

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

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

For the fiscal year ended July 31, 2021

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  
(State or other jurisdiction of  
incorporation or organization)

24 North Main Street  
Pennington, NJ  
(Address of principal executive offices)

98-0573252  
(I.R.S. Employer  
Identification Number)

08534  
(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	Trading Symbol	Name of Exchange on which Registered:
Common Stock, par value \$0.0001 per share	ONCS	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

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

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

Indicate by check mark whether the registrant has submitted electronically, 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  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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

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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of January 31, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$162 million, 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 29, 2021, there were 39,202,590 outstanding shares of the Company's common stock.

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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 negative of these 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;
- the ability to achieve the clinical and operational objectives set by management and the board;
- our ability to successfully file and obtain timely marketing approval from the U.S. Food and Drug Administration, (“FDA”), or comparable foreign regulatory agency for one or more Biologics License Applications, (“BLAs”), or New Drug Applications, (“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;
- 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 continued compliance with the listing requirements of the Nasdaq Capital Market;
- 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 1A 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 subsidiary.*

*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 and OncoSec. 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](http://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.*

## SUMMARY RISK FACTORS

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described in Item 1A, and the other reports and documents that we have filed with the SEC.

### Risks Inherent in Drug Development

- 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 address any serious safety concerns as part of ongoing or post-marketing surveillance efforts; otherwise we may need to modify, limit or discontinue development efforts related to some of 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.
- Our in-licensed intellectual property may not provide us with sufficient rights and may not prevent competitors from pursuing similar technology.

### Risks Pertaining to the Need for and Impact of Existing and Additional Financing Activities

- 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.

### Risks Related to Our Business

- We have never generated, and may never generate, revenue from our 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 are significantly dependent on the success of our ImmunoPulse® technology platform and our product candidates based on this platform, including our lead product candidate TAVO-EP.
- Our business and operations could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic.
- Our business and operations could suffer in the event of cyber-attacks or system failures.
- Recent changes in the Company's executive management team and Board of Directors, including the creation of a temporary Leadership Committee, may be disruptive to, or cause uncertainty in, its business, results of operations and the price of the Company's common stock.

### Risks Pertaining to Reliance on Third Parties

- 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.

### Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof

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

### Risks Pertaining to the Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

- We are subject to new legislation and regulatory proposals that may affect costs for compliance and adversely affect revenue.
- Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

### Risks Related to Our Growth Strategy

- 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.
- 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.

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

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a late-stage immuno-oncology company focused on designing, developing and commercializing innovative, proprietary, intra-tumoral DNA-based therapeutics to stimulate and to augment anti-tumor immune responses for the treatment of cancers. Our core technology platform ImmunoPulse® is a drug-device therapeutic modality platform comprised of proprietary intratumoral electroporation (“EP”) delivery devices (the “OncoSec Medical System (“OMS”) Electroporation Device” or “OMS EP Device”) and a proprietary DNA plasmid that triggers transient expression of target protein in cells. The OMS EP Device is designed to deliver plasmid DNA-encoded drugs directly into a solid tumor and promote an immunological response against cancer. The OMS EP 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 is a DNA-encoded interleukin-12 (“IL-12”) called tavokinogene telseplasmid (“TAVO”). The OMS EP Device is used to deliver TAVO intratumorally, 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 2017, we received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration 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) in melanoma and triple negative breast cancer (“TNBC”).

Our KEYNOTE-695 study targets advanced melanoma patients who are definitive anti-PD-1 therapy non-responders. In May 2017, we entered into a clinical trial collaboration and supply agreement with a subsidiary of Merck in connection with the 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 are the study sponsor and are responsible for external costs. The KEYNOTE-695 study is a registration-directed, Phase 2b open-label, single-arm, multicenter study in approximately 100 patients treated with TAVO in combination with KEYTRUDA® (pembrolizumab) in anti-PD-1 checkpoint (nivolumab or pembrolizumab) relapsed or refractory metastatic melanoma, being conducted in the United States, Canada, Australia and Europe. The study completed enrollment in December 2020. In December 2020, the protocol was amended to include an additional cohort, consisting of patients who progressed on prior treatment of both ipilimumab and nivolumab. Enrollment in this cohort was stopped in September 2021 because of sufficient data collected in this patient subpopulation. The amendment also enabled enrollment of approximately 25 additional patients to be treated with an updated version of the OMS EP Device (using the GenPulse generator and Series 3 Applicator), in preparation for FDA clearance. Based on and subject to the outcome of the study and feedback from FDA, we plan to file for accelerated approval with the FDA for this patient population in the second half of 2022.

In May 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, Cohort 1. 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 are the study sponsor and are responsible for external costs. The KEYNOTE-890 study, Cohort 1 final patient treatment was completed in December 2020. Interim data for Cohort 1 was initially presented at the San Antonio Breast Cancer Symposium (“SABCS”) in December 2019, and an update on this cohort is planned for SABCS in December 2021. The study is a Phase 2 open-label, single-arm, multicenter study in the United States and Australia.

In May 2019, the Company commenced an investigator-initiated Phase 1 clinical trial conducted by the University of California San Francisco (“UCSF”) Helen Diller Family Comprehensive Cancer Center (“OMS-131”). This study targets patients with Squamous Cell Carcinoma Head & Neck Cancer and is a single-arm open-label clinical trial in which 68 evaluable patients will receive TAVO, KEYTRUDA® and epacadostat. Recruitment on this study has been halted after the last patient was treated in June 2021 while OncoSec and UCSF consider alterations in the design of the study.

In June 2020, we amended our second clinical trial collaboration and supply agreement with Merck to include another Phase 2 study of TAVO in combination with KEYTRUDA® plus chemotherapy to evaluate the safety and efficacy of the combination in patients with inoperable locally advanced or metastatic triple negative breast cancer. This study is referred to as KEYNOTE-890, Cohort 2. Pursuant to the terms of the amended agreement, both companies will bear their own costs related to the manufacture and supply of their product, as well as be responsible for their own internal costs. We are the study sponsor and are responsible for external costs. The KEYNOTE-890, Cohort 2 study began enrolling patients in January of 2021. We expect to complete enrollment in this cohort in 2022. The study is a Phase 2 open-label, single arm, multicenter study in the United States and Australia.

In August 2020, we commenced an Investigator-Initiated Phase 2 study conducted by the H. Lee Moffitt Cancer Center and Research Institute and the University of South Florida Morsani College of Medicine to evaluate TAVO™ as neoadjuvant treatment (administered before surgery) in combination with intravenous OPDIVO® (nivolumab) in up to 33 patients with operable locally/regionally advanced melanoma. This Investigator-Initiated Phase 2 study has been designed to evaluate whether the addition of TAVO can increase the published anti-tumor response observed with monotherapy OPDIVO®, an anti-PD-1 checkpoint inhibitor, in patients with locally/regionally advanced melanoma prior to surgical resection of tumors. This study began enrolling patients in December of 2020 and is expected to complete enrollment within eighteen months of the start of enrollment.

In November 2020, we obtained exclusively licensed rights to the Cliniporator® electroporation gene electrotransfer platform from IGEA Clinical Biophysics. The license encompasses a broad field of use for gene delivery in oncology, including use as part of our visceral lesion applicator (“VLA”) program. This platform has been used for electrochemotherapy in and outside of Europe in over 200 major oncological centers to treat cutaneous metastatic cancer nodules, including melanoma.

In April 2020, we announced that Providence Cancer Institute, a part of Providence St. Joseph Health (“Providence”), is pursuing a first-in-human Phase 1 clinical trial of OncoSec’s novel DNA-encodable, investigational vaccine, CORVax12, which is designed to act as a prophylactic vaccine to prevent COVID-19. CORVax12 consists of our existing product candidate, TAVO™, in combination with an immunogenic component of the SARS-CoV-2 virus developed by researchers at the National Institutes of Health National Institute of Allergy and Infectious Diseases (“NIAID”). Providence investigators filed and received an Investigator-Initiated Investigational New Drug (“IND”) Application; however, at this time, Providence does not intend to continue further enrollment in this study and has transferred the Investigator Initiated IND to the Company.

In April 2021, OncoSec Medical announced that it has received authorization to CE mark, GenPulse™, OMS EP Device for use in solid tumors. The CE mark certification augments the Notified Body certification to the International Organization for Standardization's ("ISO") 13485 standard for the design, development, manufacture and distribution of electroporation devices, which is renewed annually, subject to a successful audit. The CE mark certification involved a comprehensive audit of our quality system, as well as thorough evaluation and testing of the OMS EP Device to assure it performs safely and as designed. A CE mark indicates the OMS EP Device complies with Directives of the European Commission and therefore can be marketed within the 31-nation European Economic Area and Switzerland. The GenPulse is being used in certain clinical trial sites in Australia and the EU. We are currently seeking FDA agreement to use GenPulse in U.S. clinical sites.

In July 2021, we entered into a clinical trial collaboration and supply agreement with Merck with respect to a Phase 3 study of TAVO™ in combination with KEYTRUDA® to evaluate the safety and efficacy of the combination in patients with Stage III or IV unresectable, metastatic melanoma, and who are refractory to prior checkpoint therapy. This study is referred to as KEYNOTE-C87. 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 are the study sponsor and are responsible for external costs. The trial is designed to be a global Phase 3 randomized clinical trial and is intended to support accelerated approval by the U.S. FDA and/or serve as a pivotal study to support a full licensure.

We intend to continue to pursue potential new trials and studies related to TAVO, in various tumor types. In addition, we are also developing our next-generation EP 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 and delivered intratumorally using EP. Specifically, we are developing a new, propriety technology to potentially treat liver, lung, bladder, pancreatic and other difficult to treat visceral lesions through the direct delivery of plasmid-based IL-12 with a new Visceral Lesions Applicator ("VLA").

The new VLA has been designed to work with low voltage EP generators, including but not limited to our proprietary APOLLO™ EP generator and Cliniporator® to leverage plasmid-optimized EP and enhance the depth of transfection of immunologically relevant genes into cells located in visceral organs. In early 2020, we had two poster presentations, one at the Society for Interventional Oncology ("SIO") and one at the Society for Interventional Radiology, where it presented preclinical data on both the new VLA and APOLLO generator. Additionally, we successfully completed several large animal studies and aim to bring the new VLA into the clinic in 2023. By using our next-generation technology with the new VLA (and in cutaneous/subcutaneous settings as well), our goal is to reverse the immunosuppressive mechanisms of a tumor, as well as to expand our pipeline. We believe that the flexibility of our proprietary plasmid-DNA technology will allow us to deliver other immunologically relevant molecules into the tumor microenvironment in addition to the delivery of plasmid-DNA encoding for IL-12.

We have established a collaboration with Emerge Health Pty ("Emerge"), the leading Australian company providing full registration, reimbursement, sales, marketing and distribution services of therapeutic products in Australia and New Zealand, to commercialize TAVO and have made it available under Australia's Special Access Scheme ("SAS"). Emerge was acquired in late 2019 and in June 2021 informed the Company that oncology will not be a core therapeutic focus for Emerge into the future. The collaboration was terminated effective October 1, 2021, and the Company will not continue to participate in the SAS program.

## **Cancer Immunotherapy Treatments: Background**

Many traditional modalities for treating cancer, such as chemotherapy, have limited survival benefit and are frequently associated with significant negative side effects. Immunotherapy, which has received significant attention in recent years, focuses on modulating the immune system to identify and eradicate cancer cells. Systemic delivery of immune-modulating cytokine proteins such as interleukin-2 (IL-2), interleukin-10 (IL-10), or interleukin-12 (IL-12) had shown early indications of efficacy but was associated with mechanism-based toxicity.

The development of monoclonal antibody drugs which target and block critical “immune checkpoint” proteins such as anti-CTLA-4 (cytotoxic T-lymphocyte-associated protein-4), anti-PD-1 (program cell-death-1) or anti-PD-L1 (programmed death-ligand-1), has been successful at augmenting anti-tumor immunity with more easily controlled toxicity than systemic cytokines, and several agents have been approved for the treatment of multiple solid tumor cancers. Although these new immuno-oncology agents have shown clinical benefit for patients with solid tumors across multiple tumor types, a majority of patients will not respond (primary refractory) or will relapse. One hypothesis for the primary refractory patients is that the tumor lacks infiltrating immune cells (immune desert) or the pre-existing immune cells are unproductive (exhausted) or productive and limited to the periphery of the tumor (immune excluded). Thus, novel agents that can alter the tumor immune environment directly, is an area of intense research.

The TAVO EP platform was developed to address two unmet needs – the ability to safely deliver a powerful, well characterized, immune cytokine, Interleukin-12 to the tumor where it is needed. Second, to leverage electroporation as a mechanism to deliver DNA medicines that are otherwise too toxic to administer systemically and/or more effective in the tumor microenvironment.

## **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 with plasmid DNA-encoded, IL-12, and is delivered into a tumor using our proprietary EP Device. Our clinical data indicates that the in vivo gene transfer of plasmid DNA-encoded IL-12 using EP 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 96,480 new melanoma cases were diagnosed in 2019, representing 5.5% of all new cancer cases in the U.S. Overall, the five-year survival rate for melanoma, regardless of disease stage, is high (92.2%); however, according to SEER 2019, for patients who present with metastatic disease and receive systemic treatment, the five-year survival rate is considerably lower at less than 25%. Despite recent advances in therapy, advanced metastatic melanoma continues to present a major and increasing burden with significant morbidity and mortality.

#### ***KEYNOTE-695 Study (ongoing)***

The KEYNOTE-695 study is a Phase 2b, open-label, single-arm, multi-center study of TAVO-EP in combination with an intravenous anti-PD-1 antibody, Merck’s KEYTRUDA®, in patients with unresectable locally advanced or metastatic melanoma and confirmed progression on immediate prior anti-PD1 therapy. The KEYNOTE-695 study completed enrollment of the original patient cohort (105 patients) in December of 2020 during the Covid pandemic, approximately half of the cohort was enrolled. The study is currently enrolling approximately 25 additional patients in an expansion cohort in Australia, Canada and Europe to gain patient experience with the OMS EP Device (using the GenPulse generator and Series 3 Applicator). The data from this study will support filing for accelerated approval with the FDA in 2022.

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 histological or cytological confirmed diagnosis of unresectable melanoma (Stage III or IV) with progressive locally advanced or metastatic diseases, be refractory/relapse 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 12 weeks of the last dose of anti-PD-1 monoclonal antibodies according to RECIST v1.1, measured by radiologic assessment. Patients can have no intervening therapies between failure of anti-PD-1 therapy and the TAVO / KEYTRUDA® combination treatment with the exception of approved BRAF/MEK inhibitor combinations. Patients that are BRAF eligible may have received BRAF treatment. The primary endpoint of the study, by blinded independent central review, is to assess the objective response rate (“ORR”) based on RECIST v1.1.

KEYNOTE-695 is a registration directed 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. Prior to the commencement of the study, we reviewed the patient inclusion and progression criteria, and other study requirements with FDA. In light of this review, we strictly defined the patient population to be enrolled in KEYNOTE-695 to include only those patients who have definitively progressed on prior anti-PD-1 checkpoint therapy.

### ***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 (“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<sup>+</sup>/PD-1<sup>+</sup>/CTLA-4<sup>+</sup> 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<sup>+</sup> T-cells at the tumor margin or generally have a low frequency of CD8<sup>+</sup>/PD-L1<sup>+</sup>/CTLA-4<sup>+</sup> TILs are unlikely to respond to anti-PD-1 therapies such as KEYTRUDA®, while tumors with a frequency of CTLA-4<sup>+</sup>/PD-L1<sup>+</sup>/CD8<sup>+</sup> >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 us to progress on 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. Data from this study was published in the Clinical Cancer Research journal in May 2020.

### ***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 presented 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 EP 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  $\geq 30\%$ , 17.4% (20/115) were assessed. Of the 26 patients with  $\geq 1$  assessed lesion, 12 patients (46.2%) had  $\geq 1$  assessed distant lesion with major regression ( $\geq 30\%$ ). 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.

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 complete and the Company presented final data at the Melanoma Bridge Conference held on November 29 – December 1, 2018. The data was selected for an oral presentation and included 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. Final data from this study was published in the Annals of Oncology in March 2020.

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.

#### ***PHASE 2 INVESTIGATOR-INITIATED NEOADJUVANT STUDY***

In August 2020, we commenced an investigator-initiated Phase 2 study conducted by the H. Lee Moffitt Cancer Center and Research Institute and the University of South Florida Morsani College of Medicine to evaluate TAVO™ as neoadjuvant treatment (administered before surgery) in combination with intravenous OPDIVO® (nivolumab) in up to 33 patients with operable locally/regionally advanced melanoma. This investigator-initiated Phase 2 study has been designed to evaluate whether the addition of TAVO can increase the published anti-tumor response observed with monotherapy OPDIVO®, an anti-PD-1 checkpoint inhibitor, in patients with locally/regionally advanced melanoma prior to surgical resection of tumors. This study is currently enrolling.

#### ***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, according to breastcancer.org. According to the American Cancer Society, for patients who present with Stage 4 metastatic disease, the five-year survival rate is considerably lower at approximately 22%.

TNBC frequently affects younger women (under 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.

#### ***KEYNOTE-890 study (ongoing)***

KEYNOTE-890 is a Phase 2, open-label, single-arm, multi-center study 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, KEYNOTE-890, Cohort 1 completed enrollment in early 2020. Enrollment in Cohort 2 began in the first quarter of 2021. We previously provided interim data from Cohort 1 in December, 2019 on the first group of patients enrolled from this study at the SABCS. The fully enrolled Cohort 1 efficacy, durability, and safety data will be presented at SABCS the week of December 6, 2021. Based on the outcome of the study and feedback from FDA, we amended the KEYNOTE-890 clinical protocol to include TAVO in combination with KEYTRUDA® plus chemotherapy to evaluate the safety and efficacy of the combination in treatment-naïve patients with inoperable locally advanced or metastatic triple negative breast cancer, Cohort 2. The study is a Phase 2 open-label, single-arm, multicenter study in the United States and Australia.

### ***OMS-140 (completed)***

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 tumor infiltrating lymphocytes (“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 SABCs annual meeting in 2018 and enrollment in this trial (n=10) is now complete. The clinical observations from this study prompted us to conduct KEYNOTE-890, which is currently underway.

### ***SQUAMOUS CELL CARCINOMA HEAD & NECK CANCER (SCCHN)***

Head and neck cancer represent approximately 4% of all cancers in the U.S., and it is estimated over 65,000 patients will develop head and neck cancer this year with over 14,000 deaths.

### ***OMS-131 (ongoing)***

OMS-131 is an investigator-initiated Phase 2 clinical trial conducted by the University of California San Francisco Helen Diller Family Comprehensive Cancer Center. This study stopped enrolling and amendments to the protocol are under consideration.

OMS-131, also referred to as the “TRIFECTA” study, was formed from the clinical observations from a 2017 pilot study of TAVO in head and neck cancer patients, which demonstrated clinical and biological results including evidence of synergy between TAVO and PD-1 antibodies in the disease.

### ***ROSWELL PARK COMPREHENSIVE CANCER CENTER***

The Company has an ongoing research collaboration with Roswell Park Comprehensive Cancer Center (“Roswell Park”) to evaluate the use of Roswell Park’s intravital microscopy (“IVM”) and TAVO<sup>PLUS</sup> (enhanced IL-12 DNA-plasmid), in combination with our APOLLO™ EP generator in preclinical studies. The collaboration is led by Joseph Skitzki, MD, FACS, Associate Professor of Immunology, Associate Professor of Surgery and Chair of the Melanoma/Sarcoma Disease Site Research Group at Roswell Park.

### ***DUKE UNIVERSITY***

The Company has an ongoing research collaboration with Duke University’s Center for Applied Therapeutics (“Duke University”) to evaluate TAVO<sup>PLUS</sup> in combination or sequenced with a HER2-plasmid vaccine administered our APOLLO™ EP generator in preclinical studies. The research is led by Herbert Kim Lyerly, M.D., George Barth Geller Professor, Professor of Immunology, Surgery and Pathology at Duke University School of Medicine and a director on our board of directors. This ongoing work was recently reported in a peer reviewed journal titled “Intratumor Plasmid IL12 Expands CD8<sup>+</sup> T Cells and Induces a CXCR3 Gene Signature in Triple-negative Breast Tumors that Sensitizes Patients to Anti-PD-1 Therapy”.

In this study, Duke investigators used mouse models of TNBC, to evaluate immune activation and tumor targeting of intratumoral IL-12 plasmid followed by electroporation (tavokinogene telseplasmid; TAVO). Collaborators at Stanford further presented a single-arm, prospective clinical trial of TAVO monotherapy in patients with treatment refractory, advanced TNBC (OMS-I140). Single-cell RNA sequencing of murine tumors identified a CXCR3 gene signature (CXCR3-GS) following TAVO treatment associated with enhanced antigen presentation, T-cell infiltration and expansion, and PD-1/PD-L1 expression. Assessment of pretreatment and posttreatment tissue from patients confirmed the enrichment of this CXCR3-GS in tumors from patients that exhibited an enhancement of CD8<sup>+</sup> T-cell infiltration following treatment. One patient, previously unresponsive to anti-PD-L1 therapy, but who exhibited an increased CXCR3-GS after TAVO treatment, went on to receive additional anti-PD-1 therapy as their immediate next treatment after OMS-I140, and demonstrated a significant clinical response. These data show a safe, effective intratumoral therapy that can enhance antigen presentation and recruit CD8 T cells, which are required for the antitumor efficacy. They identify a TAVO treatment-related gene signature associated with improved outcomes and conversion of nonresponsive tumors, potentially even beyond TNBC.

### **Visceral Lesion Applicator**

We are developing our next-generation intratumoral delivery device and applicators, 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. Specifically, we are developing a new, propriety technology to potentially treat liver, lung, bladder, pancreatic and other difficult to treat visceral lesions through the direct delivery of plasmid-based IL-12 with a new VLA.

The VLA has been designed to work with low voltage EP generators. Moving forward, we see significant opportunity to leverage this innovative technology to secure new partnerships that may allow us to expand our capabilities and drive shareholder value.

Throughout 2019 and 2020, we have successfully completed five large animal studies and aim to bring the VLA into the clinic during 2023. Preclinical data was presented in posters at the 2020 Society for Interventional Oncology meeting, where it was awarded “Best Technology Scientific Abstract”, and the 2020 Society for Interventional Radiology meeting.

## **Our OMS Electroporation Device**

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 electroporation facilitated therapeutic approach. Our EP 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 EP 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, EP has been used extensively in the clinic to deliver multiple therapeutic agents, including DNA. However, unlike these other technologies, EP has not seen the same safety concerns. In fact, the use of EP 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 OMS EP Devices are 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 OMS EP Device. We are also researching other DNA-encoded, immunologically-active molecules, with an aim of developing additional immunotherapeutic drugs that, when delivered using our OMS EP Device, 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 OMS EP 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 this system and for the manufacturing, 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 Practice (“GMP”) manufacturing capabilities for any device, drug substance or drug product. We expect to increase our reliance on third-party manufacturers.

We rely upon a small number of suppliers and manufacturers for our clinical activities. For manufacturing and distributing we use Cryosite, PCI, Richter-Helm Biologics, VGXI, Baxter Oncology GmbH, SGS, Minnetronix and EG Medacys, which collectively account for approximately 90% of clinical materials and EP 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 KEYNOTE-695 and KEYNOTE-890 studies.

We are ISO 13485:2016 certified and comply with 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 could include, among others, Bristol Myers-Squibb, Iovance Therapeutics, Syndax, Dynavax Technologies, Checkmate, Immunomedics 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.

### **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 2021, we owned 66 issued patents (5 U.S. and 61 foreign) and 94 pending patent applications (13 U.S. and 81 foreign). We are currently prosecuting pending patent applications in various jurisdictions. We have issued patents in the U.S., Europe and Japan with claims directed to cytokine-based intratumoral immunotherapies in combination with a checkpoint inhibitor. The Japanese patent was issued May 7, 2021. U.S. Patent 11071860, with claims directed to electroporation systems and devices having enhanced safety features including novel monitoring and crowbar trigger circuitries was issued on July 27, 2021. Japanese patent 6860497 directed to various adaptive electroporation systems and delivery assemblies was issued on March 30, 2021. In addition, we have licensed intellectual property rights that allow us to use certain EP 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 79 issued U.S. and foreign issued patents (6 from USF, 16 from Gaeta Therapeutics, and 57 from Inovio Pharmaceuticals, Inc. (Inovio)) and 13 U.S. and foreign pending patent applications (2 from USF, 3 from Gaeta Therapeutics, and 8 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 2023 and 2041. 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. However, the Company has recently filed applications, in 2019-2021, on our next generation electroporation devices and applicator handles and our next generation DNA-based cancer immunotherapeutics and will continue to file patent applications this year.

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, verification, validation, clinical testing, manufacturing, 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 controls 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 (“cGMPs”) 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 NDA or 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 a 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 a 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 a 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 a 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 a NDA or BLA. If the FDA determines that a 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 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.

### ***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; and
- 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.

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, 2021, we had a total of 58 employees, including 54 full-time employees and 4 part-time employees. None of our employees are 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 office is located at 24 North Main Street, Pennington, NJ 08534 and the telephone number is (855) 662-6732. Our website address is [www.oncosec.com](http://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. 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, together with 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, prospects and/or operating results could be materially and adversely affected. These factors could cause the trading price of our common stock to decline, and you could lose all or a substantial part of your investment. 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

***Our majority stockholder may have significant influence over the outcome of matters submitted to our stockholders for approval, which may prevent us from engaging in certain transactions.***

As the date hereof, one shareholder owns approximately 43% of the Company’s common stock. As a result, this stockholder may exercise significant influence over all matters requiring stockholder approval, including the appointment of our directors and the approval of significant corporate transactions. This ownership and control may also have the effect of delaying or preventing a future change in control, impeding a merger, consolidation, takeover or other business combination that may be in the best interest of the Company and any other stockholders. This ownership and control may be used to prevent the Company from raising additional funds through the sale of equity which may make it more difficult for the Company to finance its operations.

***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 revenue in the near term. During our fiscal year ended July 31, 2021, we incurred a net loss of approximately \$45.2 million, and from inception through July 31, 2021, we have incurred an accumulated deficit of approximately \$252 million. We will need significant additional funding to continue our operations and pursue our strategic plans, including continued development of our 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.***

Our auditor's report on our financial statements for the year ended July 31, 2021, includes an explanatory paragraph related to the existence of substantial doubt about our ability to continue as a going concern. The Company has never generated any cash from its operations and does not expect to generate such cash in the near term. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for an extended period of time. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of filing. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the financial statements are issued.

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, 2021, we had cash and cash equivalents of approximately \$46.0 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. 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.

***We are a clinical-stage company with a limited operating history and no 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. 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 TAVO-EP and engaging in other research and development activities, including pre-clinical and other clinical studies of our other product candidates. We have not demonstrated an ability to obtain regulatory approval of a product candidate, 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 TAVO-EP.***

We have invested, and we expect to continue to invest, significant efforts and financial resources in the development of product candidates based on our electroporation technology, including primarily our lead product candidate TAVO-EP. Our ability to generate meaningful 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. We are working on updated versions of the OMS EP Device to ensure compliance with current regulatory standards as a prerequisite for FDA clearance. We anticipate that we will need to have clinical experience with this device before we seek regulatory approval for our product candidate. If we experience delays in completion of this work or FDA approval in using the updated OMS EP Device in our ongoing clinical trials, it could delay our clinical programs, necessitate enrolling more patients in our ongoing clinical trials, delay the commercialization our product candidate and have a material adverse effect on our business, results of operations, financial condition and prospects.

The success of TAVO, our OMS EP Device, or any other product candidates based on our electroporation 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;
- our ability to retain key management and scientific personnel to oversee the approval and adoption of our product candidates;
- our ability to continue as a going concern;
- 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 TAVO in melanoma will be the data we obtain from our KEYNOTE-695 study, which is our ongoing study of TAVO 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 of America 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 for 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 TAVO 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, or may never obtain such revenue, 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 have had, and may have in the future, 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 novel 2019 coronavirus (“COVID-19”);
- the competitive disease space with many trials for patients to select from;
- the availability of approved alternate treatments; and
- the proximity and availability of clinical trial sites to prospective patients.

***Business or economic disruptions or global health concerns could seriously harm our development efforts and increase our costs and expenses.***

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development or clinical activities. For example, in December 2019 an outbreak of a novel strain of coronavirus originated in Wuhan, China, and has since spread globally. To date, this outbreak has resulted in extended shutdowns of businesses and has had ripple effects to businesses around the world. The effects of the COVID-19 pandemic are unpredictable. The outbreak may result in additional or more extensive travel restrictions, closures, disruptions of businesses or facilities around the world or lead to social, economic, political or labor instability in the affected areas may impact our suppliers' or our customers' operations. Additionally, variants of the disease present additional uncertainty that could lead to further restrictions that may have a negative impact on our operations and the larger economy.

Global epidemics, such as the coronavirus, could also negatively affect the hospitals and clinical sites in which we conduct any of our clinical trials, which could have a material adverse effect on our business and our results of operations and financial condition. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

***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.

***Our business and operations could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic.***

Our operational and financial performance have already been affected by the impact of the COVID-19 pandemic. Our clinical trials have experienced delays in patient enrollment, potentially due to prioritization of hospital resources toward the COVID-19 pandemic, or concerns among patients about participating in clinical trials during a public health emergency. The COVID-19 pandemic is also affecting the operations of government entities, such as the FDA, as well as contract research organizations, third-party manufacturers, and other third-parties upon whom we rely. As a result of "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of COVID-19, many companies, including our own, have implemented work-from-home policies for their employees. The effects of these stay at home orders and work-from-home policies may be negatively impacting productivity, resulting in delays in our clinical programs and timelines. The extent of the impact on our operations depends in part on the time these restrictions remain in place, and whether restrictions are reinstated. These and similar disruptions in our operations could negatively impact our business, operating results and financial condition.

The spread of COVID-19 has also led to disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. To the extent the COVID-19 pandemic adversely affects our business, financial results and value of our common stock, it may also affect our ability to access capital and obtain financing, which could in the future negatively affect our liquidity and ability to continue as a going concern.

The global pandemic of COVID-19 continues to evolve rapidly, and the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full impact of potential delays or effects on our business, our clinical trials, our ability to access the capital markets, or supply chains or on the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

***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 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.

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 or approved products 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;
- natural disaster, epidemics, pandemics, political crisis (such as terrorism, war, political instability or other conflict), or other events outside of our control;
- 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 hold 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 re-examination, 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 address any serious safety concerns as part of ongoing or post-marketing surveillance efforts; otherwise we may need to modify, limit or discontinue development efforts related to some of our product candidates.***

Establishing the safety of a new product is one of the principal objectives of any clinical trial. Adverse events, including serious adverse events, suspected adverse reactions, and unexpected adverse events, and their proper reporting, form the basis of the critical risk-benefit analysis of investigational drug therapies. If adverse events are identified during the development of one or more of our product candidates or any future product candidates, we may need to address any serious safety concerns as part of ongoing or post-market surveillance efforts. Alternatively, we may need to modify, limit or discontinue the development of these product candidates to more narrow uses or subpopulations in which the adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In the development of new and investigational drug therapies in this industry, many compounds that initially showed promise in early stage testing have later been associated with adverse events, including serious adverse events that have subsequently prevented further development of the compound. It is not uncommon for an adverse event to be encountered during a clinical trial. Upon discovery of an adverse event, sponsors are generally required to investigate this event in order to determine whether there is enough evidence to suggest that there was a reasonable possibility that the drug caused the adverse event.

In the event that adverse events, including serious adverse events, suspected adverse reactions, and unexpected adverse events are identified during any of our clinical trials, these trials could be modified, limited, suspended or terminated. Such adverse events may trigger a notification requirement to the FDA or comparable foreign regulatory authorities, who in turn could order us to cease further clinical investigation or deny approval of one or more of our product candidates or any future product candidates 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. Adverse events or undesirable side effects caused by one or more of our product candidates or any future product candidates could also result in the inclusion of unfavorable information in our product labeling, such as a Black Box warning, or 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. Adverse events or side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

No matter how extensive clinical trials and premarket studies may be, the safety profile of a new therapeutic product can only be fully characterized by continuing safety surveillance through a spontaneous adverse event monitoring system and a post-marketing surveillance study. FDA may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. It is well understood in the drug development process that drug safety can never be considered an absolute, since the safety profile of a new therapeutic product will continue to evolve as more information is generated, gathered, and assessed over the course of general use.

Additionally, if one or more of our product candidates or any future product candidates receive 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, including specific warnings, black box warnings, adverse reactions, precautions, and/or contraindications;
- regulatory authorities may suspend or withdraw their approval of the product, and/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 candidates, or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues, or any 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 Clinical Research Organizations (“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 eliminate 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 well-studied 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 for 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 and continue to participate in clinical trials conducted under an approved investigator-sponsored IND application. We also have plans to participate in future investigator-sponsored trials under both INDs and Investigational Device Exemptions (“IDEs”), since our product candidates are drug-device combination products. 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 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 INDs and IDEs include a requirement that the sponsor of a clinical trial perform the study in accordance with an approved investigational plan, and provide ongoing communication with the FDA as it pertains to the safety of the drug, device, or 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 may 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 of 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, or with more permissible, or less-restricted, claims and gain market traction against which we are not able to compete. 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 U.S. or other countries until we have completed a rigorous and extensive regulatory review process, including approval of a brand name. Any brand names we intend to use for our product candidates in the U.S. will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office (“USPTO”). The FDA typically conducts a review of proposed product brand names, including an evaluation, for example, of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name implies inappropriate promotional 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 and patent applications that cover our current and future clinical platforms. These patents will expire between 2024 and 2032. 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 with Inovio in 2011 for certain electroporation technology, which includes among other things, patents protecting our OMS EP Device. Under the terms of the agreement, Inovio granted us a non-exclusive, worldwide license under certain of its electroporation patents, and in exchange, we granted to Inovio an exclusive license to certain aspects of our technology in a limited field of use. However, with the expiration of patents in 2020, no patents acquired by OncoSec under the agreement and licensed to Inovio remain active. Although we do not currently rely on the technology covered by the intellectual property licensed from Inovio, our product candidates could in the future utilize this technology. This license is non-exclusive. As such, Inovio could use the technology to compete with us or other competitors could use the technology that was covered by the intellectual property to compete with us.

We entered into a license agreement with Gaeta Therapeutics in May 2019. Under the license, we obtained exclusive worldwide rights to Gaeta Therapeutics’ portfolio of patents and applications covering the combination use of IL-12 protein or DNA and various checkpoint inhibitor therapies, including anti-CTLA-4 and anti-PD-1 compounds, in key global markets. Although we do not currently rely on the intellectual property we have licensed from Gaeta, our product candidates could in the future utilize this intellectual property. The in-licensing of this portfolio provides patent protection on our current clinical methods in certain countries until at least 2032 and also gives us the potential to block others utilizing IL-12 in combination with various checkpoint inhibitors, which may not be part of our current clinical platform.

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. Further, patent law is a constantly evolving body of law, and changes can affect our rights and our ability to execute on our strategy and our financial results. In the past several years, the U.S. Supreme Court has 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 current 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 current 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 USPTO, 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.

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.

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 could include, among others, Bristol Myers-Squibb, Iovance Therapeutics, Syndax, Dynavax Technologies, Checkmate Pharmaceuticals 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, or with more or more-extensive claims, 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 EP 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.

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, but 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, restrictions on imports and exports, 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; and
- 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 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 KEYNOTE-695 and 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.

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 U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and residential real estate market in the U.S. 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.

***Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, weakened demand for our drug candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services.

Following its June 23, 2016 vote to leave the European Union, on March 29, 2017, the United Kingdom invoked Article 50 of the Lisbon Treaty and formally began the process of exiting the European Union. Although Brexit has already and may continue to adversely affect European and/or worldwide economic or market, political or regulatory conditions and may contribute to instability in the global financial markets, political institutions and regulatory agencies, the resulting immediate changes in foreign currency exchange rates have had a limited overall impact due to natural hedging. The long-term impact of Brexit, including on our business and our industry, will depend on the terms that are negotiated in relation to the United Kingdom's future relationship with the European Union, and we are closely monitoring the Brexit developments in order to determine, quantify and proactively address changes as they become clear. Despite the Brexit developments, we do not expect macroeconomic conditions to have a significant impact on our liquidity needs, financial condition or results of operations.

***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, such as the United Kingdom Bribery Act 2010, and similar antibribery and anticorruption laws in other jurisdictions;
- difficulties complying with foreign laws, regulations, standards and regulatory guidance governing the collection, use, disclosure, retention, security and transfer of personal data, including the European Union General Data Privacy Regulation, which introduces strict requirements for processing personal data of individuals within the European Union;
- difficulties maintaining compliance with the varied and potentially conflicting laws and regulations of multiple jurisdictions that may be applicable to our business, many of which may be unfamiliar to us;
- difficulties in managing foreign operations;
- financial risks, such as longer payment cycles, difficulty in enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- 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 uncertainty, 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;
- possible failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries; and
- business interruptions resulting from geopolitical actions, economic instability, or the impact of and response to natural disasters, including, but not limited to, wars and terrorism, political unrest, outbreak of disease, earthquakes, boycotts, curtailment of trade, and other business restrictions.

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.

***Recent changes in the Company's executive management team and Board of Directors may be disruptive to, or cause uncertainty in, its business, results of operations and the price of the Company's common stock.***

On June 24, 2021, Daniel J. O'Connor stepped down from his positions as Chief Executive Officer, President and Director of the Company, and the Company's Board of Directors appointed Brian A. Leuthner, formerly Chief Operating Officer, as the Company's interim Chief Executive Officer. The Company's Board of Directors commenced a search to recruit a permanent successor with the assistance of an executive search firm. Subsequently, on August 13, 2021, Mr. Brian A. Leuthner stepped down from his role as interim Chief Executive Officer of the Company. Also on August 13, 2021, the Company's Board of Directors formed a temporary Leadership Committee consisting of three board members, Margaret Dalesandro, Ph.D., Herbert Kim Lysterly, M.D. and Yuhang Zhao, Ph.D., MBA, to lead all development efforts, with a focus on the Company's lead asset, TAVO™, until a permanent Chief Executive Officer is hired. These changes in the Company's executive management team and to the Board of Directors, may be disruptive to, or cause uncertainty in, the Company's business, and any additional changes to the executive management team or the Board of Directors could have a negative impact on the Company's ability to manage and grow its business effectively. Any such disruption or uncertainty or difficulty in efficiently and effectively filling key roles could have a material adverse impact on the Company's results of operations and the price of the Company's common stock.

***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 ("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 Food, Drug, and Cosmetic Act ("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, design, verification, validation, clinical 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; injunctions; 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, different, 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 and other state and federal regulatory agencies, 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; and
- state law equivalents of each of these federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by applicable federal laws, thus complicating compliance efforts.

Additionally, the healthcare compliance environment is continuously changing, with proposed revisions to or replacement of the Affordable Care Act at the federal level and with some states mandating implementation of compliance programs, compliance with industry ethics codes, 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.

*We are subject to new legislation and regulatory proposals that may affect costs for compliance and adversely affect revenue.*

The 117<sup>th</sup> Congress has closely monitored drug pricing and health care spending in the United States. Many members of Congress have prioritized policies targeting drug prices and health care spending and are committed to lowering spending in federal government programs. Legislative efforts to reduce health care spending within federal programs may affect overall health care spending in the United States. The Prescription Drug Pricing Reduction Act, or PDPRA, which was introduced in Congress in 2019, and again in 2020, proposed to, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries, and several changes to how drugs are reimbursed in Medicare Part B. A similar drug pricing bill, the Elijah E. Cummings Lower Drug Costs Now Act, proposes to enable direct price negotiations by the federal government for certain drugs (with the maximum price paid by Medicare capped based on an international index), requires manufacturers to offer these negotiated prices to other payers, and restricts manufacturers from raising prices on drugs covered by Medicare Parts B and D. This Act passed in the House of Representatives when it was introduced in 2019, and it has been introduced again in the 2021 term. In September 2021, provisions from this Act were included in budget reconciliation recommendations from several House committees. These recommendations include a provision advanced by the Ways and Means Committee that would limit federal tax credits associated with the clinical study of certain drugs intended for use in certain rare diseases. If passed, this law could increase the costs associated with clinical development and regulatory approval of OncoSec's products. Further, the House and Senate Judiciary Committees have also focused heavily on patent and exclusivity reform for prescription drugs. While we cannot predict what proposals may ultimately become law, elements under consideration could significantly change health care spending in which the U.S. biotechnology and pharmaceutical markets operate.

President Joseph Biden, like his predecessor, has prioritized drug pricing and price transparency in the health care industry. On July 9, 2021, President Biden signed an Executive Order ("EO") directing federal agencies to develop and implement policies to lower drug prices. The EO expresses the Biden Administration's support for a range of drug policy proposals, including Medicare drug pricing negotiation, inflationary rebates, and drug importation from foreign countries, including Canada. Under the previous Administration, the Department of Health and Human Services ("HHS") proposed or enacted several drug pricing measures, including finalization of a regulation that would prohibit rebates from drug manufacturers to payors (referred to as the Rebate Rule). The Rebate Rule's implementation was delayed by courts, and Congress may prevent its implementation through legislation. Legislative or regulatory changes to the framework of permissible rebates could impact our ability to negotiate with payors to obtain coverage and reimbursement, which may ultimately impact our ability to market our products.

On June 24, 2019, President Donald Trump signed an EO directing federal agencies to improve price transparency. Since then, under both the Trump and Biden Administrations, HHS has proposed and implemented regulations to improve price transparency in both provider and payor industries. These transparency measures may shift bargaining power among various stakeholders within the U.S. drug supply chain and could ultimately impact drug pricing and health care costs generally.

Further, the Centers for Medicare & Medicaid Services (“CMS”), within HHS, has significant regulatory authority to promulgate regulations and impose other compliance requirements that may increase our compliance costs and impact our ability to attain profitability and market our products. CMS sets coverage and reimbursement rates for Medicare and oversees the implementation of Medicaid at the state level. CMS could modify or impose coverage restrictions or modify reimbursement rates on any of our products in a manner that could adversely impact our business. For example, on January 8, 2021, CMS approved Tennessee’s Medicaid section 1115 demonstration application, granting the state the unprecedented ability to implement a closed drug formulary without foregoing the state’s entitlement to rebates under the Medicaid Drug Rebate Program. Implementation of a closed formulary could mean that our products could be excluded from coverage under Medicaid. Further, CMS has implemented regulations that encourage the implementation of value-based payment models for drugs within the Medicaid program. Such payment mechanisms, if implemented, could lead to reduced payment for any of our products.

Within CMS, the Center for Medicare and Medicaid Innovation (“CMMI”), as established by the Affordable Care Act, has broad authority to design, implement, and test new health care payment models that could potentially lower health care spending while maintaining quality or increase quality without increasing spending. CMMI has considered implementing models that could have a significant adverse effect on our business. For example, on November 27, 2020, CMMI finalized a mandatory Medicare Part B drug payment model that would have aligned payment for drugs with international reference prices, entitled the Most Favored Nation (“MFN”) Model. The MFN Model was enjoined by a Federal court on December 28, 2020 for failure to comply with rulemaking procedural requirements. The Biden Administration has withdrawn the MFN Model, but it is unclear whether the Administration will propose and implement the same or a similar model in future rulemaking, and we cannot predict how future regulatory actions by CMMI or any other component of CMS may impact our business.

In addition to significant uncertainty with respect to legislation and regulation at the federal level, similar developments by state governments may impact our business. State legislative and regulatory developments could impact drug development, manufacturing, pricing, marketing, distribution, coverage, or payment. Jurisdictional and preemption issues between federal and state laws and regulations are complex and increase the costs of compliance. Further, similar legislative and regulatory uncertainties may arise in foreign drug markets, some of which are heavily regulated. We cannot predict how developments at the state level may impact our business.

*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 might obtain marketing approval, along with the manufacturing processes and facilities, post-approval 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, industry standards and regulatory requirements (e.g. cGMPs and good documentation practices) 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, studies, and surveillance to monitor the safety or efficacy of the product. We also may be subject to state laws and registration requirements covering the marketing, promotion, and distribution of products. Later discovery of previously unknown problems with products, manufacturers or manufacturing processes, or failure to comply with legal and regulatory requirements, may result in actions such as:

- restrictions on product manufacturing, distribution or use;
- restrictions on the labeling, marketing, or promotion of a product;
- requirements to conduct post-marketing studies or clinical trials;
- Inspectional observations or warning letters from regulatory authorities;
- 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 experience one or more of the actions above, resulting in decreased revenue from milestones, product sales or royalties.

***We are heavily dependent on the success of our clinical product candidates and we cannot provide any assurance that any of our product candidates will be approved, commercialized or successfully marketed in the future.***

We plan to seek regulatory approval to commercialize our product candidates in the United States, and potentially in the European Union and additional foreign countries. While the scope of regulatory review and approval can be similar in other countries, to obtain separate regulatory review and approval in many other countries, we must comply with the numerous and varying regulatory requirements of such countries, including those regarding safety and efficacy, clinical trials, manufacturing, post-marketing commitments, and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in those jurisdictions.

In addition, the clinical trial requirements of the FDA, the European Commission, the European Medicines Agency, or the EMA, the competent authorities of the European Union, or EU, Member States and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied product candidates. Even if we are successful in developing additional product candidates, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for these product candidates in either the United States or the EU, or how long it will take to commercialize any other products for which we receive marketing approval. In addition, any future marketing authorization granted by the European Commission may not be indicative of what FDA may require for approval and vice versa.

Further, in the U.S., the European Union member states, and elsewhere, there have been, and we expect there will continue to be, efforts to control and reduce healthcare costs. In the U.S. for example, the price of drugs has come under intense scrutiny by the U.S. Congress. Third party payers decide which drugs they will pay for and establish reimbursement and co-payment levels. Government and other third-party payers are increasingly challenging the prices charged for healthcare products, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs.

***Europe has enacted a new data privacy regulation, the General Data Protection Regulation, a violation of which could subject us to significant fines.***

In May 2018, a new privacy regime, the General Data Protection Regulation, or GDPR, took effect across all member states of the European Economic Area. The new regime increases our obligations with respect to clinical trials conducted in the member states by expanding the definition of personal data to include coded data, and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, it increases the scrutiny that clinical trial sites located in the member states should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The regime imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. Compliance with these directives is a rigorous and time-intensive process that may increase our cost of doing business, and the failure to comply with these laws could subject us to significant fines.

***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, to provide accurate information to the FDA, to comply with manufacturing standards, including those we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately, to comply with internal procedures, policies or agreements to which such employees, consultants or partners are subject, or to 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, 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 OMS EP Devices, our primary U.S. and foreign patents providing such protection expired in 2017 and 2018, and the final foreign patents expired in late 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 expired between 2017 and 2019, we also own or have exclusively licensed certain patents and applications that cover our current clinical methods. These patents/patent applications will expire between 2024 and 2037. These method patents protect the use of a product for a specified method under certain defined parameters. These types of method patents do 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 2024 and 2032 may not have as broad a scope as our patents that 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, in the past several years, 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, 2021, 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.

***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 made 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 reduced the top corporate income tax rate to 21% and repealed 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 Company accounted for the identified changes and adjusted the carrying amounts of gross deferred tax assets and corresponding valuation allowance in the year ended July 31, 2018. There was no net impact to the Company’s financial statements as a result. 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. Additionally, in September 2021, the Ways and Means Committee advanced a provision that would limit federal tax credits associated with the clinical study of certain drugs intended for use in certain rare diseases. If passed, this law could increase the costs associated with clinical development and regulatory approval of OncoSec’s products.

**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 management and scientific 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 2020 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 a company. This type of litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

***The possibility of the economy's return to recessionary conditions and the possibility of further turmoil or volatility in the financial markets would likely have an adverse effect on our business, financial position, and results of operations.***

The economy in the United States and globally has experienced volatility in recent years and may continue to experience such volatility for the foreseeable future. There can be no assurance that economic conditions will not worsen. Unfavorable or uncertain economic conditions can be caused by declines in economic growth, business activity, or investor or business confidence, limitations on the availability or increases in the cost of credit and capital, the timing and impact of changing governmental policies, natural disasters, epidemics / pandemics, such as COVID-19, terrorist attacks, acts of war, or a combination of these or other factors. A worsening of business and economic conditions could have adverse effects on our business, including substantial fluctuations in the market price of our common stock, which could decline below current levels.

***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 100,000,000 shares of our common stock. In addition to capital-raising activities, on which we have historically relied for cash to fund our operations, 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, 2021, we had outstanding (i) options to purchase approximately 3.1 million shares of our common stock, (ii) warrants to purchase approximately 1.7 million shares of our common stock, and (iii) approximately 0.4 million restricted stock units. In addition, as of July 31, 2021, there were approximately 0.8 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**

Our corporate and executive office is located in Pennington, New Jersey, where we lease space at 24 N. Main Street, Pennington, New Jersey, pursuant to a lease agreement which expires in 2022. Our Company also has an office located in San Diego, California, where we lease space at 3565 General Atomics Court, Suite 100, San Diego, CA, 92121, pursuant to lease which expires in 2023. Additionally, we entered into a lease assignment agreement for space located at 5820 Nancy Ridge Drive, San Diego, California, 92121 which expires in 2025. We have also entered into lease arrangements for lab 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.

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:

	<u>High</u>	<u>Low</u>
<b>Fiscal Year Ended July 31, 2021</b>		
First Quarter ended October 31, 2020	\$ 5.40	\$ 3.06
Second Quarter ended January 31, 2021	\$ 7.82	\$ 3.69
Third Quarter ended April 30, 2021	\$ 8.16	\$ 4.17
Fourth Quarter ended July 31, 2021	\$ 5.08	\$ 2.08
<b>Fiscal Year Ended July 31, 2020</b>		
First Quarter ended October 31, 2019	\$ 2.65	\$ 1.60
Second Quarter ended January 31, 2020	\$ 2.50	\$ 1.70
Third Quarter ended April 30, 2020	\$ 2.54	\$ 1.04
Fourth Quarter ended July 31, 2020	\$ 4.89	\$ 1.51

#### Holders

As of October 29, 2021, there were 44 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.

#### Unregistered Sales of Equity Securities and Use of Proceeds

From May 3, 2021 to July 2, 2021, we issued a total of 37,500 shares of our common stock to a third-party firm pursuant to a consulting agreement at an average market price of \$3.92 per share for services rendered.

The securities above were offered and sold without registration under the Securities Act of 1933, as amended, or the Securities Act, pursuant to the exemption provided in Section 4(a)(2) under the Securities Act as a transaction not involving a public offering as well as similar exemptions under applicable state laws, in reliance on the following facts: no general solicitation was used in the offer or sale of such shares; the recipient of such shares represented that it was acquiring the shares for investment for its own account and not with a view to or for resale in connection with any distribution thereof within the meaning of the Securities Act; the recipient of such shares had adequate access to information about us; the recipient of such shares represented that it had a preexisting business or personal relationship with us or had the capacity to protect its own interests in connection with acquiring such shares; and such shares were issued as restricted securities with restricted legends referring to the Securities Act.

## 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 late-stage immuno-oncology company focused on designing, developing and commercializing innovative, proprietary, intra-tumoral DNA-based therapeutics to stimulate and to augment anti-tumor immune responses for the treatment of cancers. Our core technology platform ImmunoPulse® is a drug-device therapeutic modality platform comprised of proprietary intratumoral electroporation ("EP") delivery devices (the "OncoSec Medical System ("OMS") Electroporation Device" or "OMS EP Device") and a proprietary DNA plasmid that triggers transient expression of target protein in cells. The OMS EP Device is designed to deliver plasmid DNA-encoded drugs directly into a solid tumor and promote an immunological response against cancer. The OMS EP 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 is a DNA-encoded interleukin-12 ("IL-12") called tavokinogene telseplasmid ("TAVO"). The OMS EP Device is used to deliver TAVO intratumorally, 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 2017, we received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration 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) in melanoma and triple negative breast cancer.

### Performance Outlook

We expect to use our available working capital in the near term primarily for the advancement of our existing and planned clinical programs, including performance of the KEYNOTE-695 and KEYNOTE-890 studies and, to a lesser extent, the continuation of our other clinical trials and studies. We anticipate our spending on clinical programs and the development of our next-generation OMS EP Device will continue throughout our current fiscal year, primarily in support of the KEYNOTE-695 and KEYNOTE-890 studies, while our spending on research and development programs will be prioritized, based on our focus on the KEYNOTE-695 and KEYNOTE-890 studies. We expect our cash-based general and administrative expenses to remain relatively flat in the near term, as we seek to continue to leverage internal resources and automate processes to decrease our outside services expenses. See "Results of Operations" below for more information.

Our operational and financial performance have already been affected by the impact of the COVID-19 pandemic. Our clinical trials have experienced delays in patient enrollment, potentially due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a public health emergency. The COVID-19 pandemic is also affecting the operations of government entities, such as the FDA, as well as contract research organizations, third-party manufacturers, and other third-parties upon whom we rely. The extent of the impact on our operations cannot be ascertained at this time.

### Results of Operations for the Year Ended July 31, 2021 Compared to the Year Ended July 31, 2020

The financial data for the years ended July 31, 2021 and July 31, 2020 is presented in the following table and the results of these two periods are included in the discussion thereafter.

	July 31, 2021	July 31, 2020	\$ Change	% Change
<b>Revenue</b>	\$ -	\$ -	\$ -	-
<b>Expenses</b>				
Research and development	34,097,641	25,096,817	9,000,824	36
General and administrative	14,282,417	18,312,268	(4,029,851)	(22)
<b>Loss from operations</b>	(48,380,058)	(43,409,085)	(4,970,973)	11
Other (loss) income, net	(704)	185,052	(185,756)	(100)
Interest expense	(15,857)	(5,114)	(10,743)	210
Gain on extinguishment of debt	960,790	-	960,790	100
Foreign currency exchange gain/(loss), net	(144,085)	103,136	(247,221)	(240)
<b>Loss before income taxes</b>	(47,579,914)	(43,126,011)	(4,453,903)	10
Income tax benefit	(2,412,183)	(872,585)	(1,539,598)	176
<b>Net loss</b>	\$ (45,167,731)	\$ (42,253,426)	\$ (2,914,305)	7

#### Revenue

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

#### Research and Development Expenses

Our research and development expenses increased by approximately \$9.0 million, from \$25.1 million during the year ended July 31, 2020 to \$34.1 million during the year ended July 31, 2021. This increase was primarily due to the following approximate increases: (i) \$5.4 million in clinical trial-related costs to support our various clinical studies and costs for discovery research and product development (ii) \$2.2 million increase in payroll and related benefits expenses, primarily due to additional headcount and merit increases, and (iii) \$1.2 million increases in stock-based compensation expense for employees and consultants.

#### General and Administrative

Our general and administrative expenses decreased by approximately \$4.0 million, from \$18.3 million during the year ended July 31, 2020, to \$14.3 million during the year ended July 31, 2021. This decrease was largely due to the following: (i) \$5.3 million decrease in legal costs primarily related to the Alpha Holdings litigation and the contested proxy in prior year and \$1.0 million in insurance recoveries from the Alpha Holdings litigation in the current period; (ii) \$1.0 million in consulting costs, primarily related to business development and public relations in the prior period and (iii) \$0.9 million in proxy costs related to the Company's special meeting to approve the CGP transaction in the prior period. The decrease was offset by a \$2.0 million increase in payroll and related benefits expenses primarily due to a severance payment of \$1,795,500 to the former CEO of the Company.

### ***Gain on Extinguishment of Debt***

Gain on Extinguishment of Debt increased by approximately \$1.0 million from \$0 for the year ended July 31, 2020 to \$1.0 million for the year ended July 31, 2021. During the year ended July 31, 2021, the PPP loan was forgiven, which resulted in a gain on extinguishment of debt of approximately \$1.0 million.

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

Other (loss) income, net, decreased by approximately \$0.2 million from \$0.2 million other income for the year ended July 31, 2020 to \$0.01 million other loss for the year ended July 31, 2021. This decrease was primarily due to reduced interest income as a result of a lower return on our investments during the current period.

### ***Foreign Currency Exchange Gain/(Loss), Net***

Foreign currency exchange gain/(loss), net, decreased by approximately \$0.2 million from a gain of \$0.1 million for the year ended July 31, 2020 to a loss of \$0.1 million for the year ended July 31, 2021. The decrease was primarily due to unrealized foreign currency transaction losses recognized in connection with the Australian subsidiary's intercompany loan.

### ***Income Tax expense (benefit)***

In June 2021, the Company received \$2.4 million in net proceeds from the sale of its New Jersey Net Operating Losses ("NOL") under the State of New Jersey NOL Transfer Program. In May 2020, the Company received \$0.9 million in net proceeds from the sale of its New Jersey Net Operating Losses under the State of New Jersey NOL Transfer Program.

## **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, 2021	At July 31, 2020
Current assets	\$ 49,179,424	\$ 22,821,685
Current liabilities	7,961,916	9,678,030
Working capital	<u>\$ 41,217,508</u>	<u>\$ 13,143,655</u>

### ***Current Assets***

Current assets as of July 31, 2021 increased by \$26.4 million to \$49.2 million, from \$22.8 million as of July 31, 2020. This increase was primarily due to the \$52.6 million net proceeds received from the August 2020 and January 2021 offerings, \$5.0 million received from the co-promotion agreement with Sirtex, \$5.4 million received from warrant and option exercises and \$5.8 million from the purchase of shares under the CGP and Sirtex stock purchase agreements originally entered into on October 10, 2019. The increase was partially offset by cash used to support our operations during the year ended July 31, 2021.

### ***Current Liabilities***

Current liabilities as of July 31, 2021 decreased by \$1.7 million to \$8.0 million, from \$9.7 million as of July 31, 2020. This decrease was primarily due to a decrease in accounts payable and accrued expenses pertaining to our legal costs and our manufacturing and clinical research activities. In addition, the PPP loan was forgiven.

## **Cash Flow**

### *Cash Used in Operating Activities*

Net cash used in operating activities for the year ended July 31, 2021 was \$41.8 million, as compared to \$33.1 million for the year ended July 31, 2020. The \$8.7 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 year ended July 31, 2021 was \$0.8 million, as compared to \$0 for the year ended July 31, 2020. During the year ended July 31, 2021, the Company licensed generator technology and purchased property and equipment for use in its clinical trials and other research and development efforts.

### *Cash Provided by Financing Activities*

Net cash provided by financing activities was \$68.2 million for the year ended July 31, 2021, as compared to \$28.4 million provided by financing activities for the year ended July 31, 2020. Net proceeds during the year ended July 31, 2021 was primarily attributable to the \$52.6 million net proceeds received from the August 2020 and January 2021 offerings, \$5.0 million received from the co-promotion agreement with Sirtex, \$5.4 million received from warrant and option exercises and \$5.8 million from the purchase of shares under the CGP and Sirtex stock purchase agreements originally entered into on October 10, 2019 (see "Sources of Capital" below). Net proceeds during the year ended July 31, 2020 was primarily attributable to the \$28.0 million received from the CGP and Sirtex offering (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 and 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 KEYNOTE-695 and 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 EP 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.

### *Going Concern and Management's Plans*

The Company has sustained losses in all reporting periods since inception, with an accumulated deficit of approximately \$252 million as of July 31, 2021. These losses are expected to continue for an extended period of time. Further, the Company has never generated any cash from its operations and does not expect to generate such cash in the near term. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the issuance date of the consolidated financial statements. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the consolidated financial statements are issued.

As of October 12, 2021, the Company had cash and cash equivalents of \$37.5 million. Since inception, cash flows from financing activities has been the primary source of the Company's liquidity. Based on its current cash levels, the Company believes its cash resources are insufficient to meet the Company's anticipated needs for the 12 months following the date the consolidated financial statements are issued.

The Company recognizes it will need to raise 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. There is no assurance that additional financing will be available to the Company when needed, that management will be able to obtain financing on terms acceptable to the Company, or whether the Company will become profitable and generate positive operating cash flow. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. The ongoing COVID-19 pandemic has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all. If the Company is unable to raise sufficient additional funds when needed, on favorable terms or at all, the Company will not be able to continue the development of its product candidates as currently planned or at all, will need to reevaluate its planned operations and may need to delay, scale back or eliminate some or all of its development programs, reduce expenses or cease operations, any of which would have a significant negative impact on its prospects and financial condition.

#### *Sources of Capital*

We have not generated any revenue since our inception, and we do not anticipate generating meaningful 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.

#### *Public Offering*

On January 25, 2021, the Company completed the offer and sale of an aggregate of 7,711,284 shares of its common stock at a purchase price of \$5.45 per share in a public offering. The gross proceeds from the offering were approximately \$42.0 million, and the net proceeds, after deducting the placement agent's fee and other offering fees and expenses paid by the Company, were approximately \$39.1 million. In connection with the offering, the Company paid the placement agent and other financial advisors an aggregate cash fee equal to 6.0% of the gross proceeds of the offering, as well as legal and other expenses equal to approximately \$0.4 million.

#### *Registered Direct Offering*

On August 19, 2020, the Company completed the offer and sale of an aggregate of 4,608,589 shares of its common stock at a purchase price of \$3.25 per share in a registered direct offering. The gross proceeds of the offering were approximately \$15.0 million, and the net proceeds, after deducting the placement agent's fee and other offering fees and expenses paid by the Company, were approximately \$13.5 million. In connection with the offering, the Company paid the placement agent and other financial advisors an aggregate cash fee equal to 8.0% of the gross proceeds of the offering, as well as legal and other expenses equal to approximately \$0.3 million.

#### *Common Stock Option Exercise*

During the year ended July 31, 2021, shares of common stock issued related to option exercises totaled 377,361. The Company realized proceeds of approximately \$0.6 million from the stock option exercises.

#### *Common Stock Warrant Exercise*

During the year ended July 31, 2021, shares of common stock issued related to warrant exercises totaled 1,389,261. The Company realized proceeds of approximately \$4.8 million from the warrant exercises.

#### *Sale of New Jersey Net Operating Losses (NOLs)*

In June 2021, the Company received \$2.4 million in net proceeds from the sale of its New Jersey NOL under the State of New Jersey NOL Transfer Program for the period ended July 31, 2020. In May 2020, the Company received \$0.9 million in net proceeds from the sale of its New Jersey NOL under the State of New Jersey NOL Transfer Program for the period ended July 31, 2019.

#### *Small Business Administration Loan*

On April 27, 2020, the Company was granted a loan from the Banc of California in the aggregate amount of \$952,744, pursuant to the Paycheck Protection Program under the CARES Act, which was enacted March 27, 2020. The term of the loan is two years. Monthly payments will be due beginning August 15, 2021 if the Loan is not forgiven. Interest accrues at 1% per year, effective on the date of initial disbursement. The Company submitted its application for full loan forgiveness on January 6, 2021.

On February 12, 2021, the Company received notice that the full Loan amount of \$952,744 and \$8,046 of accrued interest had been forgiven.

#### *CGP and Sirtex*

On February 7, 2020, the Company closed a strategic transaction with CGP and its affiliate, Sirtex. On October 10, 2019, the Company, CGP and Sirtex entered into Stock Purchase Agreements, as amended, pursuant to which the Company agreed to sell and issue to CGP and Sirtex 10,000,000 shares and 2,000,000 shares, respectively, of the Company's common stock for an aggregate purchase price of \$30.0 million. The net proceeds, after deducting offering fees and expenses paid by us, were approximately \$28.0 million.

In January 2021, the Company entered into a co-promotion agreement with Sirtex, pursuant to which the Company granted Sirtex the option to co-promote TAVO for the treatment of anti-PD-1 refractory locally advanced or metastatic melanoma in the U.S., including its territories and possessions. In consideration for the option, the Company received an upfront, non-refundable payment of \$5.0 million from Sirtex.

During the year ended July 31, 2021, shares of common stock issued to third party investors related to warrant exercises totaled 1,389,261. On April 16, 2021, in accordance with their respective stock purchase agreements originally entered into on October 10, 2019, CGP and Sirtex, related parties of the Company, exercised their rights to purchase additional shares of common stock at a purchase price equal to the same exercise price paid by each warrant holder in order to maintain their respective ownership percentages of the outstanding shares of common stock of the Company as of October 10, 2019. These significant related party relationships are based on Sirtex's approximate 8% ownership of the outstanding shares of the Company's common stock, and that of its significant equity holder, CGP (which owns 49% of Sirtex), which owns approximately 42% of the outstanding shares of the Company's common stock. The Company issued 1,409,838 shares of common stock to CGP at an exercise price of \$3.45 per share, resulting in gross proceeds of approximately \$4.8 million. The Company issued 281,968 shares of common stock to Sirtex at an exercise price of \$3.45 per share, resulting in gross proceeds of approximately \$1.0 million.

## Critical Accounting Policies

### *Use of Estimates*

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP"), which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Such estimates include going concern, stock-based compensation, the accrual of research, product development and clinical obligations, impairment of long-lived assets, determining the Incremental Borrowing Rate for calculating Right-Of-Use ("ROU") assets and lease liabilities 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 may differ from these estimates.

### *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(s);
- 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 assets. 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.

### *Research and Development Expenses*

Research and development expenses consist of costs incurred for internal projects, as well as partner-funded collaborative research and development activities. These costs include direct and research-related overhead expenses, which include salaries, stock-based compensation and other personnel-related expenses, facility costs, supplies, depreciation of facilities and laboratory equipment, as well as research consultants and the cost of funding research at universities and other research institutions, and are expensed as incurred. Costs to acquire technologies that are utilized in research and development that have no alternative future use, are expensed when incurred. In accordance with ASC 730-20, the Company accounts for upfront, non-refundable research and development payments received from a related party as a long-term liability as there has not been a substantive and genuine transfer of risk and there is a presumption that the Company is obligated to repay the related party.

### *Accruals for Research and Development Expenses and Clinical Trials*

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts vary from contract to contract and may result in payment terms that do not match the periods over which materials or services are provided under such contracts. The Company accounts for these expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company determines accrual estimates through financial models and takes into account discussion with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates.

### *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, directors and consultants, the fair value of the award is measured on the grant date. 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.

### *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% 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 Company's consolidated statements of operations.

### *Leases*

The Company determines if an arrangement is a lease at inception. Operating lease right of use ("ROU") assets represent the Company's right to use an underlying asset during the lease term, and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating leases are included in ROU assets, current operating lease liabilities, and long-term operating lease liabilities on the Company's consolidated balance sheets.

Lease ROU assets and lease liabilities are initially recognized based on the present value of the future minimum lease payments over the lease term at commencement date calculated using our incremental borrowing rate applicable to the lease asset, unless the implicit rate is readily determinable. ROU assets also include any lease payments made at or before lease commencement and exclude any lease incentives received. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the consolidated balance sheet. The Company's leases do not contain any residual value guarantees. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The Company accounts for lease and non-lease components as a single lease component for all its leases.

### ***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 are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

### **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 Interim Principal Executive Officer and Principal Accounting 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 President and Chief Executive Officer and Principal Accounting Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of July 31, 2021. Based on such evaluation, our Interim Principal Executive Officer and Principal Accounting Officer concluded that, as of July 31, 2021, 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 Interim Principal Executive Officer and Principal Accounting Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of July 31, 2021. 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, 2021, 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, 2021, 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

#### Board of Directors

The following table sets forth the names, ages as of July 31, 2021, and certain other information for each member of our board of directors (our “Board”):

<b>Name</b>	<b>Position with the Company</b>	<b>Age</b>	<b>Director Since</b>
Margaret Dalesandro, Ph.D.	Chair of the Board	74	April 2019
Dr. James M. DeMesa, M.D.	Director	63	February 2011
Joon Kim	Director	55	December 2018
Dr. Herbert Kim Lyerly, M.D.	Director	63	April 2020
Kevin R. Smith	Director	50	February 2020
Robert E. Ward	Director	64	November 2018
Yuhang Zhao, Ph.D.	Director	56	February 2020
Chao Zhou	Director	32	February 2020

*Margaret Dalesandro, Ph.D.*, has served on our Board since April 2019 and as the Chair of our Board since April 2020. Dr. Dalesandro is currently a pharmaceutical development consultant with Brecon Pharma Consulting LLC and has over twenty-five years of experience leading strategic product development in the pharmaceutical, biotechnology and diagnostics industries. Since August 2020, Dr. Dalesandro has served as an independent director on the Board of Directors of Skye Bioscience Inc. She has previously served as a Business Director of Integrative Pharmacology at Corning, Incorporated, as a Vice President of Project, Portfolio and Alliance Management at ImClone Systems Inc., as an Executive Director of Project and Portfolio Management at GlaxoSmithKline, and as a Senior Consultant at Cambridge Pharma Consultancy over the course of her career. Dr. Dalesandro earned her Ph.D. in Biochemistry from Bryn Mawr College and completed a NIH Post-Doctoral Fellowship in Molecular Immunology at the Wake Forest University School of Medicine. Dr. Dalesandro’s extensive experience and expertise in the biopharmaceuticals industry are the primary qualifications the Board considered in nominating her as a director of the Company.

*James M. DeMesa, M.D.*, has served on our Board since February 2011. Dr. DeMesa is currently President and CEO, and a director, of Emerald Health Pharmaceuticals Inc., a pharmaceutical development company, and a director of Induce Biologics, a regenerative medicine company. In 2008, Dr. DeMesa retired from his role as President, Chief Executive Officer and a director of Migenix Inc., a publicly traded biotechnology company. From 1997 to 2001, he was President, Chief Executive Officer and a director of GenSci Regeneration Sciences Inc., (now part of Integra LifeSciences, NASD: IART), a publicly-traded biotechnology company. From 1992 to 1997, Dr. DeMesa was Vice President, Medical and Regulatory Affairs at Biodynamics International, Inc. (now part of RTI Surgical, NASD: RTIX), a surgical implant company, and from 1989 to 1992 he was Vice President, Medical and Regulatory Affairs of Bentley Pharmaceuticals (now part of Teva Pharmaceuticals), a multinational pharmaceutical company. Dr. DeMesa is a co-founder of CommGeniX, a medical communications company, and MedXcel, a medical education company. Dr. DeMesa was formerly a practicing physician until 1989. Dr. DeMesa attended the University of South Florida where he received his B.A. (Chemistry), M.D., and M.B.A. degrees and completed his medical residency at the University of North Carolina. He is the author of two books and speaks regularly to companies and organizations throughout North America.

Dr. DeMesa has served as a senior executive with several international pharmaceutical and biotech companies, and provides the Board with extensive experience in the areas of corporate management, regulatory affairs and pre-clinical and clinical pharmaceutical product development. Dr. DeMesa also contributes expertise based on his professional training and experience as a medical doctor. We believe that Dr. DeMesa is qualified to serve on our Board of Directors due to his leadership and management experience, his service as an executive of a biopharmaceutical companies and his knowledge of our business and industry.

*Mr. Joon Kim* has served in our Board since December 2018. Mr. Kim is an accomplished litigator with extensive experience in both business and criminal litigation matters. With a particularly strong background in representing clients in court proceedings, Mr. Kim has a comprehensive understanding of every stage of the litigation process, including all aspects of initial investigatory/discovery proceedings, settlement negotiations, contested hearings, pretrial and trial motions, evidentiary issues, trials, and the handling of post-judgment challenges and appeals. Mr. Kim advises corporate clients of varying sizes on a variety of subject matters, inclusive of assisting the top management with strategic decision-making.

As a partner in Lee & Ko's International Litigation and Dispute Resolution and White Collar Crime Practice Groups, Mr. Kim advised clients, both domestic and international, on a broad range of litigation and dispute-resolution matters. In addition, Mr. Kim served as a public prosecutor in California, representing the People of the State of California in criminal proceedings. In that capacity, Mr. Kim has first-chaired both jury and non-jury trials, and has been trained in all aspects of litigation. During his time as a public prosecutor, Mr. Kim also had the experience of serving as a research fellow at the Institute of Justice, under the auspices of the Ministry of Justice of the Republic of Korea, where he worked closely with Korean public prosecutors. Mr. Kim received his J.D. from Berkeley School of Law and his B.S. from the Berkeley School of Business. Mr. Kim's experience and expertise are the primary qualifications for him to serve as a director of the Company.

*Herbert Kim Lyerly, M.D.*, is the George Barth Geller Professor of Cancer Research, Professor of Surgery, Immunology and Pathology, and Director of the Surgical Sciences Applied Therapeutics section at Duke University, and former Director of the Duke Comprehensive Cancer Center. He is an internationally-recognized expert in cancer therapy and immunotherapy, has published over 300 scientific articles and book chapters, and has edited ten textbooks on surgery, cancer immunotherapy and novel cancer therapies. He serves on the editorial board of 12 scientific journals.

Dr. Lyerly was appointed in 2008 by President George W. Bush to serve on the National Cancer Advisory Board, which oversees the National Cancer Institute, where he served until 2014. He has served as Chair of the Cancer Center's Subcommittee and served on the Global Health Subcommittee of the National Cancer Advisory Board. He has served on the National Institutes of Health ("NIH") Council of Councils, and on the board of the NIH Office of AIDS Research. He has also been a member of the scientific advisory boards of the Susan G. Komen Foundation and the Burroughs Wellcome Foundation. He is a highly sought-after consultant and advisor and has served on the Cancer Center's external advisory boards for the M.D. Anderson Cancer Center, University of Michigan, University of Chicago, University of Alabama, University of Arizona, Boston University and Purdue University. He has served as an advisor to the University of Washington and Case Western Reserve Clinical and Translational Science Institutes. Dr. Lyerly's experience and expertise are the primary qualifications for him to serve as a director of the Company.

*Kevin R. Smith* is currently the Chief Executive Officer of Sirtex Medical US Holdings, Inc. ("Sirtex"). He combines more than 20 years of sales and marketing experience in the medical device industry with the keen instincts of an entrepreneur. Prior to his appointment to CEO, Mr. Smith was Sirtex's Executive Vice President of Sales & Marketing, Americas. Before joining Sirtex, Mr. Smith was Executive Vice President of Business Development at Gel-e, Inc., a company based at the University of Maryland specializing in advanced material hemostasis products. His previous positions include Chief Commercial Officer of Sensium Healthcare along with Global Vice President of Sales & Marketing at Teleflex, where he was the senior sales and marketing executive in the company's cardiac business unit. Kevin holds a Master of Business Administration in Global Management from the University of Phoenix and a Bachelor of Science in Marketing from the University of Kentucky. Mr. Smith's leadership experience, as well as his experience in the marketing and sales sector of the medical device industry, are the primary qualifications the Board considered in nominating him as a director of the Company.

*Robert E. Ward* was appointed to the Board of Directors in November 2018. Mr. Ward served as Chairman of the Board of Directors and Chief Executive Officer for Eloxix Pharmaceuticals, Inc. from December 2017 to March 2020. Mr. Ward previously served as the Chief Executive Officer, President and member of the Board of Directors at Radius Health, Inc., completing the IPO and FDA approval of TYMLOS, from December 2013 to July 2017. He was a Nonexecutive Director and Chair of the Governance Committee of Akari Therapeutics Plc from October 2016 to August 2018. Prior to joining Radius, Mr. Ward was Vice President for Strategy and External Alliances for the New Opportunities iMed of AstraZeneca from 2011 to December 2013. He has held a series of progressive management and executive roles with established companies such as NPS Pharmaceuticals, Schering-Plough (Merck), Pharmacia (Pfizer), Bristol-Myers Squibb and Genentech. Mr. Ward was awarded a B.A. in Biology and a B.S. in Physiological Psychology, both from the University of California, Santa Barbara; an M.S. in Management from the New Jersey Institute of Technology and an M.A. in Immunology from The Johns Hopkins University School of Medicine. We believe Mr. Ward is qualified to serve on our Board of Directors because of his service and experience as an executive of a public pharmaceutical company.

*Yuhang Zhao*, Ph.D., a graduate from Peking University, received her Doctorate in Molecular Biology from Rockefeller University and her MBA in Finance from NYU Stern Business School. Dr. Zhao was most recently a member of the Bayer Global Leadership Circle. She established one of Bayer's four Global Clinical Development sites, located in Beijing, China in 2009. She then became Head of Global Strategy for Bayer Consumer Health, reporting to the President. Prior to her positions in the pharmaceutical industry, Dr. Zhao held positions as a stock analyst at PaineWebber and was a management consultant specializing in strategies for life science companies. Dr. Zhao currently serves on the board of R2 Technologies and is a senior adviser to China Grand Enterprises. This experience and expertise are the primary qualifications the Board considered in nominating Dr. Zhao as a director of the Company.

*Mr. Chao Zhou* is currently the Executive Deputy Officer of China Grand Pharmaceutical and Healthcare Holdings Limited, a public company listed on the Hong Kong stock exchange that develops, manufactures and distributes pharmaceutical products and medical devices to retailers and medical organizations with significant experience in R&D and product commercialization in China. Since 2018, Mr. Zhou has served on the Board of Directors of Grand Pharma Sphere Pty Ltd, a Singapore based company, Sirtex Medical Pty Ltd., the Australian based global medical device company and Cloudbreak pharmaceutical Inc, a Cayman Islands based company which is engaged in the business of the research, development, manufacturing and commercialization of biopharmaceutical product. Prior to his role as Executive Deputy Officer, Mr. Zhou served as a Management Director in the Department of Legal Security for China Grand Enterprises, Inc., an investment company engaged in the operation and management of businesses covering pharmaceuticals and healthcare, commodity trading, real estate investment, financial service and other sectors. He earned his Bachelor in Law from Ocean University of China and a Master in International Law from the University of International Business and Economics. We believe that Mr. Zhou is qualified to serve on our Board of Directors due to his commercial experience in the biopharmaceutical industry.

#### *Arrangements with Members of Our Board*

Dr. Yuhang Zhao, Chao Zhou, and Kevin R. Smith were appointed as directors in February 2020. On February 7, 2020, the Company closed (the "Closing") a strategic transaction (the "Transaction") with Grand Decade Developments Limited, a direct, wholly-owned subsidiary of China Grand Pharmaceutical and Healthcare Holdings Limited, a company formed under the laws of the British Virgin Islands ("CGP"), and its affiliate, Sirtex Medical US Holdings, Inc., a Delaware corporation ("Sirtex"). In connection with the Closing, the Company entered into Stockholders Agreements (the "Stockholders Agreements") with each of CGP and Sirtex, pursuant to which, among other things, CGP exercised its option to nominate two (2) members to the Board and Sirtex exercised its option to nominate one (1) director to the Board. Pursuant to the Stockholders Agreements, CGP nominated Dr. Yuhang Zhao and Chao Zhou to the Company's Board, and Sirtex nominated Kevin R. Smith to the Company's Board. In December 2018, OncoSec appointed Joon Kim as a director to the Board. On August 31, 2018, OncoSec and Alpha Holdings, Inc. ("Alpha") entered into a stock purchase agreement (the "Alpha Transaction Agreement"), pursuant to which OncoSec agreed to issue and sell to Alpha shares of its common stock. Mr. Kim was appointed to the Board in accordance with the terms of the Alpha Transaction Agreement in conjunction with the closing of the Alpha Transaction in December 2018.

Additionally, on August 16, 2021, OncoSec announced the establishment of a temporary Leadership Committee consisting of three board members, Margaret Dalesandro, Ph.D., Herbert Kim Lyerly, M.D. and Yuhang Zhao, Ph.D., MBA, to lead all development efforts, with a focus on the Company's lead asset, TAVO™, until a permanent Chief Executive Officer is hired.

Other than as described above, there is no arrangement or understanding between any nominee and any other person or persons pursuant to which any nominee was or is to be selected as a director or director nominee of the Company. There are no family relationships between any of the director nominees named below or our executive officers.

Set forth below is information regarding the current executive officers of the Company, including biographical summaries.

<b>Name</b>	<b>Position(s) with the Company</b>	<b>Age</b>	<b>Officer Since</b>
Robert J. DelAversano	VP, Finance and Principal Accounting Officer and Controller	50	January 2020

*Robert J. DelAversano* was appointed our Vice President of Finance in January 2021 and Principal Accounting Officer and Controller in January 2020. Mr. DelAversano is a certified public accountant and has over sixteen years of experience in accounting including thirteen years in public accounting. Prior to these appointments, Mr. DelAversano served as our Executive Director of Finance since 2018 where he had global responsibility for accounting, external financial reporting, and financial controls covering all aspects of our business. Prior to joining our Company, Mr. DelAversano was the Director of Financial Reporting and Taxation at Brio Financial Group (“Brio”), where he served as the firm’s Director of Financial Reporting and Taxation, consulting with various public companies in financial reporting, internal control development and evaluation, budgeting and forecasting. Prior to joining Brio, Mr. DelAversano was a manager at Bartolomei Pucciarelli, LLC and oversaw their accounting and tax practice with industry focuses in manufacturing, wholesalers and medical devices services. In addition, he performed audit services, outsourced chief financial officer functions, and consulted clients through difficult U.S. Securities and Exchange Commission comment periods, particularly through application of complex accounting principles for a large public company client base. Mr. DelAversano received a B.S. in Accounting from Rider University.

## **CORPORATE GOVERNANCE**

### **Role of the Board**

The primary functions and responsibilities of the Board are to oversee management’s operation of the business and affairs of the Company, the determination of our objectives and strategies, and the management of our risks. The functions of the Board are carried out by the full Board and, when delegated, by our Board committees, and each director is a full and equal participant in the major strategic and policy decisions of the Company. The Board has adopted Corporate Governance Guidelines to assist the Board and its committees in performing their duties and serving the best interests of the Company and its stockholders. These Corporate Governance Guidelines are available on our website, located at [www.oncosec.com](http://www.oncosec.com), on the Governance page under the Investors tab.

Between August 1, 2020 and July 31, 2021 (“Fiscal Year 2021”), our Board of Directors held 13 meetings and took two actions by unanimous written consent.

### **Board Committees**

The Board has established the following standing committees: Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee. The Board may also create additional, temporary committees from time to time, including committees relating to financings, strategic transactions or other significant corporate matters. The Board has adopted a written charter for each of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee, current copies of which are available on our website, located at [www.oncosec.com](http://www.oncosec.com), on the Governance page under the Investors tab.

### *Audit Committee*

The primary functions of the Audit Committee are, among other things: overseeing our accounting and financial reporting processes and the audits of our financial statements and internal control over financial reporting; reviewing the policies and procedures adopted by the Company to fulfill its responsibilities regarding the fair and accurate presentation of financial statements; appointing, retaining and overseeing the work of our independent registered public accounting firm; reviewing and discussing reports from our independent registered public accounting firm regarding critical accounting policies and practices, alternative treatments of financial information and any material written communications between such firm and management; reviewing and discussing with management and our independent registered public accounting firm the Company's financial statements and financial disclosures prior to the filing thereof in any report filed with the SEC; taking appropriate action to oversee and ensure the independence of our independent registered public accounting firm; and establishing procedures for the confidential and anonymous submission by our employees of concerns regarding questionable accounting or auditing matters. The Audit Committee met 5 times in Fiscal Year 2021.

Nasdaq has established rules and regulations regarding the composition of audit committees and the qualifications of audit committee members. As a controlled company, we are not required to have a compensation committee composed entirely of independent directors. However, our Board of Directors has examined the composition of our Audit Committee and the qualifications of our Audit Committee members in light of the current rules and regulations governing compensation committees. Based upon this examination, our Board of Directors has determined that each member of our Audit Committee is independent and is otherwise qualified to be a member of our Audit Committee in accordance with such rules.

Additionally, the U.S. Securities and Exchange Commission ("SEC") requires that at least one member of the Audit Committee have a "heightened" level of financial and accounting sophistication. Such a person is known as the "audit committee financial expert" under the SEC's rules. Our Board of Directors has determined that Robert E. Ward is an "audit committee financial expert," as the SEC defines that term, and that each member of the Audit Committee has sufficient knowledge in reading and understanding the Company's financial statements to serve on such committee.

### *Compensation Committee*

The primary functions of the Compensation Committee are, among other things: reviewing and approving compensation programs and arrangements applicable to our officers; determining the objectives of our executive officer compensation programs, including reviewing and establishing goals and objectives relevant to Chief Executive Officer compensation, and determining the extent to which they are achieved and any related compensation earned; administering our incentive compensation and equity-based plans; reviewing management's risk assessment regarding the compensation policies and practices of the Company and taking steps to provide that such policies and practices do not encourage unnecessary or excessive risk-taking; and reviewing and approving director compensation and benefits. The Compensation Committee met 13 times in Fiscal Year 2021.

While certain members of senior management, including primarily our Chief Executive Officer, present their views regarding attainment of business objectives and recommended compensation, the Compensation Committee performs its own independent analysis and makes final determinations regarding compensation-related matters. Our Chief Executive Officer is not present during the Compensation Committee's or the Board's voting or deliberations regarding his own compensation.

The Compensation Committee's charter gives the Compensation Committee the authority, without any approval of the Board or management, to engage and compensate compensation consultants and other advisors as it deems necessary or desirable to carry out its duties, including its evaluation of director or executive officer compensation. Pursuant to its charter and in accordance with applicable NASDAQ and SEC rules, the Compensation Committee would assess the independence of any compensation consultant, including the existence of any conflicts of interest, prior to any engagement.

In Fiscal Year 2021, the Compensation Committee engaged Anderson Pay Advisors, LLC, an independent compensation consultant, to review and evaluate all elements of our executive compensation program. Based on their evaluation, they concluded executive compensation generally was below market median. Their input may be considered by the Compensation Committee in making future compensation decisions.

Nasdaq has established rules and regulations regarding the composition of compensation committees and the qualifications of compensation committee members. As a controlled company, we are not required to have a compensation committee composed entirely of independent directors. However, our Board of Directors has examined the composition of our Compensation Committee and the qualifications of our Compensation Committee members in light of the current rules and regulations governing compensation committees. Based upon this examination, our Board of Directors has determined that each member of our Compensation Committee is independent and is otherwise qualified to be a member of our Compensation Committee in accordance with such rules.

#### *Nominating and Corporate Governance Committee*

The primary functions of the Nominating and Corporate Governance Committee are, among other things: assisting in the identification of nominees for election to our Board, consistent with qualifications and criteria approved by the Board; determining the composition of the Board and its committees; recommending to the Board the director nominees for the annual meeting of stockholders; establishing and monitoring a process of assessing the Board's effectiveness; developing and overseeing a set of corporate governance guidelines and procedures; and overseeing the evaluation of the Board and the Company's management. The Nominating and Corporate Governance Committee met 4 times in Fiscal Year 2021.

#### **Nomination of Directors**

Our Nominating and Corporate Governance Committee is responsible for identifying and evaluating individuals qualified to become directors and recommending these candidates to our Board for nomination or appointment.

#### *Director Qualifications*

In considering potential new directors, the Nominating and Corporate Governance Committee may review individuals from various disciplines and backgrounds. Among the qualifications to be considered in the selection of candidates are broad experience in business, finance or administration; familiarity with the Company's industry; and prominence and reputation. Since prominence and reputation in a particular profession or field of endeavor are what bring most persons to the Board's attention, there is further consideration of whether the individual has the time available to devote to the work of the Board on one or more of its committees. To this end, our Corporate Governance Guidelines provide that no director is to hold more than four directorships of publicly traded companies, and no member of our Audit Committee is to sit on the Audit Committee of more than two other publicly traded companies. The Nominating and Corporate Governance Committee also reviews the activities and associations of each candidate to ensure there is no legal impediment, conflict of interest or other consideration that might hinder or prevent service on the Board. With respect to the nomination of continuing directors for re-election, an individual's past contributions to the Board are also considered.

Other than the foregoing, there are no stated minimum criteria for director nominees and the Nominating and Corporate Governance Committee may also consider these factors and any such other factors as it deems appropriate and in the best interests of the Company and our stockholders. The Nominating and Corporate Governance Committee does, however, recognize that under applicable regulatory requirements at least one member of the Board should meet the criteria for an "audit committee financial expert" as defined by SEC rules and the members of certain of our Board committees must satisfy enhanced independence criteria under applicable NASDAQ and SEC rules. Further, although the Company does not have a formal diversity policy, the Nominating and Corporate Governance Committee seeks to assemble a Board that brings to the Company a variety of perspectives, skills, expertise, and sound business understanding and judgment, derived from a broad range of business, professional, governmental, finance, community and industry experience.

### *Identification and Evaluation of Director Nominees*

The Nominating and Corporate Governance Committee utilizes a variety of methods for identifying and evaluating nominees for director. Potential director candidates may come to the attention of the Nominating and Corporate Governance Committee through current members of the Board, executive officers, professional search firms, stockholders or others. These candidates are evaluated at regular or special meetings of the Nominating and Corporate Governance Committee and may be considered at any point during the year. The Nominating and Corporate Governance Committee recommends the director nominees to our Board for approval for election at each annual meeting of stockholders. Under our bylaws, any director appointed by our Board is subject to re-election by our stockholders at our next annual meeting of stockholders.

### **Code of Business Conduct and Ethics**

The Board has adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial and accounting officer. The Code of Business Conduct and Ethics is available for review on our website at [www.oncosec.com](http://www.oncosec.com), on the Governance page under the Investors tab, and is also available in print, without charge, to any stockholder who requests a copy by writing to us at OncoSec Medical Incorporated, 24 N. Main Street, Pennington, NJ 08534, Attention: Investor Relations. We intend to post on our website any amendments to certain provisions of our Code of Business Conduct and Ethics or any waivers of any such provisions applicable to any director or principal executive, financial or accounting officer or persons performing similar functions, to the extent required by applicable NASDAQ or SEC rules.

### **Delinquent Section 16(a) Reports**

Section 16(a) of the Exchange Act requires our officers, directors and persons who beneficially own more than 10% of our common stock to file reports of securities ownership and changes in such ownership with the SEC. To our knowledge, based solely on our review of such reports filed electronically with the SEC or written representations from persons subject to Section 16(a), we believe that during Fiscal Year 2021, all Section 16(a) reporting requirements applicable to our directors, executive officers and 10% stockholders were completed in a timely manner, except for (i) a late Form 3 was filed by Brian A. Leuthner, and (ii) a late Form 4 was filed by the following reporting persons (each relating to one transaction, except as noted): Brian Leuthner, Alpha Holdings, Inc., and China Grand Pharmaceutical & Healthcare Holdings Ltd. (relating to two transactions).

### **Family Relationships**

There are no family relationships among our current directors and executive officers.

## ITEM 11. EXECUTIVE COMPENSATION

### Summary Compensation Table

The following table sets forth the total compensation awarded to, earned by or paid to those individuals who served as our executive officers during Fiscal Year 2021.

Name and Principal Position	Fiscal Year	Salary (\$)	Bonus (\$)(1)	Stock Awards (\$)(2)	Option Awards (\$)(2)	Nonequity Incentive Plan Compensation (\$)	All Other Compensation (\$)(3)	Total (\$)
<b>Daniel J. O'Connor, J.D.</b> Former President and Chief Executive Officer (4)	2021	517,731	262,500	–	410,872	–	1,812,101	3,003,204
	2020	513,462	326,993	–	502,086	–	10,645	1,353,186
<b>Robert J. DeAversano</b> Principal Accounting Officer and Controller (5)	2021	270,285	83,500	66,850	150,373	–	7,391	578,399
	2020	202,432	91,557	–	89,319	–	6,613	389,921
<b>Brian A. Leuthner</b> Former Interim Chief Executive Officer, Former Chief Operating Officer (6)	2021	167,058	–	606,720	856,477	–	54,446	1,684,701
	2020	–	–	–	–	–	–	–
<b>Kellie Malloy Foerter</b> Former Chief Operating Officer (7)	2021	90,692	–	–	175,702	–	1,222	267,616
	2020	328,203	146,493	–	283,441	–	10,858	768,995

- (1) Reflects discretionary bonuses approved by the Compensation Committee on December 24, 2020 and February 2, 2021. (See *Compensation Matters* below)
- (2) Amounts represent the aggregate grant date fair value of stock and option awards granted during each period, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 *Share Based Payments* (“FASB Topic 718”). For a description of the assumptions and methodologies used to calculate these amounts, see Note 7—Stock-Based Compensation.
- (3) Amounts for fiscal year include for Mr. O'Connor: severance pay of \$1,795,500, group term life insurance, 401(k) company match and tax preparation; for Mr. DeAversano: group term life insurance and 401(k) company match; for Ms. Foerter: group term life insurance and 401(k) company match; for Mr. Leuthner: 401(k) company match and moving expenses.
- (4) Mr. O'Connor voluntarily resigned from his position effective as of June 24, 2021.
- (5) Mr. DeAversano was appointed as the Company's Principal Accounting Officer and Controller effective as of January 30, 2020.
- (6) Mr. Leuthner was appointed as the Company's Chief Operating Officer effective as of February 2, 2021. Mr. Leuthner was appointed as the Company's Interim Chief Executive Officer effective as of June 24, 2021. Mr. Leuthner voluntarily resigned from his position effective as of August 13, 2021.
- (7) Ms. Foerter was appointed as the Company's Chief Operating Officer effective as of July 27, 2020. Ms. Foerter voluntarily resigned from her position effective as of October 16, 2020.

## Outstanding Equity Awards at Fiscal Year End

The following table sets forth information regarding equity awards held by the named executive officers as of July 31, 2021:

Name	Option Awards(1)				Stock Awards(2)	
	Number of Securities Underlying Unexercised Options, Exercisable (#)	Number of Securities Underlying Unexercised Options, Not Exercisable (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
Daniel J. O'Connor	304,000(4)	–	1.56	6/24/2023(10)	–	–
	152,000(5)	–	3.82	6/24/2023(10)	–	–
Robert J. DelAversano	54,000(4)	–	1.56	4/14/2030	–	–
	6,750(5)	20,250(5)	3.82	8/24/2030	–	–
	8,750(6)	26,250(6)	3.16	6/28/2031	–	–
	–	–	–	–	7,656(7)	16,690
Brian A. Leuthner	51,563(9)	98,437(9)	7.45	2/2/2031(11)	–	–
	8,250(6)	24,750(6)	3.16	6/28/2031(11)	–	–
	–	–	–	–	144,000(8)	313,920
Kellie Malloy Foerter	–	–	–	–	–(12)	–

- (1) Except as otherwise noted, all option awards reflect stock options granted under the Company's 2011 Stock Incentive Plan (the "2011 Plan") that vest as follows: 25% of the shares subject to the award vested on the date of grant and 1/36th of the remaining 75% of the shares subject to the award will vest on each of the 36 monthly anniversaries of the date of grant, subject to continuing service by the named executive officer on each vesting date. Additionally, the stock options may vest immediately upon a corporate transaction or change in control, as defined in the 2011 Plan.
- (2) Except as otherwise noted, all stock awards reflect restricted stock units granted under the 2011 Plan that vest in full on the three-year anniversary of the date of grant. Additionally, the restricted stock units may vest immediately upon a corporate transaction or change in control, as defined in the 2011 Plan.
- (3) Determined by multiplying the unvested portion of the stock awards by \$2.18, the closing price of our common stock on July 31, 2021.
- (4) Represents an option award approved by our Compensation Committee and granted on April 14, 2020, subject to stockholder approval of an amendment to the Issuer's 2011 Incentive Plan to increase the number of authorized shares. Our stockholders approved the plan amendment on May 29, 2020. The options vested 25% on the date of the grant and the remainder vests quarterly over a three-year period from the date of grant. On August 24, 2020, the Compensation Committee approved the accelerated vesting of these awards and the awards were fully vested on such date.

- (5) Represents an option award approved by our Compensation Committee and granted on August 24, 2020. The options vest quarterly over a three-year period from the date of grant.
- (6) Represents an option award approved by our Compensation Committee and granted on June 28, 2021. The options vested 25% on the date of the grant and the remainder vests quarterly over a two-year period from the date of grant.
- (7) Represents a restricted stock unit award granted on February 1, 2021. The units vest in equal quarterly installments of 1,904 units beginning on May 1, 2021 and ending on February 1, 2023.
- (8) Represents a restricted stock unit award granted on June 28, 2021. The units vested 25% on the date of grant and the remainder vests quarterly over a two-year period from the date of grant.
- (9) Represents a one-time inducement option award granted outside of the 2011 Plan on February 2, 2021. The options vested 25% on the date of the grant and the remainder vests quarterly over a two-year period from the date of grant.
- (10) Mr. O'Connor voluntarily resigned from his position effective as of June 24, 2021 and all Mr. O'Connor's stock options vested immediately on the resignation date and will remain exercisable for 24 months after the resignation date.
- (11) Mr. Leuthner voluntarily resigned from his position effective as of August 13, 2021 and 109,125 unvested options and 144,000 restricted stock units were forfeited on such date.
- (12) Ms. Foerter voluntarily resigned from her position effective as of October 16, 2020 and the 2,500 restricted stock units outstanding on such date were forfeited.

## **Compensation Matters**

### *Cash Bonuses*

On December 24, 2020, the Compensation Committee approved discretionary cash bonus awards to certain of our employees, including our named executive officers, as follows: (i) Mr. O'Connor received a cash bonus of \$262,500 and (ii) Mr. DelAversano received a cash bonus of \$73,500. On February 2, 2021, the Compensation Committee approved discretionary cash bonus awards to certain of our employees, including Mr. DelAversano in the amount of \$10,000.

### *Equity Awards*

The named executive officers received grants of equity awards in Fiscal Year 2021 as described below.

#### Daniel J. O'Connor

On August 24, 2020, the Compensation Committee approved the grant of 152,000 options to Mr. O'Connor. The options vests quarterly over a three-year period from the date of grant.

#### Robert J. DelAversano

On August 24, 2020, the Compensation Committee approved the grant of 27,000 options to Mr. DelAversano. The options vests quarterly over a three-year period from the date of grant.

On February 1, 2021, the Compensation Committee approved the grant of 8,750 restricted stock units to Mr. DelAversano. The units vest in equal quarterly installments of 1,904 units beginning on May 1, 2021 and ending on February 1, 2023.

On June 28, 2021, the Compensation Committee approved the grant of 35,000 options to Mr. DeAversano. The options vested 25% on the date of the grant and the remainder vests quarterly over a two-year period from the date of grant.

Brian A. Leuthner

On February 2, 2021, in connection with the appointment of Mr. Leuthner as the Company's Chief Operating Officer, Mr. Leuthner received a one-time inducement award of 150,000 stock options to purchase the Company's common stock. A total of 37,500 of the options vested on February 2, 2021, and the remaining 112,500 options vests quarterly over a two-year period.

On June 28, 2021, the Compensation Committee approved the grant of 33,000 options to Mr. Leuthner. The options vested 25% on the date of the grant and the remainder vests quarterly over a two-year period from the date of grant.

On June 28, 2021, the Compensation Committee approved the grant of 192,000 restricted stock units to Mr. Leuthner. The units vested 25% on the date of the grant and the remainder vests quarterly over a two-year period from the date of grant.

Mr. Leuthner voluntarily resigned from his position effective as of August 13, 2021 and 109,124 unvested options and 144,000 restricted stock units were forfeited on such date.

Kellie Malloy Foerter

On August 24, 2020, the Compensation Committee approved the grant of 65,000 options to Ms. Foerter. The options vests quarterly over a three-year period from the date of grant. Ms. Foerter voluntarily resigned from her position effective as of October 16, 2020 and the 65,000 unvested stock options on such date were forfeited, therefore, no value was realized by Ms. Foerter.

**Employment Agreements**

The following is a description of the prior employment agreement for Mr. O'Connor, our former Chief Executive Officer. We do not have an employment agreement with Mr. DeAversano, Mr. Leuthner or Ms. Foerter.

On November 7, 2017, we entered into an executive employment agreement with Mr. O'Connor, our former Chief Executive Officer. The employment agreement provides for the following, among other things:

- An initial term of three years, subject to certain provisions for automatic renewals thereafter. (on April 17, 2020, the contract term was extended an additional two years, subject to certain provisions for automatic renewals thereafter);
- An initial annual base salary of \$400,000 in cash; provided that, subject to certain conditions as described in Mr. O'Connor's employment agreement, Mr. O'Connor may elect on an annual basis to receive all or a portion of such salary in the form of shares of our common stock (Mr. O'Connor's current base salary is \$525,000);
- As a one-time grant in connection with his appointment as Chief Executive Officer, an appointment stock option award to purchase up to 200,000 shares of our common stock. Of the total grant, options on 100,000 shares vested upon stockholder approval and options on 100,000 shares will vest over a two-year period from the date of grant. Effective November 18, 2019, Mr. O'Connor voluntarily forfeited all of these stock options for no consideration, therefore, no value was realized by Mr. O'Connor;

- A performance stock option award to purchase up to 50,000 shares of our common stock, which is subject to vesting as to 25,000 of such shares on the date of achievement of 100% enrollment in the first cohort in KEYNOTE-695 and as to the remaining 25,000 of such shares in one installment on the one-year anniversary of the date of achievement of such enrollment. Effective November 18, 2019, Mr. O'Connor voluntarily forfeited all of these stock options for no consideration, therefore, no value was realized by Mr. O'Connor;
- Eligibility to receive an annual performance-based bonus, payable in cash or shares of our common stock at the Company's election, in a target amount of 50% of Mr. O'Connor's then-current annual base salary;
- Eligibility to receive additional equity awards at the discretion of the Board or a committee thereof;
- If Mr. O'Connor is terminated other than for cause, if we fail to renew his employment agreement after the end of the initial term, or if Mr. O'Connor terminates his employment with us for good cause, then he will be entitled to receive severance compensation of (i) if such termination occurs at least six months but less than 12 months after the commencement date of his employment, cash payments equal to 1/2 of Mr. O'Connor's then-current annual base salary and annual performance-based bonus plus six months' of medical and dental COBRA premiums; (ii) if such termination occurs at least 12 months but less than 24 months after the commencement date of his employment, cash payments equal to Mr. O'Connor's then-current annual base salary and annual performance-based bonus plus 12 months' of medical and dental COBRA premiums; or (iii) if such termination occurs at least 24 months after the commencement date of his employment, cash payments equal to twice the amount of Mr. O'Connor's then-current annual base salary and annual performance-based bonus plus 24 months' of medical and dental COBRA premiums; and
- Certain additional benefits, including reimbursement of certain income tax return preparation fees and other benefits customarily made available to our other senior employees.

### **Other Elements of Compensation**

#### *Health and Welfare Plans*

Our executive officers are eligible to participate in our employee benefit plans, including our health and welfare plans, on the same basis as our other employees.

#### *401(k) Plan*

We currently maintain a defined contribution savings plan pursuant to Section 401(k) of the Code. The plan is for the benefit of all qualifying employees, including our executive officers, and permits voluntary contributions by employees of up to 100% of eligible compensation, subject to maximum limits imposed by the Internal Revenue Service. The terms of the plan allow for discretionary employer contributions, and we currently match 100% of each employee's contributions, up to a maximum of 3% of such employee's annual compensation

## **DIRECTOR COMPENSATION**

### **Director Compensation Policy**

The Board determines the form and amount of director compensation after its review of recommendations made by the Compensation Committee. Directors who are also employees of our Company do not receive any separate compensation for their service as directors, except that all directors receive reimbursement for reasonable out-of-pocket expenses incurred in attending Board or Board committee meetings or otherwise in connection with performance of their duties as directors. Under our director compensation policy in place for Fiscal Year 2021, our directors' cash compensation was as follows:

- Non-employee independent directors receive annual cash compensation of \$50,000 for services as a director. Non-independent directors do not receive cash compensation;

- The Chair of the Board receives additional annual cash compensation of \$40,000 for services in such capacity; and
- The Committee Chairs and Committee Members receive additional annual cash compensation as follows:
  - i) Audit Committee Chair - \$17,000
  - ii) Audit Committee Member - \$8,500
  - iii) Compensation Committee Chair - \$15,000
  - iv) Compensation Committee Member - \$7,500
  - v) Nominating and Corporate Governance Committee Chair - \$10,000
  - vi) Nominating and Corporate Governance Committee Member - \$5,000

In addition, each non-employee independent director will receive a stock option award of 50,000 upon election and 25,000 annually thereafter.

#### Director Compensation Table

The following table provides information about the compensation of our non-employee directors for Fiscal Year 2021:

Name	Fees Earned or Paid in			Total (\$)
	Cash (\$)	Stock Awards (\$)	Option Awards \$(1)(6)	
Robert E. Ward	66,500	–	114,136(2)(3)	180,636
Dr. James M. DeMesa, M.D.	69,500	–	173,341(3)(4)	242,841
Margaret Dalesandro, Ph.D.	101,250	–	141,602(2)(5)	242,852
Joon Kim	–	–	54,931(3)	54,931
Dr. Herbert Kim Lyerly, M.D.	62,000	–	114,136(2)(3)	176,136
Yuhang Zhao, Ph.D.	–	–	54,931(3)	54,931
Chao Zhou	–	–	54,931(3)	54,931
Kevin R. Smith	–	–	54,931(3)	54,931

- (1) Amounts represent the aggregate grant date fair value of option awards computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 Share Based Payments (“FASB Topic 718”). For a description of the assumptions and methodologies used to calculate these amounts, see Note 7—Stock-Based Compensation to our consolidated financial statements included elsewhere in this Form 10-K.
- (2) Includes an option award granted to purchase up to 25,000 shares that was approved by our Compensation Committee on September 14, 2020. The options vested 25% on the date of the grant and the remainder vests quarterly over a three-year period from the date of grant.
- (3) Includes an option award granted to purchase up to 25,000 shares that was approved by our Compensation Committee on June 28, 2021. The options shall vest in equal quarterly installments over one year.
- (4) Includes an option award granted to purchase up to 50,000 shares that was approved by our Compensation Committee on September 14, 2020. The options shall vest in equal quarterly installments over one year.
- (5) Includes an option award granted to purchase up to 37,500 shares that was approved by our Compensation Committee on June 28, 2021. The options shall vest in equal quarterly installments over one year.
- (6) As of July 31, 2021, the number of shares subject to all outstanding option awards and stock awards held by our non-employee directors were as follows:

<b>Director</b>	<b>Number of Shares Subject to Option Awards</b>	<b>Number of Shares Subject to Stock Awards</b>
Robert E. Ward	75,000	—
Dr. James M. DeMesa, M.D.	112,500	—
Margaret Dalesandro, Ph.D.	100,000	—
Joon Kim	65,000	—
Dr. Herbert Kim Lyerly, M.D.	75,000	—
Yuhang Zhao, Ph.D.	50,000	—
Chao Zhou	50,000	—
Kevin R. Smith	50,000	—

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

The table below sets forth certain information regarding the beneficial ownership of our common stock of (i) each person who, to our knowledge, owns more than 5% of our common stock as of October 29, 2021, (ii) each of our directors and named executive officers (consisting of the persons described under “Executive Compensation” below), and (iii) all of our current directors and executive officers as a group. Unless otherwise indicated in the footnotes to the table below, the address of each person named in the table is: c/o OncoSec Medical Incorporated, 24 N. Main Street, Pennington, NJ 08534.

Beneficial ownership is determined and calculated in accordance with applicable SEC rules, and generally includes sole or shared voting and/or investment power with respect to securities. These rules provide that shares of our common stock subject to options, warrants, restricted stock units or other rights that are currently exercisable or subject to vesting within 60 days after October 29, 2021 are deemed to be beneficially owned and outstanding for purposes of computing the share and percentage ownership of the person holding such options, warrants, restricted stock units or other rights, but are not deemed outstanding for computing the percentage ownership of any other person.

<b>Name of Beneficial Owner</b>	<b>Amount and Nature of Beneficial Ownership (No. of Shares)</b>	<b>Percentage Beneficially Owned (%)<sup>(1)</sup></b>
<b>Directors and Named Executive Officers</b>		
Daniel J. O'Connor, J.D. <sup>(2)</sup>	545,950	1.38
Robert J. DelAversano <sup>(3)</sup>	99,662	*
Brian A. Leuthner <sup>(4)</sup>	108,262	*
Kellie Malloy Foerter	31,494	*
Margaret Dalesandro, Ph.D. <sup>(5)</sup>	101,250	*
Dr. James M. DeMesa, M.D. <sup>(6)</sup>	101,250	*
Joon Kim <sup>(7)</sup>	40,000	*
Dr. Herbert Kim Lyerly, M.D. <sup>(8)</sup>	62,500	*
Kevin R. Smith <sup>(9)</sup>	25,000	*
Yuhang Zhao, Ph.D. <sup>(9)</sup>	37,000	*
Chao Zhou <sup>(9)</sup>	25,000	*
Robert E. Ward <sup>(10)</sup>	56,250	*
All directors, nominees and current executive officers as a group (12 persons)	1,233,618	3.07
<b>5% Stockholders</b>		
China Grand Pharmaceutical & Healthcare Holdings Ltd. and Grand Decade Developments Limited <sup>(11)</sup>	16,798,036	42.8
Sirtex Medical US Holdings, Inc. <sup>(12)</sup>	3,359,607	8.6
Avidity Partners Management LP <sup>(13)</sup>	1,952,000	5.5

\* Less than 1%.

- (1) Based on 39,202,590 shares of our common stock issued and outstanding as of October 29, 2021. Except as otherwise indicated, we believe the beneficial owners of our common stock listed in this table, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable.
- (2) Includes 456,000 stock options that are vested or will vest within 60 days after October 29, 2021.
- (3) Includes 80,563 stock options that are vested or will vest within 60 days after October 29, 2021, and 1,093 restricted stock units that will vest within 60 days after October 29, 2021.
- (4) Includes 73,875 stock options that are vested or will vest within 60 days after October 29, 2021.
- (5) Includes 81,250 shares of common stock issuable upon exercise of options currently exercisable or exercisable within 60 days after October 29, 2021.
- (6) Includes 100,000 shares of common stock issuable upon exercise of options currently exercisable or exercisable within 60 days after October 29, 2021.
- (7) Includes 40,000 shares of common stock issuable upon exercise of options currently exercisable or exercisable within 60 days after October 29, 2021.
- (8) Includes 62,500 shares of common stock issuable upon exercise of options currently exercisable or exercisable within 60 days after October 29, 2021.
- (9) Includes 25,000 shares of common stock issuable upon exercise of options currently exercisable or exercisable within 60 days after October 29, 2021.
- (10) Includes 56,250 shares of common stock issuable upon exercise of options currently exercisable or exercisable within 60 days after October 29, 2021.
- (11) Based solely upon a Form 4 filed on April 26, 2021 by China Grand Pharmaceutical & Healthcare Holdings Ltd (“CGP”) and Grand Decade Developments Limited (“Grand Decade”). CGP and Grand Decade may each be deemed to beneficially own 16,798,036 shares of our common stock and have shared dispositive power as to 16,798,036 shares of our common stock. The address of CGP and Grand Decade is Unit 3302,33/F, The Center, 99 Queen’s Road Central, Hong Kong.
- (12) Based solely upon a Form 4 filed on April 26, 2021 by Sirtex Medical US Holdings, Inc. (“Sirtex”). Sirtex beneficially owns 3,359,607 shares of our common stock and has sole dispositive power as to 3,359,607 shares of our common stock. The address of Sirtex is 300 Unicorn Park Drive, Woburn MA 01801, USA.
- (13) Based solely upon a Schedule 13G/A filed on February 16, 2021 by Avidity Partners Management LP, Avidity Partners Management LP, Avidity Partners Management (GP) LLC, Avidity Capital Partners Fund (GP) LP, Avidity Capital Partners (GP) LLC, Avidity Master Fund LP, David Witzke, and Michael Gregory (“Avidity”). Avidity beneficially owns 1,952,000 shares of our common stock and has sole dispositive power as to 1,952,000 shares of our common stock. The address of Avidity is 2828 N Harwood Street, Suite 1220 Dallas, Texas 75201.

## Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of July 31, 2021 regarding compensation plans under which our equity securities are authorized for issuance:

	Equity Compensation Plan Information		
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	2,964,391(1)	\$ 2.87	838,310(2)
Equity compensation plans not approved by security holders	590,000(3)	\$ 5.00	-
<b>TOTAL</b>	<b>3,554,391</b>	<b>3.27</b>	<b>838,310</b>

- (1) 2,521,642 of these shares were subject to stock options outstanding under the OncoSec Medical Incorporated 2011 Stock Incentive Plan (the "2011 Plan") and 442,749 were subject to restricted stock units outstanding under the 2011 Plan.
- (2) Represents (i) an aggregate of 808,516 shares of common stock available for future issuance under the 2011 Plan, and (ii) an aggregate of 29,794 shares of common stock available for future issuance under the OncoSec Medical Incorporated 2015 Employee Stock Purchase Plan.
- (3) Represents (i) 590,000 stock option awards that were not granted under the 2011 Plan. These out-of-plan stock option awards were granted as follows: (i) a stock option award to purchase up to 300,000 shares on October 9, 2020 to a new employee as an inducement material to entering into employment with the Company, 25% vested at grant and remaining 75% cliff vesting at 1 year anniversary; (ii) a stock option award to purchase up to 150,000 shares on February 2, 2021 to a new employee as an inducement material to entering into employment with the Company, 25% vested at grant remaining 75% vesting quarterly over 2 years; (iii) a stock option award to purchase up to 35,000 shares on February 2, 2021 to a new employee as an inducement material to entering into employment with the Company, 25% vested at grant remaining 75% vesting quarterly over 2 years; (iv) a stock option award to purchase up to 35,000 shares on February 18, 2021 to a new employee as an inducement material to entering into employment with the Company, 25% vested at grant remaining 75% vesting quarterly over 2 years; (v) a stock option award to purchase up to 35,000 shares on May 17, 2021 to a new employee as an inducement material to entering into employment with the Company, 25% vested at grant remaining 75% vesting quarterly over 2 years; and (vi) a stock option award to purchase up to 35,000 shares on June 14, 2021 to a new employee as an inducement material to entering into employment with the Company, 25% at grant remaining 75% vesting quarterly over 2 years.

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

### *Related Party Transactions*

Except as described below and except for employment arrangements and compensation for Board service, which are described under "Executive Compensation" above, since August 1, 2019, there has not been, nor is there currently proposed, any transaction in which we are or were a participant, the amount involved exceeds the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and any of our directors, executive officers, holders of more than 5% of our common stock or any immediate family member of any of the foregoing had or will have a direct or indirect material interest.

We have entered into indemnification agreements with each of our directors and executive officers. In general, these indemnification agreements require the Company to indemnify a director to the fullest extent permitted by law against liabilities that may arise in connection with that director's service as a director for the Company.

*Policies and Procedures for Review and Approval of Related Party Transactions*

Pursuant to its charter and in accordance with applicable NASDAQ rules, our Audit Committee has the responsibility to review and approve in advance any transactions with a related party. In addition, our Code of Business Conduct and Ethics addresses conflicts of interest and requires that the existence of any actual or potential conflict be disclosed to the Chairman of the Audit Committee to enable the committee's full review of the potential conflict. The Audit Committee intends to approve only those related party or conflict of interest transactions that are considered to be in the best interests of the Company and our stockholders. In considering whether to approve any such transaction, the Audit Committee considers such factors as it deems appropriate, and generally focuses on whether the terms of the transaction are at least as favorable to us as terms we would receive on an arm's-length basis from an unaffiliated third party and whether any such transaction might impair the independence of a director or present a conflict of interest for a director or executive officer.

**Director Independence and Controlled Company Exemption**

The Company's common stock is listed on the NASDAQ Capital Market. The rules of NASDAQ require our Board to make an affirmative determination as to the independence of each director and require a majority of the Company's directors be "independent directors," as defined by NASDAQ rules. In addition, NASDAQ rules require that, subject to specified exceptions, each member of a company's audit, compensation and nominating committee be independent. Audit committee and compensation committee members must also satisfy enhanced independence criteria under certain SEC rules and corresponding NASDAQ rules.

Consistent with these rules, our Board undertook its annual review of director independence on May 6, 2021. During the review, our Board considered relationships and transactions during Fiscal Year 2021 and since inception between each director or any member of his immediate family, on the one hand, and the Company and our subsidiaries and affiliates, on the other hand. The purpose of this review was to determine whether any such relationships or transactions were inconsistent with a determination that the director is independent. Based on this review, our Board determined that Dr. Margaret Dalesandro Ph.D., Dr. James M. DeMesa, M.D., Dr. Herbert Kim Lyerly, M.D., and Mr. Robert E. Ward are independent under the criteria established by Nasdaq and our Board.

Upon the Closing of the Transaction described above, CGP and Sirtex, acting as a "group" for purposes of Section 13(d) of the Exchange Act, collectively beneficially owns common stock representing more than 50% of the voting power of our Common Stock eligible to vote in the election of directors. As a result, we qualify as a "controlled company" and avail ourselves of certain "controlled company" exemptions under the Nasdaq corporate governance rules. As a controlled company, we are not required to have a majority of "independent directors" on our Board as defined under the Nasdaq rules, or have a compensation, nominating or governance committee composed entirely of independent directors. In light of our status as a controlled company, our Board has determined to utilize the majority board independence exemption.

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table presents the aggregate fees billed to the Company for professional services rendered by Mayer Hoffman McCann P.C. (“MHM”) in our fiscal years ended July 31, 2021 and 2020.

	Fiscal Year	
	2021	2020
Audit Fees (1)	\$ 329,443	\$ 273,250
Audit Related Fees (2)	—	—
Tax Fees (3)	—	—
All Other Fees (4)	—	—
Total (5)	<u>\$ 329,443</u>	<u>\$ 273,250</u>

- (1) *Audit Fees* consist of fees for professional services rendered by MHM for the audit of our annual consolidated financial statements and review of our interim consolidated financial statements included in our quarterly reports on Form 10-Q, as well as audit services that are normally provided in connection with other statutory and regulatory filings, including consents related to registration statements on Forms S-3 and S-8, and prospectus supplement review or comfort letter preparation related thereto.
- (2) *Audit-Related Fees* consist of fees for assurance and related services that are reasonably related to the performance of the audit or review of the Company’s financial statements and are not reported as Audit Fees. No such fees were billed by MHM for these services during the periods presented.
- (3) *Tax Fees* consist of fees for professional services rendered for tax compliance, tax advice and tax planning. No such fees were billed by MHM for these services during the periods presented.
- (4) *All Other Fees* consist of fees billed for all products and services provided that are not included in (1), (2) and (3) above. No such fees were billed by MHM for any such services during the periods presented.
- (5) Substantially all MHM’s personnel, who work under the control of MHM shareholders, are employees of wholly-owned subsidiaries of CBIZ, Inc., which provides personnel and various services to MHM in an alternative practice structure.

#### Pre-Approval Policies and Procedures

Our Audit Committee’s charter requires the Audit Committee to pre-approve all audit and permissible non-audit services to be performed for the Company by our independent registered public accounting firm, as well as the fees and terms for these services, subject to certain exceptions for “de minimis” amounts as permitted by applicable SEC rules. In considering such services and fees for approval, the Audit Committee considers whether the provision of the services and the payment of the related fees are compatible with maintaining the independence of our independent registered public accounting firm.

#### 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 href="#">Report of Independent Registered Public Accounting Firm</a>	F-1
<a href="#">Consolidated Balance Sheets at July 31, 2021 and 2020</a>	F-2
<a href="#">Consolidated Statements of Operations for the Years Ended July 31, 2021 and 2020</a>	F-3
<a href="#">Consolidated Statements of Comprehensive Loss for the Years Ended July 31, 2021 and 2020</a>	F-4
<a href="#">Consolidated Statements of Stockholders’ Equity for the Years Ended July 31, 2021 and 2020</a>	F-5
<a href="#">Consolidated Statements of Cash Flows for the Years Ended July 31, 2021 and 2020</a>	F-6
<a href="#">Notes to Consolidated Financial Statements</a>	F-7

(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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended July 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

### Going Concern Uncertainty

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has incurred recurring losses from operations, and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are described in Note 3 to the financial statements. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

### 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.

### Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

#### *Co-Promotion and Funded Research Agreement*

As described in Note 12 to the financial statements, in January 2021 the Company entered into a co-promotion and funded research agreement with a related party, pursuant to which the Company granted the related party the option to co-promote one of the Company’s product candidates. In consideration for the option, the Company received an upfront, non-refundable payment of \$5.0 million. If the related party exercises the option, the Company will receive an additional non-refundable and non-creditable option exercise fee of \$25.0 million, comprised of \$20.0 million in cash, and \$5.0 million purchase of common shares. Under the terms of the co-promotion agreement, if the related party exercises the co-promote option, the Company will pay to the related party a royalty fee for sales of the product candidate in accordance with the terms of the agreement.

We identified auditing the Company’s classification and presentation of the co-promotion and funded research agreement as a critical audit matter. The principal consideration for this determination was due to the judgments involved by management in determining whether a substantive and genuine transfer of risk exists due to the related party relationship with the counterparty. Auditing management’s conclusions related to this matter involved especially challenging auditor judgment due to the subjectivity necessary to evaluate the audit evidence required to address this matter.

The primary procedures we performed to address this critical audit matter included:

- Obtaining and reading the co-promotion and funded research agreement to understand the documented terms, conditions and economic substance of the transaction.
- Evaluating management’s conclusion that successful commercialization of the products were not considered to be probable, therefore, concluding that ASC 470-10-25 does not apply.
- Evaluating the provisions of the co-promotion and funded research agreement against management’s conclusions that the arrangement does not result in a substantive and genuine transfer of risk due to the related party relationship with the counterparty, and therefore, the entire balance of the arrangement represents a R&D Funding arrangement under ASC 730-20-25.

*/s/ Mayer Hoffman McCann P.C.*

We have served as the Company’s auditor since 2011.

San Diego, California  
October 29, 2021

**OncoSec Medical Incorporated**  
**Consolidated Balance Sheets**

	<u>July 31, 2021</u>	<u>July 31, 2020</u>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 45,951,233	\$ 20,354,462
Prepaid expenses and other current assets	3,228,191	2,467,223
Total Current Assets	<u>49,179,424</u>	<u>22,821,685</u>
Property and equipment, net	928,821	814,494
Intangible assets, net	448,412	-
Operating right-of-use assets	5,445,744	5,948,224
Other long-term assets	273,523	319,058
Total Assets	<u>\$ 56,275,924</u>	<u>\$ 29,903,461</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Liabilities</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 5,561,645	\$ 7,923,036
Accrued compensation related	320,655	285,127
Operating lease liabilities	845,483	500,357
Notes payable	1,234,133	969,509
Total Current Liabilities	<u>7,961,916</u>	<u>9,678,029</u>
Operating lease liabilities, net of current portion	5,238,207	5,874,442
Liability under co-promotion agreement - related party	5,000,000	-
Notes payable, net of current portion	-	480,554
Total Liabilities	<u>18,200,123</u>	<u>16,033,025</u>
<b>Commitments and Contingencies (Note 9)</b>		
<b>Stockholders' Equity</b>		
Common stock authorized - 100,000,000 common shares with a par value of \$0.0001 as of July 31, 2021 and July 31, 2020, common stock issued and outstanding 39,152,610 and 23,054,474 common shares as of July 31, 2021 and July 31, 2020, respectively		
	3,916	2,305
Additional paid-in capital	286,337,291	214,789,808
Warrants issued and outstanding – 1,706,190 and 3,114,288 warrants as of July 31, 2021 and July 31, 2020, respectively	3,591,734	5,708,127
Accumulated other comprehensive loss	(79,109)	(19,504)
Accumulated deficit	(251,778,031)	(206,610,300)
Total Stockholders' Equity	<u>38,075,801</u>	<u>13,870,436</u>
Total Liabilities and Stockholders' Equity	<u>\$ 56,275,924</u>	<u>\$ 29,903,461</u>

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

**OncoSec Medical Incorporated**  
**Consolidated Statements of Operations**

	<b>Year Ended July 31, 2021</b>	<b>Year Ended July 31, 2020</b>
Revenue	\$ -	\$ -
Expenses:		
Research and development	34,097,641	25,096,817
General and administrative	14,282,417	18,312,268
Loss from operations	(48,380,058)	(43,409,085)
Gain on extinguishment of debt	960,790	-
Other (loss) income, net	(704)	185,052
Interest expense	(15,857)	(5,114)
Foreign currency exchange gain (loss), net	(144,085)	103,136
Loss before income taxes	(47,579,914)	(43,126,011)
Income tax benefit	(2,412,183)	(872,585)
Net loss	\$ (45,167,731)	\$ (42,253,426)
Basic and diluted net loss per common share	\$ (1.37)	\$ (2.56)
Weighted average shares used in computing basic and diluted net loss per common share	32,903,366	16,534,551

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

**OncoSec Medical Incorporated**  
**Consolidated Statements of Comprehensive Loss**

	<u>Year Ended</u> <u>July 31, 2021</u>	<u>Year Ended</u> <u>July 31, 2020</u>
Net Loss	\$ (45,167,731)	\$ (42,253,426)
Foreign currency translation adjustments	(59,605)	(188,541)
Comprehensive Loss	<u>\$ (45,227,336)</u>	<u>\$ (42,441,967)</u>

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
	Shares	Amount	Capital	Shares	Amount	Income (Loss)	Deficit	Stockholders' Equity
Balance, July 31, 2019	<u>10,633,043</u>	<u>\$ 1,063</u>	<u>\$ 177,656,149</u>	<u>3,631,953</u>	<u>\$ 10,809,724</u>	<u>\$ 169,037</u>	<u>\$ (164,356,874)</u>	<u>\$ 24,279,099</u>
Common stock issued for employee stock purchase plan	4,199	—	7,012	—	—	—	—	7,012
Stock-based compensation expense	220,233	22	3,517,106	—	—	—	—	3,517,128
Cash paid for stock options cancellation	—	—	(25,819)	—	—	—	—	(25,819)
Repurchase of warrants	—	—	2,457,976	(266,098)	(2,636,201)	—	—	(178,225)
Tax withholdings paid on equity awards	—	—	(26,859)	—	—	—	—	(26,859)
Tax shares sold to pay for tax withholdings on equity awards	—	—	26,495	—	—	—	—	26,495
Tax withholdings paid related to net share settlement of equity awards	—	—	(263,100)	—	—	—	—	(263,100)
Cancellation of expired warrants	—	—	2,465,396	(251,567)	(2,465,396)	—	—	—
February 2020 Financing, net of issuance costs of \$1,954,678	12,000,000	1,200	28,044,122	—	—	—	—	28,045,322
Common stock issued for services	196,999	20	931,330	—	—	—	—	931,350
Other comprehensive loss	—	—	—	—	—	(188,541)	—	(188,541)
Net loss	—	—	—	—	—	—	(42,253,426)	(42,253,426)
Balance, July 31, 2020	<u>23,054,474</u>	<u>2,305</u>	<u>214,789,808</u>	<u>3,114,288</u>	<u>5,708,127</u>	<u>(19,504)</u>	<u>(206,610,300)</u>	<u>13,870,436</u>
Common stock issued for employee stock purchase plan	3,795	—	9,973	—	—	—	—	9,973
Exercise of common stock warrants	1,389,261	139	6,580,106	(1,389,261)	(1,787,294)	—	—	4,792,951
Exercise of common stock options	377,361	38	636,955	—	—	—	—	636,993
Stock-based compensation expense	178,540	19	5,137,049	—	—	—	—	5,137,068
Tax withholdings paid on equity awards	—	—	(238,976)	—	—	—	—	(238,976)
Tax shares sold to pay for tax withholdings on equity awards	—	—	220,490	—	—	—	—	220,490
Cancellation of expired warrants	—	—	329,099	(18,837)	(329,099)	—	—	—
August 2020 Registered Direct Offering, net of \$1,464,276 issuance costs	4,608,589	461	13,513,177	—	—	—	—	13,513,638
January 2021 Public Offering, net of \$2,970,165 issuance costs	7,711,284	771	39,055,562	—	—	—	—	39,056,333
Purchase of shares under CGP and Sirtex stock purchase agreements	1,691,806	169	5,836,562	—	—	—	—	5,836,731
Common stock issued for services	137,500	14	467,486	—	—	—	—	467,500
Other comprehensive loss	—	—	—	—	—	(59,605)	—	(59,605)
Net loss	—	—	—	—	—	—	(45,167,731)	(45,167,731)
Balance, July 31, 2021	<u>39,152,610</u>	<u>\$ 3,916</u>	<u>\$ 286,337,291</u>	<u>1,706,190</u>	<u>\$ 3,591,734</u>	<u>\$ (79,109)</u>	<u>\$ (251,778,031)</u>	<u>\$ 38,075,801</u>

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

**OncoSec Medical Incorporated**  
**Consolidated Statements of Cash Flows**

	<b>Year Ended July 31, 2021</b>	<b>Year Ended July 31, 2020</b>
<i>Operating activities</i>		
Net loss	\$ (45,167,731)	\$ (42,253,426)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	236,864	216,635
Amortization of right-of-use assets	841,299	773,653
Stock-based compensation	5,137,068	3,517,128
Common stock issued for services	467,500	931,350
Foreign currency exchange loss (gain), net	144,085	(103,136)
Gain on extinguishment of debt	(960,790)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	613,432	1,470,982
Other long-term assets	49,854	42,431
Accounts payable and accrued liabilities	(2,561,215)	3,617,923
Accrued compensation related	35,528	(391,096)
Operating lease liabilities	(629,928)	(967,808)
Net cash used in operating activities	<u>(41,794,034)</u>	<u>(33,145,364)</u>
<i>Investing activities</i>		
Purchases of property and equipment	(304,603)	-
Purchase of intangible assets	(495,000)	-
Net cash used in investing activities	<u>(799,603)</u>	<u>-</u>
<i>Financing activities</i>		
Proceeds from issuance of common stock through ESPP	9,973	7,012
Proceeds from issuance of common stock and/or warrants	57,004,412	30,000,000
Payment of financing and offering costs	(4,434,441)	(1,954,678)
Cash paid for stock options cancellation	-	(25,819)
Cash paid for repurchase of warrants	-	(178,225)
Proceeds from exercise of stock options	636,993	-
Proceeds from exercise of warrants	4,792,951	-
Purchase of shares under CGP and Sirtex stock purchase agreements	5,836,731	-
Proceeds from note payable	-	952,744
Principal payments on note payable	(619,105)	(138,244)
Tax withholdings paid on equity awards	(238,976)	(26,859)
Tax withholdings paid related to net share settlement of equity awards	-	(263,100)
Tax shares sold to pay for tax withholdings on equity awards	220,490	26,495
Proceeds from co-promotion agreement	5,000,000	-
Net cash provided by financing activities	<u>68,209,028</u>	<u>28,399,326</u>
Effect of exchange rate changes on cash	<u>(18,620)</u>	<u>(47,280)</u>
Net increase (decrease) in cash and cash equivalents	25,596,771	(4,793,318)
Cash and cash equivalents, at beginning of year	<u>20,354,462</u>	<u>25,147,780</u>
Cash and cash equivalents, at end of year	<u>\$ 45,951,233</u>	<u>\$ 20,354,462</u>
Supplemental disclosure for cash flow information:		
Cash paid during the period for:		
Interest	\$ 10,302	\$ 3,179
Income taxes	\$ 4,992	\$ 2,450
Noncash investing and financing transactions:		
Expiration of warrants	\$ 329,099	\$ 2,465,396
Increase in right-of-use assets and operating lease liabilities resulting from contract modification	\$ 338,819	\$ 5,288,981
Note issued for insurance premium	\$ 1,355,919	\$ 551,803

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 subsidiary, unless the context indicates otherwise, being collectively referred to as the “Company”) began its operations as a biotechnology company in March 2011. The Company has not generated 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 late-stage immuno-oncology company focused on designing, developing and commercializing innovative, proprietary, intra-tumoral DNA-based therapeutics to stimulate and to augment anti-tumor immune responses for the treatment of cancers. Its core technology platform ImmunoPulse® is a drug-device therapeutic modality platform comprised of proprietary intratumoral electroporation (“EP”) delivery devices (the “OncoSec Medical System (“OMS”) Electroporation Device” or “OMS EP Device”) and a proprietary DNA plasmid that triggers transient expression of target protein in cells. The OMS EP Device is designed to deliver plasmid DNA-encoded drugs directly into a solid tumor and promote an immunological response against cancer. The OMS EP Device can be adapted to treat different tumor types, and consists of an electrical pulse generator, a reusable handle and disposable applicators. The Company’s lead product candidate is a DNA-encoded interleukin-12 (“IL-12”) called tavokinogene telseplasmid (“TAVO”). The OMS EP Device is used to deliver TAVO intratumorally, 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 2017, the Company received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration 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 primary focus is to pursue its study of TAVO in combination with KEYTRUDA® (pembrolizumab) in melanoma and triple negative breast cancer (“TNBC”).

The Company’s KEYNOTE-695 study targets advanced melanoma patients who are definitive anti-PD-1 therapy non-responders. In May 2017, the Company entered into a clinical trial collaboration and supply agreement with a subsidiary of Merck in connection with the 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 is the study sponsor and are responsible for external costs. The KEYNOTE-695 study is a registration-directed, Phase 2b open-label, single-arm, multicenter study in approximately 100 patients treated with TAVO in combination with KEYTRUDA® (pembrolizumab) in anti-PD-1 checkpoint (nivolumab or pembrolizumab) relapsed or refractory metastatic melanoma, being conducted in the United States, Canada, Australia and Europe. The study completed enrollment in December 2020. In December 2020, the protocol was amended to include an additional cohort, consisting of patients who progressed on prior treatment of both ipilimumab and nivolumab. Enrollment in this cohort was stopped in September 2021 because of sufficient data collected in this patient subpopulation. The amendment also enabled enrollment of approximately 25 additional patients to be treated with an updated version of the OMS EP Device (using the GenPulse generator and Series 3 Applicator), in preparation for FDA clearance. Based on and subject to the outcome of the study and feedback from FDA, the Company plans to file for accelerated approval with the FDA for this patient population in the second half of 2022.

In May 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, Cohort 1. 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 is the study sponsor and are responsible for external costs. The KEYNOTE-890 study, Cohort 1 final patient treatment was completed in December 2020. Interim data for Cohort 1 was initially presented at the San Antonio Breast Cancer Symposium (“SABCS”) in December 2019, and an update on this cohort is planned for SABCS in December 2021. The study is a Phase 2 open-label, single-arm, multicenter study in the United States and Australia.

In May 2019, the Company commenced an investigator-initiated Phase 1 clinical trial conducted by the University of California San Francisco (“UCSF”) Helen Diller Family Comprehensive Cancer Center (“OMS-131”). This study targets patients with Squamous Cell Carcinoma Head & Neck Cancer and is a single-arm open-label clinical trial in which 68 evaluable patients will receive TAVO, KEYTRUDA® and epacadostat. Recruitment on this study has been halted after the last patient was treated in June 2021 while the Company and UCSF consider alterations in the design of the study.

In June 2020, the Company amended its second clinical trial collaboration and supply agreement with Merck to include another Phase 2 study of TAVO in combination with KEYTRUDA® plus chemotherapy to evaluate the safety and efficacy of the combination in patients with inoperable locally advanced or metastatic triple negative breast cancer. This study is referred to as KEYNOTE-890, Cohort 2. Pursuant to the terms of the amended agreement, both companies will bear their own costs related to the manufacture and supply of their product, as well as be responsible for their own internal costs. The Company is the study sponsor and is responsible for external costs. The KEYNOTE-890, Cohort 2 study began enrolling patients in January of 2021. The Company expects to complete enrollment in this cohort in 2022. The study is a Phase 2 open-label, single arm, multicenter study in the United States and Australia.

In August 2020, the Company commenced an Investigator-Initiated Phase 2 study conducted by the H. Lee Moffitt Cancer Center and Research Institute and the University of South Florida Morsani College of Medicine to evaluate TAVO™ as neoadjuvant treatment (administered before surgery) in combination with intravenous OPDIVO®(nivolumab) in up to 33 patients with operable locally/regionally advanced melanoma. This Investigator-Initiated Phase 2 study has been designed to evaluate whether the addition of TAVO can increase the published anti-tumor response observed with monotherapy OPDIVO®, an anti-PD-1 checkpoint inhibitor, in patients with locally/regionally advanced melanoma prior to surgical resection of tumors. This study began enrolling patients in December of 2020 and is expected to complete enrollment within eighteen months of the start of enrollment.

In November 2020, the Company obtained exclusively licensed rights to the Cliniporator® electroporation gene electrotransfer platform from IGEA Clinical Biophysics. The license encompasses a broad field of use for gene delivery in oncology, including use as part of the Company’s visceral lesion applicator (“VLA”) program. This platform has been used for electrochemotherapy in and outside of Europe in over 200 major oncological centers to treat cutaneous metastatic cancer nodules, including melanoma.

In April 2020, the Company announced that Providence Cancer Institute, a part of Providence St. Joseph Health (“Providence”), is pursuing a first-in-human Phase 1 clinical trial of OncoSec’s novel DNA-encodable, investigational vaccine, CORVax12, which is designed to act as a prophylactic vaccine to prevent COVID-19. CORVax12 consists of the Company’s existing product candidate, TAVO™, in combination with an immunogenic component of the SARS-CoV-2 virus developed by researchers at the National Institutes of Health National Institute of Allergy and Infectious Diseases (“NIAID”). Providence investigators filed and received an Investigator-Initiated Investigational New Drug (“IND”) Application; however, at this time, Providence does not intend to continue further enrollment in this study and has transferred the Investigator Initiated IND to the Company.

In April 2021, the Company announced that it has received authorization to CE mark, GenPulse™, OMS EP Device for use in solid tumors. The CE mark certification augments the Notified Body certification to the International Organization for Standardization's ("ISO") 13485 standard for the design, development, manufacture and distribution of electroporation devices, which is renewed annually, subject to a successful audit. The CE mark certification involved a comprehensive audit of the Company's quality system, as well as thorough evaluation and testing of the OMS EP Device to assure it performs safely and as designed. A CE mark indicates the OMS EP Device complies with Directives of the European Commission and therefore can be marketed within the 31-nation European Economic Area and Switzerland. The GenPulse is being used in certain clinical trial sites in Australia and the EU. The Company is currently seeking FDA agreement to use GenPulse in U.S. clinical sites.

In July 2021, the Company entered into a clinical trial collaboration and supply agreement with Merck with respect to a Phase 3 study of TAVO™ in combination with KEYTRUDA® to evaluate the safety and efficacy of the combination in patients with Stage III or IV unresectable, metastatic melanoma, and who are refractory to prior checkpoint therapy. This study is referred to as KEYNOTE-C87. 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 is the study sponsor and is responsible for external costs. The trial is designed to be a global Phase 3 randomized clinical trial and is intended to support accelerated approval by the U.S. FDA and/or serve as a pivotal study to support a full licensure.

The Company intends to continue to pursue potential new trials and studies related to TAVO, in various tumor types. In addition, the Company is also developing its next-generation EP 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 and delivered intratumorally using EP. Specifically, the Company is developing a new, propriety technology to potentially treat liver, lung, bladder, pancreatic and other difficult to treat visceral lesions through the direct delivery of plasmid-based IL-12 with a new Visceral Lesions Applicator ("VLA").

The new VLA has been designed to work with low voltage EP generators, including but not limited to the Company's proprietary APOLLO™ EP generator and Cliniporator® to leverage plasmid-optimized EP and enhance the depth of transfection of immunologically relevant genes into cells located in visceral organs. In early 2020, the Company had two poster presentations, one at the Society for Interventional Oncology ("SIO") and one at the Society for Interventional Radiology, where it presented preclinical data on both the new VLA and APOLLO generator. Additionally, the Company has successfully completed several large animal studies and aim to bring the new VLA into the clinic in 2023. By using the Company's next-generation technology with the new VLA (and in cutaneous/subcutaneous settings as well), the Company's goal is to reverse the immunosuppressive mechanisms of a tumor, as well as to expand the Company's pipeline. The Company believes that the flexibility of the Company's proprietary plasmid-DNA technology allows the Company to deliver other immunologically relevant molecules into the tumor microenvironment in addition to the delivery of plasmid-DNA encoding for IL-12.

The Company established a collaboration with Emerge Health Pty ("Emerge"), the leading Australian company providing full registration, reimbursement, sales, marketing and distribution services of therapeutic products in Australia and New Zealand, to commercialize TAVO and make it available under Australia's Special Access Scheme ("SAS"). Emerge was acquired in late 2019 and in June 2021 informed the Company that oncology will not be a core therapeutic focus for Emerge into the future. The collaboration was terminated effective October 1, 2021, and the Company will not continue to participate in the SAS program.

## Note 2—Significant Accounting Policies

### *Principles of Consolidation*

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, OncoSec Medical Australia PTY LTD. All significant intercompany accounts and transactions have been eliminated in consolidation.

### *Use of Estimates*

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America (“U.S. GAAP”), which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Such estimates include going concern, stock-based compensation, the accrual of research, product development and clinical obligations, impairment of long-lived assets, determining the Incremental Borrowing Rate for calculating Right-Of-Use (“ROU”) assets and lease liabilities 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 may differ 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 in both the United States and Australia and such balances commonly exceed the \$250,000 amount insured by the Federal Deposit Insurance Corporation and \$250,000 AUD (approximately \$183,000 USD) insured by the Australian Financial Claims Scheme. 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.

### *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

Construction-in-progress is stated at cost, which relates to the cost of equipment not yet placed into service. No depreciation expense is recorded on construction-in-progress until such time as the relevant assets are completed and put into use.

#### *Intangible Assets*

Definite life intangible assets include a license. Intangible assets are recorded at cost. License agreements cost represent the fair value of the license agreement on the date acquired. Intangible assets are amortized on a straight-line basis over their estimated 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(s);
- 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 assets. 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.

#### *Research and Development Expenses*

Research and development expenses consist of costs incurred for internal projects, as well as partner-funded collaborative research and development activities. These costs include direct and research-related overhead expenses, which include salaries, stock-based compensation and other personnel-related expenses, facility costs, supplies, depreciation of facilities and laboratory equipment, as well as research consultants and the cost of funding research at universities and other research institutions, and are expensed as incurred. Costs to acquire technologies that are utilized in research and development that have no alternative future use, are expensed when incurred. In accordance with ASC 730-20, the Company accounts for upfront, non-refundable research and development payments received from a related party as a long-term liability as there has not been a substantive and genuine transfer of risk and there is a presumption that the Company is obligated to repay the related party.

#### *Accruals for Research and Development Expenses and Clinical Trials*

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts vary from contract to contract and may result in payment terms that do not match the periods over which materials or services are provided under such contracts. The Company accounts for these expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company determines accrual estimates through financial models and takes into account discussion with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates.

### *Fair Value of Financial Instruments*

The carrying amounts for cash and cash equivalents, prepaid expenses, accounts payable and accrued expenses and notes payable 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 the 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.
- 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.
- 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 management.

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.

The Company had no assets or liabilities that required remeasurement on a recurring basis as of July 31, 2021 and July 31, 2020.

### *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, 2021 and July 31, 2020, 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:

	<u>July 31, 2021</u>	<u>July 31, 2020</u>
Stock options	3,111,642	1,442,856
Restricted stock units	442,749	34,914
Warrants	1,706,190	3,114,288
Total	<u>5,260,581</u>	<u>4,592,058</u>

### Stock-Based Compensation

The Company grants equity-based awards (typically stock options or restricted stock units) under its stock-based compensation plan and outside of its stock-based compensation plan, with terms generally similar to the terms under the Company's stock-based compensation plan. The Company estimates the fair value of stock option awards using the Black-Scholes option valuation model. For employees, directors and consultants, the fair value of the award is measured on the grant date. 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.

### 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 and (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.

### Leases

The Company determines if an arrangement is a lease at inception. Operating lease ROU assets represent the Company's right to use an underlying asset during the lease term, and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating leases are included in ROU assets, current operating lease liabilities, and long-term operating lease liabilities on the Company's consolidated balance sheets.

Lease ROU assets and lease liabilities are initially recognized based on the present value of the future minimum lease payments over the lease term at commencement date calculated using the Company's incremental borrowing rate applicable to the lease asset, unless the implicit rate is readily determinable. ROU assets also include any lease payments made at or before lease commencement and exclude any lease incentives received. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the consolidated balance sheets. The Company's leases do not contain any residual value guarantees. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The Company accounts for lease and non-lease components as a single lease component for all its leases.

#### *Foreign Currency Translation*

The Company uses the U.S. Dollar as the reporting currency for its financial statements. Functional currency is the currency of the primary economic environment in which an entity operates. The functional currency of the Company's wholly owned subsidiary is the Australian dollar.

Assets and liabilities of the Company's subsidiary are translated into U.S. Dollars at period-end foreign exchange rates, and revenues and expenses are translated at average rates prevailing throughout the period. Translation adjustments are included in "Accumulated other comprehensive income" as a separate component of stockholders' equity, and in the "Effect of exchange rate changes on cash and cash equivalents," on the Company's consolidated statements of cash flows. Transaction gains and losses including intercompany transactions denominated in a currency other than the functional currency of the entity involved are included in "Foreign currency exchange gain (loss), net" on the Company's consolidated statements of operations.

#### *Accumulated 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 wholly-owned Australian 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% 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 Accounting Standards Codification ("ASC") 740 "Income Taxes" 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. The effects of the 2017 Tax Act did not have a significant impact on the Company's consolidated financial statements during the years ended July 31, 2021 and 2020.

On March 27, 2020, the president signed into law the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) providing nearly \$2 trillion in economic relief to eligible businesses impacted by the coronavirus outbreak. The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer social security payments, net operating loss (“NOL”) utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. In addition to the Small Business Administration (“SBA”) loan received in April 2020 (See Note 5), the Company continues to review, and intends to seek, any other available potential benefits under the CARES Act as well as any future legislation signed into law during 2021. Other than the forgiveness of the SBA loan, the effects of the CARES Act did not have a significant impact on the Company’s consolidated financial statements during the year ended July 31, 2021.

#### *Recent Accounting Pronouncements*

In August 2020, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40)—Accounting For Convertible Instruments and Contracts in an Entity’s Own Equity. The ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The ASU also simplifies the diluted net income per share calculation in certain areas. The new guidance is effective for annual and interim periods beginning after December 15, 2020, and early adoption is permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently evaluating the impact that this new guidance will have on its consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force). The ASU clarifies and reduces diversity in an issuer’s accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The ASU provides guidance that will clarify whether an issuer should account for a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as (1) an adjustment to equity and, if so, the related earnings per share (EPS) effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The new guidance is effective for annual and interim periods beginning after December 15, 2021, and early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the impact that this new guidance will have on its consolidated financial statements.

#### **Note 3—Going Concern and Management’s Plans**

The Company has sustained losses in all reporting periods since inception, with an accumulated deficit of approximately \$252 million as of July 31, 2021. These losses are expected to continue for an extended period of time. Further, the Company has never generated any cash from its operations and does not expect to generate such cash in the near term. The aforementioned factors raise substantial doubt about the Company’s ability to continue as a going concern within one year from the issuance date of the consolidated financial statements. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the consolidated financial statements are issued.

As of October 12, 2021, the Company had cash and cash equivalents of \$37.5 million. Since inception, cash flows from financing activities has been the primary source of the Company’s liquidity. Based on the Company’s current cash levels, the Company believes its cash resources are insufficient to meet the Company’s anticipated needs for the 12 months following the date the consolidated financial statements are issued.

The Company recognizes it will need to raise 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. There is no assurance that additional financing will be available to the Company when needed, that management will be able to obtain financing on terms acceptable to the Company, or whether the Company will become profitable and generate positive operating cash flow. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. The ongoing COVID-19 pandemic has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all. If the Company is unable to raise sufficient additional funds when needed, on favorable terms or at all, the Company will not be able to continue the development of its product candidates as currently planned or at all, will need to reevaluate its planned operations and may need to delay, scale back or eliminate some or all of its development programs, reduce expenses or cease operations, any of which would have a significant negative impact on its prospects and financial condition.

#### Note 4 – Balance Sheet Details

##### Property and Equipment

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

	<u>July 31, 2021</u>	<u>July 31, 2020</u>
Equipment and furniture	\$ 1,919,301	\$ 1,859,824
Computer software	109,242	109,242
Leasehold improvements	32,651	21,934
Construction in progress	234,409	-
Property and equipment, gross	<u>2,295,603</u>	<u>1,991,000</u>
Accumulated depreciation and amortization	<u>(1,366,782)</u>	<u>(1,176,506)</u>
Total	<u>\$ 928,821</u>	<u>\$ 814,494</u>

Depreciation and amortization expense recorded for the years ended July 31, 2021 and 2020 was approximately \$0.2 million.

##### Intangible Assets

Intangible assets, net, is comprised of the following:

	<u>July 31, 2021</u>
License	\$ 495,000
Accumulated amortization	(46,588)
Total	<u>\$ 448,412</u>

In November 2020, the Company licensed generator technology for use in its clinical trials and other research and development efforts. Unless earlier terminated, the term of the license agreement will remain in effect for 85 months. The Company has determined that the license has alternative future uses in research and development projects. The value of the acquired license is recorded as an intangible asset with amortization over the estimated useful life of 85 months.

Intangible asset amortization expense recorded for the years ended July 31, 2021 and 2020 was less than \$0.1 million and \$0, respectively.

At July 31, 2021, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows:

**Years ending July 31,**

2022	\$	69,882
2023		69,882
2024		69,882
2025		69,882
2026		69,882
Thereafter		99,002
<b>Total</b>	<b>\$</b>	<b>448,412</b>

*Accounts Payable and Accrued Liabilities*

Accounts payable and accrued liabilities are comprised of the following:

	<u>July 31, 2021</u>	<u>July 31, 2020</u>
Research and development costs	\$ 4,206,926	\$ 4,730,347
Professional services fees	1,229,040	3,097,881
Other	125,679	94,808
<b>Total</b>	<b>\$ 5,561,645</b>	<b>\$ 7,923,036</b>

*Accrued Compensation*

Accrued compensation is comprised of the following:

	<u>July 31, 2021</u>	<u>July 31, 2020</u>
Accrued payroll	\$ 311,590	\$ 279,473
401K payable	9,065	5,654
<b>Total</b>	<b>\$ 320,655</b>	<b>\$ 285,127</b>

**Note 5 – Notes Payable**

On April 27, 2020, the Company was granted a two-year loan (the “Loan”) from the Banc of California in the aggregate amount of \$952,744, pursuant to the Paycheck Protection Program (the “PPP”) under the CARES Act, which was enacted March 27, 2020. Interest accrues at 1% per year, effective on the date of initial disbursement.

The Company submitted its application for full loan forgiveness on January 6, 2021. On February 12, 2021, the Company received notice that the full Loan amount of \$952,744 and \$8,046 of accrued interest had been forgiven. As a result, the Company recorded a \$960,790 gain on extinguishment of debt in its consolidated statement of operations for the year ended July 31, 2021.

On June 18, 2020, the Company entered into a finance agreement with AFCO Premium Credit LLC (“AFCO”). Pursuant to the terms of the agreement, AFCO loaned the Company the principal amount of \$551,803, which accrues interest at 3.381% per annum, to partially fund the payment of the premium of the Company’s director & officer insurance. The agreement requires the Company to make ten monthly payments of \$56,039, including interest, starting on July 18, 2020. As of July 31, 2021, the outstanding balance related to this finance agreement was paid in full.

On July 1, 2021, the Company entered into a finance agreement with AFCO Premium Credit LLC (“AFCO”). Pursuant to the terms of the agreement, AFCO loaned the Company the principal amount of \$1,355,919, which would accrue interest at 2.894% per annum, to partially fund the payment of the premium of the Company’s Director & Officer insurance. The agreement requires the Company to make eleven monthly payments of \$125,056, including interest starting on July 18, 2021. At July 31, 2021, the outstanding balance related to this finance agreement was \$1,234,133.

Future minimum payments under note payable liabilities as of July 31, 2021 are as follows:

<b>Years ending July 31,</b>		
2022	\$	1,234,133
Total	\$	<u>1,234,133</u>

#### **Note 6 – Stockholders’ Equity**

##### *January 2021 Offering*

On January 25, 2021, the Company completed the offer and sale of an aggregate of 7,711,284 shares of its common stock at a purchase price of \$5.45 per share in a public offering. The gross proceeds from the offering were approximately \$42.0 million, and the net proceeds, after deducting the placement agent’s fee and other offering fees and expenses paid by the Company, were approximately \$39.1 million. In connection with the offering, the Company paid the placement agent and other financial advisors an aggregate cash fee equal to 6.0% of the gross proceeds of the offering, as well as legal and other expenses equal to approximately \$0.4 million.

##### *August 2020 Offering*

On August 19, 2020, the Company completed the offer and sale of an aggregate of 4,608,589 shares of its common stock at a purchase price of \$3.25 per share in a registered direct offering. The gross proceeds from the offering were approximately \$15.0 million, and the net proceeds, after deducting the placement agent’s fee and other offering fees and expenses paid by the Company, were approximately \$13.5 million. In connection with the offering, the Company paid the placement agent and other financial advisors an aggregate cash fee equal to 8.0% of the gross proceeds of the offering, as well as legal and other expenses equal to approximately \$0.3 million.

##### *China Grand Pharmaceutical and Healthcare Holdings Limited and Sirtex Medical US Holdings, Inc.*

On February 7, 2020, the Company closed (the “Closing”) a strategic transaction (the “Transaction”) with Grand Decade Developments Limited, a direct, wholly-owned subsidiary of China Grand Pharmaceutical and Healthcare Holdings Limited, a company formed under the laws of the British Virgin Islands (“CGP”), and its affiliate, Sirtex Medical US Holdings, Inc., a Delaware corporation (“Sirtex” and, together with CGP, the “Buyers”). On October 10, 2019, the Company and the Buyers entered into Stock Purchase Agreements (as amended, the “Purchase Agreements”) pursuant to which the Company agreed to sell and issue to CGP and Sirtex 10,000,000 shares and 2,000,000 shares, respectively, of the Company’s common stock for a total purchase price of \$30 million. The net proceeds, after deducting offering fees and expenses paid by the Company, were approximately \$28.0 million. The Company evaluated whether any proceeds received in the Stock Purchase Agreements should be allocated to other agreements entered into at the same time and concluded that there should not be any allocation due to the de minimis value of the other agreements. Upon Closing, CGP and Sirtex owned 43.95% and 8.79%, respectively, of the outstanding shares of common stock of the Company.

During the year ended July 31, 2021, shares of common stock issued to third party investors related to warrant exercises totaled 1,389,261. On April 16, 2021, in accordance with their respective stock purchase agreements originally entered into on October 10, 2019, CGP and Sirtex, related parties of the Company, exercised their rights to purchase additional shares of common stock at a purchase price equal to the same exercise price paid by each warrant holder in order to maintain their respective ownership percentages of the outstanding shares of common stock of the Company as of October 10, 2019. These significant related party relationships are based on Sirtex’s approximate 8% ownership of the outstanding shares of the Company’s common stock, and that of its significant equity holder, CGP (which owns 49% of Sirtex), which owns approximately 42% of the outstanding shares of the Company’s common stock. The Company issued 1,409,838 shares of common stock to CGP at an exercise price of \$3.45 per share, resulting in gross proceeds of approximately \$4.8 million. The Company issued 281,968 shares of common stock to Sirtex at an exercise price of \$3.45 per share, resulting in gross proceeds of approximately \$1.0 million.

## Purchase Agreements

The Purchase Agreements include customary covenants that obligate the Company to use commercially reasonable efforts to cause the purchased shares to be approved for listing on The Nasdaq Capital Market, and a contractual anti-dilution mechanism that accounts for the Company's outstanding options and warrants, as well as other customary covenants. In addition, the Company, CGP, and Sirtex each shall pay their respective fees and expenses in connection with the transactions contemplated by the Purchase Agreements. On the date of the Closing the Company reimbursed legal fees and expenses incurred by each of CGP and Sirtex in an aggregate amount of \$600,000, which are part of the offering fees and expenses noted above.

## Stockholders Agreements

Concurrently with the execution and delivery of the Purchase Agreements, the Company, CGP, and Sirtex entered into Stockholders Agreements (the "Stockholders Agreements"), to be effective upon the Closing, pursuant to which, among other things, CGP and Sirtex received and exercised the option to nominate a combined total of three (3) members to the Board of Directors, initially at the Closing, and thereafter at every annual meeting of the stockholders of the Company in which directors are generally elected, including at every adjournment or postponement thereof. If either CGP or Sirtex beneficially owns less than 40% of the shares acquired pursuant to the Purchase Agreements, either (as applicable) shall have the right to nominate members to the Board of Directors in proportion with their ownership of the issued and outstanding common stock.

In addition, CGP and Sirtex will have certain rights of participation in future financings as well as a right of first refusal related to future potential transactions. The Stockholder Agreements implement a 70% supermajority approval by the Board of Directors for certain actions, as well as stockholder consent rights for CGP, all of which are conditioned upon CGP and Sirtex maintaining certain ownership thresholds.

## First Amendment to the Purchase Agreements and Stockholder Agreement

On November 26, 2019, the Company entered into an amendment (the "First Amendment") to the Purchase Agreements with CGP and Sirtex and to the Stockholder Agreement with CGP. The First Amendment provided that following the Closing, the Company would, at its next annual meeting of stockholders (instead of at the Special Meeting, as previously required by the Purchase Agreements), seek, among other things, the requisite stockholder approval for the Company to amend its Articles of Incorporation to (i) increase the Company's authorized shares of common stock by 4,000,000 shares from 26,000,000 shares to 30,000,000 shares and (ii) add the corporate opportunity waiver (described below). In addition, the First Amendment (a) amended the Purchase Agreements to provide that a material breach of the Purchase Agreements shall be deemed to have occurred if the Closing does not occur within 10 business days of the satisfaction of the conditions to the Company's obligations, including the approval of the Proposed Transactions by the Company's shareholders and (b) amended the Stockholder Agreement with CGP to provide that rescission of the corporate opportunity waiver is subject to the enhanced voting requirements described below.

In connection with approving the First Amendment, to the extent permitted by applicable law, the Board has (i) renounced any interest or expectancy of the Company in, or in being offered an opportunity to participate in, business opportunities that are presented to CGP and certain related parties, the directors on the Board which have been nominated by CGP or Sirtex pursuant to the Stockholder Agreements, any other person or persons who are, at the time, associated with or nominated by, or serving as representatives of either CGP or Sirtex, or the respective affiliates of the foregoing parties (including their officers or directors who are employees, officers, directors, managers, stockholders or members) (the "Covered Persons"), (ii) resolved that none of such Covered Persons shall have any obligation to refrain from (a) engaging in similar activities or lines of business as the Company or developing or marketing any products or services that compete, directly or indirectly, with those of the Company, (b) investing or owning any interest publicly or privately in, serving as a director or officer of or developing a business relationship with, any person engaged in similar activities or lines of business as, or otherwise in competition with, the Company, (c) doing business with any client or customer of the Company or (d) employing or otherwise engaging a former officer or employee of the Company, and (iii) resolved that neither the Company nor any of its subsidiaries shall have any right to be offered any opportunity to participate or invest in any venture engaged or to be engaged in by any Covered Person.

On May 29, 2020, the Company's shareholders approved amendments to its Articles of Incorporation to, among other things, increase the Company's authorized shares of common stock by 74,000,000 shares from 26,000,000 shares to 100,000,000 shares and include a waiver of the duty of certain directors to present corporate opportunities to the Company.

#### *Common Stock Option Exercise*

During the year ended July 31, 2021, shares of common stock issued related to option exercises totaled 377,361. The Company realized proceeds of \$0.6 million from the stock option exercises.

#### *Outstanding Warrants*

During the year ended July 31, 2021, shares of common stock issued related to warrant exercises totaled 1,389,261. The Company realized proceeds of approximately \$4.8 million from the warrant exercises.

At July 31, 2021, the Company had outstanding warrants to purchase 1,706,190 shares of its common stock, with exercise prices ranging from \$3.45 to \$16.80, all of which were classified as equity instruments. These warrants expire at various dates between October 2022 and May 2024.

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

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 4,600,000 shares of common stock for issuance. 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. Incentive 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.

At the Company's Annual Meeting of Stockholders on April 29, 2021, the Company's stockholders approved an amendment to the 2011 Plan to increase the number of shares authorized under the 2011 Plan by 1,250,000 shares, from 3,350,000 shares to 4,600,000 shares.

#### *Modification of Stock Option Awards*

During the year ended July 31, 2021, the Compensation Committee of the Company's Board of Directors approved the accelerated vesting of 791,019 and 91,666 previously granted time-vesting awards for all employees and four directors, respectively. The Company accounted for the effects of the stock option modifications described above under the guidance of ASC 718 as follows:

- The unamortized compensation costs associated with the time-vesting options was expensed on the date of acceleration, which was approximately \$1.2 million and \$0.1 million for the employees and directors, respectively.
- Upon modification, it is required under ASC 718 to analyze the fair value of the instruments, before and after the modification, recognizing additional compensation cost for any incremental value. The Company computed the fair value of the award immediately prior to the modification and compared the fair value to that of the modified award. Since the value of the awards were less after the modification as compared to immediately prior to the modification, no additional compensation expense was recorded.

During the year ended July 31, 2020, the Company cancelled 878,534 outstanding common stock option awards under the following terms:

- The Company entered into Stock Option Cancellation Agreements (the “Cancellation Agreements”) with certain executive officers, directors and other senior level employees of the Company, pursuant to which such individuals (the “Senior Level Option Holders”) agreed to the voluntary surrender and cancellation of certain previously granted stock options (the “Cancelled Options”) to purchase in the aggregate 699,140 shares of the Company’s common stock. Under the terms of the Cancellation Agreements, each Senior Level Option Holder and the Company acknowledged and agreed that the surrender and cancellation of the Cancelled Options was without any expectation on the part of each Senior Level Option Holder to receive, and without any obligation on the Company to pay or grant, any cash, equity awards or other consideration presently or in the future with respect to the Cancelled Options.
- The Company cancelled outstanding common stock options held by employees and consultants other than the Senior Level Option Holders, pursuant to which such individuals were previously granted stock options to purchase in the aggregate 179,394 shares of the Company’s common stock, for aggregate cash consideration of approximately \$26,000.

The Company accounted for the effects of the stock option modifications described above under the guidance of ASC 718 as follows:

- A cancellation of an award that is not accompanied by the concurrent grant of (or offer to grant) a replacement award or other valuable consideration shall be accounted for as a repurchase for no consideration. Accordingly, any previously unrecognized compensation is recognized at the cancellation date.
- The amount of cash paid to settle an equity-classified award is charged directly to equity as long as that amount is equal to or less than the fair-value-based measure of the award on the settlement date. To the extent that the settlement consideration exceeds the fair-value-based measure of the equity-classified award on the settlement date, that difference is recognized as additional compensation cost. The cash paid to settle employee and consultant equity-classified awards, other than the Senior Level Option Holders, was less than the fair-value-based measure of the award on the settlement date. The approximately \$26,000 in cash paid to settle the equity-classified awards was charged directly to additional paid in capital.

Following the cancellation of the outstanding stock option awards described above, there were 15,000 stock option awards outstanding under the 2011 Plan. The Company recorded the previously unrecognized compensation cost related to the cancelled outstanding stock option awards of approximately \$1.2 million on the date of cancellation.

#### *Modification of Award*

On October 2, 2019, the Company entered into an amendment to a consulting agreement with a consulting firm. Prior to the amendment, the Company was required to issue 3,000 shares of restricted common stock monthly for services through July 2, 2020. As per the terms of the amended agreement, starting October 2, 2019, the Company was required to issue 15,000 shares of restricted common stock monthly for services through July 2, 2020. Upon modification, it is required under ASC 718 to analyze the fair value of the instruments, before and after the modification, recognizing additional compensation cost for any incremental value. The Company computed the fair value of the award prior to the amendment and compared the fair value to that of the modified award. The incremental compensation cost of approximately \$0.2 million resulting from the modification was recognized ratably over the remaining term of the consulting agreement.

### Bonuses Paid in Common Stock

On March 11, 2020, the Compensation Committee of the Board of Directors approved the payment of discretionary bonuses to our Chief Executive Officer and seven other officers in an aggregate amount equal to \$836,250 (the “2019 Incentive Bonuses”), in recognition of the Company’s achievement of certain operational and strategic objectives in 2019 and each individual’s ongoing contributions to the success of the Company.

In order to conserve cash and improve cash flow, the Compensation Committee determined that it would be in the Company’s best interests to pay one-half of the 2019 Incentive Bonuses, or \$418,125, in cash, and one-half of the 2019 Incentive Bonuses in shares of our common stock (“Contingent Bonus Shares”), subject to approval by the Board of Directors and contingent on stockholder approval of the issuance of the Contingent Bonus Shares at the Company’s annual shareholder meeting (the “Annual Meeting”). On April 14, 2020, the Board of Directors approved the issuance of the Contingent Bonus Shares to the officers, contingent on stockholder approval at the Annual Meeting, and determined that the aggregate number of Contingent Bonus Shares would be 302,989 shares (the “Bonus Share Pool”), which was determined by dividing \$418,125 by \$1.38, the closing price of our common stock on March 11, 2020.

On May 29, 2020, the Company’s stockholders approved the Bonus Share Pool and the Contingent Bonus Shares were granted to the officers following the Annual Meeting. The Contingent Bonus Shares are subject to a six-month holding period requirement. The Company, using the net shares method, issued an aggregate of 185,003 shares of Company common stock to pay one-half of the discretionary bonuses. 117,986 shares of Company common stock were withheld at vesting to cover individual tax withholding obligations. The Company recorded compensation expense related to the Contingent Bonus Shares of \$0.7 million during the year ended July 31, 2020, which was determined by multiplying the Bonus Share Pool, or 302,989, by \$2.23, the closing price of our common stock on May 29, 2020.

### Stock Options

During the year ended July 31, 2021, the Company granted options to purchase 1,360,826, 337,500 and 25,000 shares of its common stock to employees, directors and a consultant under the 2011 Plan, respectively. The stock options issued to employees have a 10-year term, vest over two to three years and have exercise prices ranging from \$2.22 to \$7.64. The stock options issued to directors have a 10-year term, vest over one year and have an exercise price of \$3.16 to \$3.43. The stock options issued to the consultant have a 10-year term, vest over one year and have an exercise price of \$3.82.

During the year ended July 31, 2021, in accordance with Nasdaq Listing Rule 5635(c)(4), the Company granted inducement equity awards that consisted of options to purchase 590,000 shares of its common stock to employees outside the 2011 Plan. The stock options issued to the employee are nonqualified, have a 10-year term, vest over one to two years and have exercise prices ranging from \$3.56 to \$7.45.

The Company accounts for stock-based compensation based on the fair value of the stock-based awards granted and records forfeitures as they occur. As such, the Company recognizes stock-based compensation cost only for those stock-based awards that vest over their requisite service period, based on the vesting provisions of the individual grants. 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.

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

	<b>Year Ended July 31, 2021</b>	<b>Year Ended July 31, 2020</b>
Expected term (years)	5.00–6.50 years	5.00–6.50 years
Risk-free interest rate	0.27 -1.13%	0.30 – 1.70%
Volatility	85.31 – 89.08%	80.93 –87.95%
Dividend yield	0%	0%

The Company's expected volatility is derived from the historical daily change in the market price of its common stock. The Company uses the simplified method to calculate the expected term of options issued to employees, non-employees and directors, as the Company does not have much stock option exercise history and thus does not have enough information on exercise behavior to calculate a refined expected term based on that information. 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 year ended July 31, 2021:

	Options	Weighted Average Exercise Price	Weighted - average Remaining Contract	Aggregate Intrinsic Value (\$000)
<b>Outstanding - July 31, 2020</b>	1,442,856	\$ 1.65		
Granted	2,313,326	\$ 4.06		
Exercised	(377,361)	\$ 1.69		
Forfeited/Cancelled	(267,179)	\$ 3.58		
<b>Outstanding - July 31, 2021</b>	<u>3,111,642</u>	\$ 3.27	9.2	\$ 639
<b>Exercisable - July 31, 2021</b>	<u>1,685,481</u>	\$ 2.66	8.9	\$ 603

The weighted-average grant date fair value of stock options granted during the years ended July 31, 2021 and 2020 was \$2.85 and \$1.67, respectively. The total intrinsic value of options exercised during the years ended December 31, 2021 and 2020 was approximately \$1.4 million and \$0, respectively.

As of July 31, 2021, the Company has approximately \$3.3 million in unrecognized stock-based compensation expense attributable to the outstanding options, which is expected to be recognized over a weighted-average period of 1.62 years. The total fair value of shares vested during the years ended July 31, 2021 and 2020 was approximately \$3.5 million and \$2.6 million, respectively.

Stock-based compensation expense recorded in the Company's consolidated statements of operations for the year ended July 31, 2021 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$4.4 million. Of the total expense, \$2.6 million was recorded to research and development and \$1.8 million was recorded in general and administrative in the Company's consolidated statements of operations for the year ended July 31, 2021.

Stock-based compensation expense recorded in the Company's consolidated statements of operations for the year ended July 31, 2020 resulting from stock options awarded to the Company's employees, directors and consultants was approximately \$2.6 million, which included approximately \$1.2 million related to the cancellation of certain stock option awards. Of the total expense, \$1.3 million was recorded to research and development and \$1.3 million was recorded in general and administrative in the Company's consolidated statements of operations for the year ended July 31, 2020.

#### *Restricted Stock Units ("RSUs")*

For the year ended July 31, 2021, the Company recorded \$0.7 million, in stock-based compensation related to RSUs, which is reflected in the consolidated statements of operations. For the year ended July 31, 2020, the Company recorded \$0.3 million in stock-based compensation related to RSUs, which is reflected in the consolidated statements of operations.

The following table summarize restricted stock units issued and outstanding:

	RSUs	Weighted Average Grant Date Fair Value
<b>Nonvested - July 31, 2020</b>	34,914	\$ 0.71
Granted	588,875	\$ 3.23
Vested	(178,540)	\$ 2.73
Forfeited/Cancelled	(2,500)	\$ 1.64
<b>Nonvested - July 31, 2021</b>	<b>442,749</b>	<b>\$ 3.24</b>

As of July 31, 2021, there was approximately \$1.4 million unrecognized compensation cost related to unvested RSUs. This amount is expected to be recognized over a weighted-average period of 1.9 years.

#### *Shares Issued to Directors*

In April 2020, the Company granted a director 12,500 shares of common stock under the 2011 Plan for services rendered. The shares vested immediately and the closing price of the Company's common stock on the date of grant was \$1.55 per share. The Company recorded compensation expense relating to the share issuance of approximately \$19,000 during the year ended July 31, 2020.

#### *Shares Issued to Consultants*

During the year ended July 31, 2021, 137,500 shares of common stock valued at approximately \$0.5 million were issued to consultants for services. The common stock share values were based on the dates the shares were granted.

During the year ended July 31, 2020, 184,499 shares of common stock valued at approximately \$0.9 million, were issued to consultants for services. The common stock share values were based on the dates the shares were granted.

#### *2015 Employee Stock Purchase Plan*

Under the Company's 2015 Employee Stock Purchase Plan ("ESPP"), the Company is authorized to issue 50,000 shares of the Company's common stock. The eleventh offering period under the ESPP ended on July 31, 2021, with 2,257 shares purchased and distributed to employees and the tenth offering period under the ESPP ended on January 31, 2021, with 1,358 shares purchased and distributed to employees. The ninth offering period under the ESPP ended on July 31, 2020, with 1,358 shares purchased and distributed to employees, and the eighth offering period under the ESPP ended on January 31, 2020, with 2,841 shares purchased and distributed to employees. At July 31, 2021, there were 29,794 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 July 31, 2021, the following assumptions were used: six-month maturity, 0.07% risk free interest, 88.03% volatility, 0% forfeitures and \$0 dividends. For the six-month offering period ended January 31, 2021, the following assumptions were used: six-month maturity, 0.1% risk free interest, 122.84% volatility, 0% forfeitures and \$0 dividends.

For the six-month offering period ended July 31, 2020, the following assumptions were used: six-month maturity, 1.54% risk free interest, 76.59% volatility, 0% forfeitures and \$0 dividends. For the six-month offering period ended January 31, 2020, the following assumptions were used: six-month maturity, 2.04% risk free interest, 90.64% volatility, 0% forfeitures and \$0 dividends.

Approximately \$10,300 and \$3,800 was recorded as stock-based compensation during the years ended July 31, 2021 and 2020, respectively.

*Common Stock Reserved for Future Issuance*

The following table summarizes all common stock reserved for future issuance at July 31, 2021:

Common Stock options outstanding (within the 2011 Plan and outside of the terms of the 2011 Plan)	3,111,642
Common Stock reserved for restricted stock unit release	442,749
Common Stock authorized for future grant under the 2011 Plan	808,516
Common Stock reserved for warrant exercise	1,706,190
Shares issuable under CGP and Sirtex stock purchase agreements	1,924,001
Commons Stock reserved for future ESPP issuance	29,794
<b>Total common stock reserved for future issuance</b>	<b>8,022,892</b>

**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 statements of operations for the years ended July 31, 2021 and 2020.

The Company is subject to taxation in the United States, various states and in Australia. The Company’s tax years for 2007 and forward, 2010 and forward and 2017 and forward are subject to examination by the United States federal tax authorities, California tax authorities and New Jersey tax authorities, respectively, due to the carry forward of unutilized net operating losses and research and development credits.

At July 31, 2021, the Company had federal, California and New Jersey net operating loss carryforwards of approximately \$206 million, \$87 million and \$80 million, respectively. In addition, the Company has federal, California and New Jersey research and development tax credit carryforwards of approximately \$3.4 million, \$2.4 million and \$0.3 million, respectively. The Company also has California Hiring Credits of approximately \$9,300. The federal net operating losses incurred in years beginning after January 1, 2018 in the amount of \$102 million can be carried forward indefinitely. The remaining \$104 million of federal net operating loss, research tax credit carryforwards and California and New Jersey net operating loss carryforwards will begin to expire in 2029 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 \$5.2 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.

Set forth below is the (benefit) provision for income taxes for continuing operations for the years ended July 31:

All figures below are rounded to the nearest thousand	<b>2021</b>	<b>2020</b>
Current:	\$	\$
Federal	-	-
State	(2,412,000)	(872,000)
Foreign	-	-
<b>Total (benefit from) provision for income taxes</b>	<b>\$ (2,412,000)</b>	<b>\$ (872,000)</b>

Significant components of the Company's deferred tax assets as of July 31, 2021 and 2020 are listed below:

All figures below are rounded to the nearest thousand	<b>2021</b>	<b>2020</b>
Net operating loss carryforwards	\$ 56,369,000	\$ 46,623,000
Credits	5,566,000	4,311,000
Start-up costs	17,000	21,000
Accumulated depreciation	74,000	98,000
Option and stock awards	1,179,000	386,000
Other	180,000	122,000
<b>Net deferred tax assets</b>	<b>63,385,000</b>	<b>51,561,000</b>
Valuation allowance for deferred tax assets	(63,385,000)	(51,561,000)
<b>Net deferred taxes</b>	<b>\$ -</b>	<b>\$ -</b>

A valuation allowance of \$63.4 million and \$51.6 million at July 31, 2021 and 2020, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain. The valuation allowance increased by \$11.8 million and increased by \$7.8 million for the years ended July 31, 2021 and 2020, respectively.

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

	<b>2021</b>	<b>2020</b>
Federal tax benefit at the expected statutory rate	21.00%	21.00%
State income tax, net of federal tax benefit	4.01%	1.60%
Non-deductible expenses	(1.17)%	(0.76)%
Tax impact of stock option cancellations	-%	(10.04)%
Tax impact of sales of state net operating losses and credits	(1.07)%	(0.4)%
Change in valuation allowance	(20.05)%	(11.46)%
Other	2.35%	2.08%
<b>Income tax benefit - effective rate</b>	<b>5.07%</b>	<b>2.02%</b>

#### *Sale of New Jersey Net Operating Losses*

In June 2021, the Company received \$2.4 million in net proceeds from the sale of its New Jersey Net Operating Losses under the State of New Jersey NOL Transfer Program.

In May 2020, the Company received \$0.9 million in net proceeds from the sale of its New Jersey Net Operating Losses under the State of New Jersey NOL Transfer Program.

## **Note 9 – Commitments and Contingencies**

### *Contingencies*

In June 2019, Dana Farber Cancer Institute (“DFCI”) and OncoSec (each a “Party” and collectively the “Parties”) entered into a Sponsored Research Agreement (the “SRA”). On May 11, 2020, the SRA was terminated by DFCI, after a dispute arose between the parties. The Parties resolved the dispute through mediation and reached an agreement in principle. OncoSec agreed to pay DFCI a total of \$900,000 in full and complete satisfaction of any and all claims that DFCI may have for reimbursement of expenses under the SRA in two equal installments of \$450,000, the first of which was due on December 7, 2020 and the second of which was due on March 31, 2021. As of July 31, 2021, the Company paid both installments.

The Company is not a party to any other legal proceeding or aware of any other threatened action as of the date of this report.

### *Employment Agreements*

The Company has entered into employment agreements with certain 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 June 24, 2021, the Company and the Company’s former Chief Executive Officer (“CEO”) entered into a separation and release agreement in connection with the former CEO’s termination of employment with the Company, providing for severance payments and benefits to the former CEO consistent with the terms of his existing employment agreement with the Company, including a severance payment of \$1,795,500, less tax withholdings, the severance payment was paid in full as of July 31, 2021; the immediate vesting of all stock options and restricted stock units held by him and the expiration date of all stock options was extended to June 24, 2023.

## **Note 10 – Leases**

### *Lease Agreements*

On August 25, 2020, the Company entered into a second amended lease agreement (“Second Amendment”) with MawIt Inc. to further extend the lease term at 24 N. Main Street, Pennington, New Jersey, which serves as the Company’s New Jersey corporate headquarters. Under the Second Amendment, effective January 1, 2021, the lease term is extended through and included December 31, 2021 and the base rent for 2021 is \$12,416 per month. The lease term shall automatically renew for up to two additional one-year terms unless the Company gives the Landlord a notice of non-renewal at least six months prior to the end of the renewal term then in effect. During 2022, the base rent will be \$12,665 per month and during 2023, the base rent will be \$12,918 per month. The Company accounted for the Second Amendment as a contract modification, and accordingly, recorded an additional ROU asset for approximately \$388,000 and lease liabilities of approximately \$388,000 for this operating lease.

The Company has operating leases for corporate offices and lab space. These leases have remaining lease terms of approximately one year to seven years, some of which include options to extend the lease. For any lease where the Company is reasonably certain that a renewal option will be exercised, the lease payments associated with the renewal option period are included in the ROU asset and lease liability as of July 31, 2021.

Supplemental balance sheet information related to leases as of July 31, 2021 was as follows:

**Operating Leases:**

Operating lease right-of-use assets	\$ 5,445,744
<b>Operating Leases:</b>	
Current portion included in current liabilities	\$ 845,483
Long-term portion included in non-current liabilities	5,238,207
Total operating lease liabilities	<u>\$ 6,083,690</u>

Supplemental lease expense related to leases was as follows:

	<b>For the Year Ended July 31, 2021</b>
Operating lease cost	<u>\$ 1,482,956</u>
Total lease expense	<u>\$ 1,482,956</u>

Other information related to leases where the Company is the lessee is as follows:

	<b>As of July 31, 2021</b>
Weighted-average remaining lease term	<u>5 years</u>
Weighted-average discount rate	9.95%

Supplemental cash flow information related to operating leases was as follows:

	<b>For the Year Ended July 31, 2021</b>
Cash paid for operating lease liabilities	<u>\$ 1,272,290</u>
Total cash flows related to operating lease liabilities	<u>\$ 1,272,290</u>

Future minimum lease payments under non-cancellable leases as of July 31, 2021 were as follows:

<b>Years ending July 31,</b>	
2022	\$ 1,418,580
2023	1,585,224
2024	1,539,142
2025	1,516,126
2026	1,533,882
Thereafter	240,688
Total minimum lease payments	<u>7,833,642</u>
Less: Imputed interest	(1,749,952)
Total	<u>\$ 6,083,690</u>

## Note 11 – 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 \$149,072 and \$136,342 for the years ended July 31, 2021 and 2020, respectively.

## Note 12 – Related Party Transactions

Except as disclosed elsewhere herein, below are the Company's related party transactions.

### *Equity Offerings*

On January 25, 2021, the Company completed the offer and sale of an aggregate of 7,711,284 shares of its common stock at a purchase price of \$5.45 per share in a public offering (See Note 6). CGP and its affiliate Sirtex participated in the offering. Each of CGP and Sirtex exercised its right of participation in future offerings in order to maintain respective ownership percentages of the outstanding shares of common stock of the Company upon close.

On August 19, 2020, the Company completed the offer and sale of an aggregate of 4,608,589 shares of its common stock at a purchase price of \$3.25 per share in a registered direct offering (See Note 6). CGP and Sirtex participated in the registered direct offering and maintained their respective ownership percentages of the outstanding shares of common stock of the Company upon close.

### *Co-Promotion and Funded Research Agreement*

In January 2021, the Company entered into a co-promotion agreement with Sirtex, pursuant to which the Company granted Sirtex the option to co-promote TAVO for the treatment of anti-PD-1 refractory locally advanced or metastatic melanoma in the U.S., including its territories and possessions. In consideration for the option, the Company received an upfront, non-refundable payment of \$5.0 million from Sirtex (the "option fee"). The option to co-promote is non-exclusive and may be exercised at any time by Sirtex from the effective date until 90 days following the receipt by Sirtex of a complete copy of the final BLA filed by the Company with the FDA (the "option period"). If Sirtex exercises the option, the Company will receive an additional non-refundable and non-creditable option exercise fee of \$25.0 million, comprised of \$20.0 million in cash, and \$5.0 million for the issuance of common shares of the Company determined by the average closing price of the stock for the 30 days prior to the date of receipt of the exercise notice for the option.

Under the terms of the co-promotion agreement, if Sirtex exercises the co-promote option, the Company will pay to Sirtex a high-teens to low-twenties royalty ("promotion fee") of U.S. net sales of the TAVO products. The co-promotion agreement will continue until the earlier of the expiration of the option period without Sirtex extending the option or the eighth anniversary of the first FDA approval of the BLA, and can be extended by mutual agreement between the Company and Sirtex. During the co-promotion term, the Company is responsible for funding approximately two-thirds of the promotional costs incurred by Sirtex and Sirtex shall be responsible for approximately one-third.

The Company has determined that the co-promotion agreement represents a funded research and development arrangement within the scope of ASC Subtopic 730-20, Research and Development—Research and Development Arrangements (ASC 730-20). The Company concluded that there has not been a substantive and genuine transfer of risk related to the co-promotion agreement and the Company's ongoing development of TAVO as there is a presumption that the Company is obligated to repay Sirtex based on the significant related party relationship that exists between the parties. This significant related party relationship is based on Sirtex's approximate 8% ownership of the outstanding shares of the Company's common stock, and that of its significant equity holder, CGP (which owns 49% of Sirtex), which owns approximately 43% of the outstanding shares of the Company's common stock and is the Company's largest shareholder.

The Company has determined that the appropriate accounting treatment under ASC 730-20 is to record any proceeds received from Sirtex for the co-promote option or upon exercise of the option as cash and cash equivalents as the Company has the ability to direct the usage of funds, and as a corresponding long-term liability (“Liability under co-promotion agreement – related party”) on the Company’s consolidated balance sheet when received. The liability will remain on the balance sheet until (i) Sirtex exercises the option which results in royalties paid by the Company to Sirtex based on the net sales of the TAVO products, or (ii) Sirtex does not exercise the option and the co-promotion agreement is terminated by the parties.

As of July 31, 2021, the balance of the Liability under co-promotion agreement – related party relates to the option fee payment of \$5.0 million received from Sirtex.

#### *Consulting Agreement*

On February 12, 2020, the Company entered into a consulting agreement with the spouse of the Company’s Chief Scientific Officer. The term of the agreement is four months and can be extended by written agreement. The agreement provides for an hourly based fee structure for assisting the Company with matters related to oncology and device development related to the Company’s platform. In addition to an hourly based fee structure, the consultant will be eligible to receive stock option awards. On June 12, 2020, the Company amended the consulting agreement, extending the term of the existing agreement until December 12, 2020. In addition, the consultant was granted 30,000 non-qualified stock options valued at approximately \$48,000 on the date of grant. The non-qualified stock options have a 10-year term, vest immediately and have an exercise price of \$1.56. The consultant was paid consulting fees of approximately \$0.2 million during the year ended July 31, 2021. Effective October 9, 2020, the Company hired the consultant as an employee.

#### **Note 13 – Subsequent Events**

Except as disclosed elsewhere herein, below are the Company’s subsequent events.

On August 13, 2021, the Company and the former interim CEO entered into an agreement, providing for severance payments and benefits to the former interim CEO consistent with the terms of his existing offer letter with the Company, including a severance payment of \$365,000, less tax withholdings, and reimbursement of COBRA premiums (less the portion of the premium that he would have paid if he was an active employee), in each case payable for twelve months following his departure.

On August 16, 2021, the Company announced the establishment of a temporary Leadership Committee consisting of three board members, Margaret Dalesandro, Ph.D., Herbert Kim Lyerly, M.D. and Yuhang Zhao, Ph.D., MBA, to lead all development efforts, with a focus on the Company’s lead asset, TAVO™, until a permanent Chief Executive Officer is hired.

**ITEM 16. FORM 10-K SUMMARY**

The Company has elected not to provide summary information.

## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
3.1	<a href="#"><u>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).</u></a>
3.2	<a href="#"><u>Certificate of Change to amend the Articles of Incorporation of OncoSec Medical Incorporated, as filed with the Nevada Secretary of State on May 20, 2019 (incorporated by reference to Exhibit 3.1 on our Current Report on Form 8-K, filed on May 20, 2019).</u></a>
3.3	<a href="#"><u>Certificate of Change to amend the Articles of Incorporation of OncoSec Medical Incorporated, as filed with the Nevada Secretary of State on September 6, 2019 (incorporated by reference to Exhibit 3.4 on our Form 10-K filed on October 25, 2019).</u></a>
3.4	<a href="#"><u>Amended and Restated Bylaws of OncoSec Medical Incorporated (incorporated by reference to Exhibit 3.1 on Form 8-K filed with the SEC on February 10, 2020).</u></a>
3.5	<a href="#"><u>Certificate of Amendment of Amended and Restated Articles of Incorporation of OncoSec Medical Incorporated (incorporated by reference to Exhibit 3.1 on Form 8-K filed with the SEC on May 29, 2020).</u></a>
4.1	<a href="#"><u>Registration Rights Agreement, dated as of February 7, 2020, by and between OncoSec Medical Incorporated and Grand Decade Developments Limited (incorporated by reference to Exhibit 4.1 on Form 8-K filed with the SEC on February 10, 2020).</u></a>
4.2	<a href="#"><u>Registration Rights Agreement, dated as of February 7, 2020, by and between OncoSec Medical Incorporated and Sirtex Medical US Holdings, Inc. (incorporated by reference to Exhibit 4.2 on Form 8-K filed with the SEC on February 10, 2020).</u></a>
4.3	<a href="#"><u>Description of Securities of OncoSec Medical Incorporated.</u></a>
10.1†	<a href="#"><u>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).</u></a>
10.2#	<a href="#"><u>Form of Indemnification Agreement (incorporated by reference to our Current Report on Form 8-K, filed on October 29, 2015).</u></a>
10.3†	<a href="#"><u>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).</u></a>

- 10.4# [OncoSec Medical Incorporated 2011 Stock Incentive Plan, as amended and restated, dated January 12, 2018 \(incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on January 12, 2018\).](#)
- 10.5 [Assignment of Lease, dated March 9, 2018, by and between OncoSec Medical Incorporated and Vividion Therapeutics, Inc. \(incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on March 22, 2018\).](#)
- 10.6 [Sublease, dated March 9, 2018, by and between OncoSec Medical Incorporated and Vividion Therapeutics, Inc. \(incorporated by reference to Exhibit 10.3 of our Current Report on Form 10-Q, filed on June 13, 2018\).](#)
- 10.7 [Clinical Trial Collaboration and Supply Agreement between OncoSec Medical Incorporated and Merck dated May 8, 2018 \(incorporated by reference to Exhibit 10.5 of our Current Report on Form 10-Q, filed on June 13, 2018\).](#)
- 10.8 [Lease Agreement, dated February 14, 2018, between OncoSec Medical Incorporated and Mawlt Incorporated \(incorporated by reference to Exhibit 10.27 on our Current Report on Form 10-K, filed on October 19, 2018\).](#)
- 10.9 [OncoSec Medical Incorporated Change in Control Plan, effective as of June 7, 2019 \(incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on June 10, 2019\).](#)
- 10.10 [Stock Purchase Agreement, dated as of October 10, 2019 \(incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed on October 11, 2019\).](#)
- 10.11 [Stock Purchase Agreement, dated as of October 10, 2019 \(incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed on October 11, 2019\).](#)
- 10.12 [Stockholder Agreement, dated as of October 10, 2019 \(incorporated by reference to Exhibit 10.5 of our Current Report on Form 8-K, filed on October 11, 2019\).](#)
- 10.13 [Stockholder Agreement, dated as of October 10, 2019 \(incorporated by reference to Exhibit 10.6 of our Current Report on Form 8-K, filed on October 11, 2019\).](#)
- 10.14 [Lease Agreement, dated November 20, 2019, between OncoSec Medical Incorporated and 3535/3565 General Atomics Court, LLC \(incorporated by reference to Exhibit 10.1 of our form 10-Q, filed on December 13, 2019\).](#)
- 10.15 [Amendment Agreement, dated as of November 26, 2019, by and between OncoSec Medical Incorporated and Grand Decade Developments Limited, \(incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the SEC on November 26, 2019\).](#)
- 10.16 [Amendment Agreement, dated as of November 26, 2019, by and between OncoSec Medical Incorporated and Sirtex Medical US Holdings, Inc., \(incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed with the SEC on November 26, 2019\).](#)
- 10.17 [Separation Agreement between OncoSec Medical Incorporated and Mr. O'Connor, dated June 24, 2021 \(incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the SEC on June 24, 2021\).](#)
- 10.18 [Separation Agreement between OncoSec Medical Incorporated and Mr. Leuthner, dated August 13, 2021 \(incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the SEC on August 16, 2021\).](#)
- 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.

+ Certain confidential portions of this exhibit have been omitted pursuant to Item 601(b) of Regulation S-K.

**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

Date: October 29, 2021

By: /s/ Margaret Dalesandro  
Margaret Dalesandro, PhD  
*Interim Principal Executive Officer and Chair of the Board*

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.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Margaret Dalesandro</u> Margaret Dalesandro, PhD	Interim Principal Executive Officer and Chair of the Board	October 29, 2021
<u>/s/ Robert J. DelAversano</u> Robert J. DelAversano	Principal Accounting Officer and Controller <i>(Interim Principal Financial Officer and Principal Accounting Officer)</i>	October 29, 2021
<u>/s/ James DeMesa</u> Dr. James DeMesa	Director	October 29, 2021
<u>/s/ Joon Kim</u> Joon Kim	Director	October 29, 2021
<u>/s/ Herbert Kim Lyerly</u> Dr. Herbert Kim Lyerly	Director	October 29, 2021
<u>/s/ Kevin R. Smith</u> Kevin R. Smith	Director	October 29, 2021
<u>/s/ Robert Ward</u> Robert Ward	Director	October 29, 2021
<u>/s/ Yuhang Zhao</u> Yuhang Zhao	Director	October 29, 2021
<u>/s/ Chao Zhou</u> Chao Zhou	Director	October 29, 2021

**DESCRIPTION OF THE REGISTRANT'S SECURITIES  
REGISTERED PURSUANT TO SECTION 12 OF THE  
SECURITIES EXCHANGE ACT OF 1934**

*When used herein, the terms "we," "our," and "us" refer to OncoSec Medical Incorporated*

**DESCRIPTION OF CAPITAL STOCK**

**General**

Pursuant to our articles of incorporation, we are currently authorized to issue 100,000,000 shares of common stock, par value \$0.0001 per share. As of October 29, 2021, there were 39,202,590 shares of our common stock outstanding.

**Common Stock**

*Voting Rights*

The outstanding shares of our common stock are fully paid and non-assessable. Holders of our common stock are entitled to one vote, in person or by proxy, for each share held of record on all matters submitted to a vote of the stockholders. Except as otherwise provided by applicable law, holders of our common stock are not entitled to cumulative voting of their shares in elections of directors.

*Dividends*

Subject to the provisions of applicable law, including the Nevada Revised Statutes, the holders of shares of our common stock are entitled to receive, when and as declared by the board of directors, dividends or other distributions (whether payable in cash, property, or securities of OncoSec) out of the assets of OncoSec legally available for such dividends or other distributions. We have never paid cash dividends on our common stock. Moreover, we do not anticipate paying periodic cash dividends on our common stock for the foreseeable future. We intend to use all available cash and liquid assets in the operation and growth of our business. Any future determination about the payment of dividends will be made at the discretion of our board of directors and will depend upon our earnings, if any, capital requirements, operating and financial conditions and on such other factors as our board of directors deems relevant.

*Other Rights*

No stockholder of OncoSec has any preemptive right under our articles of incorporation to subscribe for, purchase, or otherwise acquire shares of any class or series of capital stock of OncoSec. The shares of our common stock are not subject to redemption by operation of a sinking fund or otherwise. In the event of any liquidation, dissolution, or winding up of OncoSec, subject to the rights, if any, of the holders of other classes of our capital stock, the holders of shares of our common stock are entitled to receive any of our assets available for distribution to our stockholders ratably in proportion to the number of shares held by them.

Our common stock is listed on the NASDAQ Capital Market under the symbol "ONCS".

**Liability and Indemnification of Directors and Officers**

The Nevada Revised Statutes provide us with the power to indemnify any of our directors and officers. The director or officer must have conducted himself/herself in good faith and reasonably believe that his/her conduct was in, or not opposed to, our best interests. In a criminal action, the director or officer must not have had reasonable cause to believe his/her conduct was unlawful.

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Under applicable sections of the Nevada Revised Statutes, advances for expenses may be made by agreement if the director or officer affirms in writing that he/she believes he/she has met the standards and will personally repay the expenses if it is determined the officer or director did not meet the standards.

Our bylaws include an indemnification provision under which we must indemnify any of our directors or officers, or any of our former directors or officers, to the full extent permitted by law. We have also entered into indemnification agreements with each of our directors and officers under which we must indemnify them to the full extent permitted by law. If Section 2115 of the California Corporations Code is applicable to us, certain laws of California relating to the indemnification of directors, officer and others also will govern.

At present, there is no pending litigation or proceeding involving any of our directors or officers for which indemnification is sought, nor are we aware of any threatened litigation that is likely to result in claims for indemnification. We also maintain insurance policies that indemnify our directors and officers against various liabilities, including liabilities arising under the Securities Act, which may be incurred by any director or officer in his or her capacity as such.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event a claim for indemnification against such liabilities (other than payment by us for expenses incurred or paid by a director, officer or controlling person of ours in successful defense of any action, suit, or proceeding) is asserted by a director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction, the question of whether such indemnification by it is against public policy in the Securities Act and will be governed by the final adjudication of such issue.

#### **Anti-Takeover Provisions of Nevada State Law**

Some features of the Nevada Revised Statutes, which are further described below, may have the effect of deterring third parties from making takeover bids for control of us or may be used to hinder or delay a takeover bid. This would decrease the chance that our stockholders would realize a premium over market price for their shares of common stock as a result of a takeover bid.

##### *Acquisition of Controlling Interest*

The Nevada Revised Statutes contain provisions governing acquisition of a controlling interest (an interest of 20% or greater) of a Nevada corporation which has 200 or more stockholders of record, 100 of whom have a Nevada address. These provisions provide generally that any person or entity that acquires a certain percentage of the outstanding voting shares of a Nevada corporation may be denied voting rights with respect to the acquired shares, unless certain criteria are satisfied. As of October 29, 2021, we have less than 200 stockholders of record, as such these provisions are not currently applicable. Furthermore, our amended and restated bylaws provide that these provisions will not apply to us or to any existing or future stockholder or stockholders.

##### *Combination with Interested Stockholder*

The Nevada Revised Statutes contain provisions governing the combination of a Nevada corporation that has 200 or more stockholders of record with an interested stockholder. These provisions may have the effect of delaying or making it more difficult to affect a change in control of our company. As of October 29, 2021, we have less than 200 stockholders of record. As such, we are not currently affected by the provisions of the Nevada Revised Statutes as described below.

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A corporation affected by these provisions may not engage in a combination within three years after the interested stockholder acquires his, her or its shares unless the combination or purchase is approved by the board of directors before the interested stockholder acquired such shares. Generally, if approval is not obtained, then after the expiration of the three-year period, the business combination may be consummated with the approval of the board of directors before the person became an interested stockholder or a majority of the voting power held by disinterested stockholders, or if the consideration to be received per share by disinterested stockholders is at least equal to the highest of:

- the highest price per share paid by the interested stockholder within the three years immediately preceding the date of the announcement of the combination or within three years immediately before, or in, the transaction in which he, she or it became an interested stockholder, whichever is higher;
- the market value per share on the date of announcement of the combination or the date the person became an interested stockholder, whichever is higher; or
- if higher for the holders of preferred stock, the highest liquidation value of the preferred stock, if any.

Generally, these provisions define an interested stockholder as a person who is the beneficial owner, directly or indirectly of 10% or more of the voting power of the outstanding voting shares of a corporation, and define combination to include any merger or consolidation with an interested stockholder, or any sale, lease, exchange, mortgage, pledge, transfer or other disposition, in one transaction or a series of transactions with an interested stockholder of assets of the corporation having:

- an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation;
- an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation; or
- representing 10% or more of the earning power or net income of the corporation.

#### *Articles of Incorporation and Bylaws*

There are no provisions in our articles of incorporation or our amended and restated bylaws that would delay, defer or prevent a change in control of our company and that would operate only with respect to an extraordinary corporate transaction involving our company or any of our subsidiaries, such as merger, reorganization, tender offer, sale or transfer of substantially all of its assets, or liquidation.

#### **Transfer Agent**

The transfer agent for our common stock is Nevada Agency and Transfer Company. The transfer agent's address is 50 West Liberty Street, Suite 880, Reno, Nevada 89501.

### **DESCRIPTION OF WARRANTS**

#### **General**

We may issue warrants for the purchase of our debt securities or common stock, or any combination thereof, in one or more series together with other securities or separately.

### **DESCRIPTION OF DEBT SECURITIES**

We may offer debt securities which may be senior, subordinated or junior subordinated and may be convertible. The terms of the debt securities will include those stated in the indenture and those made part of the indenture by reference to the Trust Indenture Act of 1939, as in effect on the date of the indenture. We have filed a copy of the form of indenture as an exhibit to our Form S-3 Registration Statement on June 23, 2020. The indenture will be subject to and governed by the terms of the Trust Indenture Act of 1939.

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## **Debt Securities**

The aggregate principal amount of debt securities that may be issued under the indenture is unlimited. The debt securities may be issued in one or more series as may be authorized from time to time pursuant to a supplemental indenture entered into between us and the trustee or an order delivered by us to the trustee.

## **General**

One or more series of debt securities may be sold as “original issue discount” securities. These debt securities would be sold at a substantial discount below their stated principal amount, bearing no interest or interest at a rate which at the time of issuance is below market rates. One or more series of debt securities may be variable rate debt securities that may be exchanged for fixed rate debt securities.

United States federal income tax consequences and special considerations, if any, applicable to any such series will be described in the applicable prospectus supplement.

Debt securities may be issued where the amount of principal and/or interest payable is determined by reference to one or more currency exchange rates, commodity prices, equity indices or other factors. Holders of such debt securities may receive a principal amount or a payment of interest that is greater than or less than the amount of principal or interest otherwise payable on such dates, depending upon the value of the applicable currencies, commodities, equity indices or other factors.

The term “debt securities” includes debt securities denominated in U.S. dollars or, if specified in the applicable prospectus supplement, in any other freely transferable currency or units based on or relating to foreign currencies. We expect most debt securities to be issued in fully registered form without coupons and in denominations of \$2,000 and any integral multiples thereof.

## **Global Securities**

The debt securities of a series may be issued in whole or in part in the form of one or more global securities that will be deposited with, or on behalf of, a depository identified in the prospectus supplement. Global securities will be issued in registered form and in either temporary or definitive form. Unless and until it is exchanged in whole or in part for the individual debt securities, a global security may not be transferred except as a whole by the depository for such global security to a nominee of such depository or by a nominee of such depository to such depository or another nominee of such depository or by such depository or any such nominee to a successor of such depository or a nominee of such successor. The specific terms of the depository arrangement with respect to any debt securities of a series and the rights of and limitations upon owners of beneficial interests in a global security will be described in the applicable prospectus supplement.

## **Governing Law**

The indenture and the debt securities shall be construed in accordance with and governed by, the laws of the State of New York.

## **DESCRIPTION OF UNITS**

We may issue units composed of any combination of our common stock, warrants and debt securities. We will issue each unit so that the holder of the unit is also the holder of each security included in the unit. As a result, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We may evidence units by unit certificates that we issue under a separate agreement. We may issue the units under a unit agreement between us and one or more unit agents. If we elect to enter into a unit agreement with a unit agent, the unit agent will act solely as our agent in connection with the units and will not assume any obligation or relationship of agency or trust for or with any registered holders of units or beneficial owners of units. We will indicate the name and address and other information regarding the unit agent in the applicable prospectus supplement relating to a particular series of units if we elect to use a unit agent.

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement No. 333-257049 on Form S-8, Registration Statement No. 333-252281 on Form S-3, Registration Statement No. 333-233447 on Form S-3, and Registration Statement No. 333-238823 on Form S-8, of our report dated October 29, 2021, (which includes an explanatory paragraph relating to the existence of substantial doubt about the Company's ability to continue as a going concern), with respect to the consolidated financial statements of OncoSec Medical Incorporated as of July 31, 2021 and 2020, and for each of the years in the two year period ended July 31, 2021, included in this Annual Report on Form 10-K for the year ended July 31, 2021.

*/s/ Mayer Hoffman McCann P.C.*

San Diego, California  
October 29, 2021

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## CERTIFICATIONS

I, Margaret Dalesandro, certify that:

1. I have reviewed this Annual Report on Form 10-K of OncoSec Medical Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

October 29, 2021

*/s/ Margaret Dalesandro*

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Margaret Dalesandro

Interim Principal Executive Officer and Chair of the Board

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## CERTIFICATIONS

I, Robert J. DelAversano, certify that:

1. I have reviewed this Annual Report on Form 10-K of OncoSec Medical Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

October 29, 2021

*/s/ Robert J. DelAversano*

Robert J. DelAversano

VP, Finance

Principal Accounting Officer and Controller

*(Interim Principal Financial Officer)*

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CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, Margaret Dalesandro, Principal Executive Officer and Chair of the Board of OncoSec Medical Incorporated (the "Company") hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Annual Report on Form 10-K of the Company for the period ended July 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 29, 2021

By: /s/ Margaret Dalesandro

Margaret Dalesandro

Interim Principal Executive Officer and Chair of the Board

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CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, Robert J. DelAversano, Principal Accounting Officer and Controller (Principal Accounting Officer) of OncoSec Medical Incorporated (the "Company") hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Annual Report on Form 10-K of the Company for the period ended July 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 29, 2021

By: /s/ Robert J. DelAversano

Robert J. DelAversano  
VP, Finance  
Principal Accounting Officer and Controller  
*(Interim Principal Financial Officer)*

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