Employment Agreement, dated July 16, 2018, by and between the Company and Sara M. Bonstein (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on July 16, 2018)
10.25	Purchase Agreement, dated February 1, 2018, between OncoSec Medical Incorporated and Piper Jaffray & Co., as representatives of the several underwriters named therein (incorporated by reference to Exhibit 1.1 of our Current Report on Form 8-K filed on February 1, 2018)
10.26	Stock Purchase Agreement, dated as of August 31, 2018, between OncoSec Medical Incorporated and Alpha Holdings, Inc. (incorporate by reference to Exhibit 10.1 on our Current Report on Form 8-K filed on August 31, 2018)
10.27*	Lease Agreement, dated February 14, 2018, between OncoSec Medical Incorporated and Mawlt Incorporated
21.1	Subsidiaries of the registrant (incorporated by reference to Exhibit 21.1 of our Annual Report on Form 10-K/A, filed on November 28, 2017)
23.1*	Consent of Independent Registered Public Accounting Firm, Mayer Hoffman McCann P.C.
31.1*	

	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instant Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

Management contract or compensatory plan or arrangement.

† Confidential treatment has been granted or requested with respect to portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 and these confidential portions have been redacted from the filing that is incorporated by reference. A complete copy of this exhibit, including the redacted terms, has been separately filed with the Securities and Exchange Commission.