ONCOSEC MEDICAL Inc
Form 10-K
October 25, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended July 31, 2017

OR

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

For the transition period from to

Commission file number 000-54318

ONCOSEC MEDICAL INCORPORATED

(Exact name of registrant as specified in its charter)

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

5820 Nancy Ridge Drive

San Diego, CA 92121

(Address of principal executive offices)(Zip Code)

7(855) 662-6732

(Registrant's telephone number, including area code)

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

Title of Class:	**Name of Exchange on which Registered:**
Common Stock, par value $0.0001 per share	**The NASDAQ Stock Market LLC (NASDAQ Capital Market)**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

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

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

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

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

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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of January 31, 2017, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $22,001,286, 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 10, 2017, there were 22,099,840 outstanding shares of the Company's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for the 2017 Annual Meeting of Stockholders, which is expected to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended July 31, 2017, are incorporated by reference in Part III of this Annual Report on Form 10-K to the extent stated herein.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER MATTERS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. Forward-looking statements relate to future events or circumstances or our future performance and are based on our current assumptions, expectations and beliefs about future developments and their potential effect on our business. All statements in this report that are not statements of historical fact could be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential” or “continue” or the negative of thes 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.

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

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

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

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

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

PART I

ITEM 1. BUSINESS

Overview

We are a biotechnology company focused on designing, developing and commercializing innovative therapies and proprietary medical approaches to stimulate and guide an anti-tumor immune response for the treatment of cancer. Our core platform technology, ImmunoPulse®, is a drug-device therapeutic modality comprised of a proprietary intratumoral electroporation delivery device. The ImmunoPulse® platform is designed to deliver DNA-encoded drugs directly into a solid tumor and promote an inflammatory response against cancer. The ImmunoPulse® device can be adapted to treat different tumor types, and consists of an electrical pulse generator, a reusable handle and disposable applicators. Our lead product candidate, ImmunoPulse® IL-12, uses our electroporation device to deliver a DNA-encoded interleukin-12, or IL-12, called tavokinogene telseplasmid, or tavo, with the aim of reversing the immunosuppressive microenvironment in the tumor and engendering a systemic anti-tumor response against untreated tumors in other parts of the body.

Our current focus is to pursue our registration-directed study of ImmunoPulse® IL-12 in combination with an approved therapy for melanoma in patients who have shown resistance to or relapse from certain other cancer therapies, which we refer to as the PISCES study. Most of our present activities are directed toward advancing the PISCES study. We also intend to continue to pursue other ongoing or potential new trials and studies related to ImmunoPulse® IL-12, all with the goal of obtaining requisite regulatory approvals from the U.S. Food and Drug Administration, or FDA, and comparable regulators in certain other jurisdictions to market and sell this product candidate.

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

Cancer Immunotherapy Treatments: Background

Many traditional modalities for treating cancer have limited clinical efficacy and are frequently associated with significant negative side effects. Immunotherapy, a relatively new therapeutic modality that has received significant attention in recent years, focuses on modulating the immune system to treat cancer rather than directly killing the cancer cells. Systemic delivery of immune-modulating proteins, such as interleukin-2, or IL-2, and IL-12, has shown early indications of efficacy, but with significant mechanism-based toxicity.

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

We believe that if we can convert an inactive, or “cold,” tumor with a low frequency of tumor infiltrating lymphocytes, or TILs, that limit the anti-tumor response and remove the interferon signature, into an active, or “hot,” tumor that can activate the anti-PD-1 or anti-PD-L1, then we can increase the subset of patients who respond to these therapies. We believe our ImmunoPulse® IL-12 platform addresses this objective, as it has the potential to reshape the tumor microenvironment in patients with an immunologically cold tumor into a highly-inflamed tumor with a fully engaged anti-PD-1 or anti-PD-L1 axis. The immunological components that enable this conversion relates to the intratumoral delivery of tavo, which increases the density of TILs, and in the presence of an anti-PD-1 antibody, a disabling of adaptive resistance and maximizing the cytotoxicity. We believe intratumoral tavo can reshape the tumor through innate and adaptive immune mechanisms, which result in a brisk infiltration of TILs in a previously cold tumor.

We believe there is a significant unmet medical need for patients who may not respond well to these therapies on their own. In particular, for patients who have “cold” tumors and would be unlikely to respond to an immune checkpoint therapy alone, our focus is to develop a therapeutic that has the ability to directly modulate the microenvironment of the tumor by stimulating a local immune reaction through the intratumroral delivery of IL-12 or other immune-modulating molecules. We believe this would enable important immune cells to enter into the tumor and, in essence, turn the tumor “hot.” In doing so, we believe intratumoral delivery of immune-modulating molecules, such as IL-12, could be used as a monotherapy, and importantly, could provide a strong biological rationale for treatment in combination with immune checkpoint inhibitors, such as anti-PD-1 or anti-CTLA-4.

Our Lead Product Candidate: ImmunoPulse® IL-12

Our lead product candidate, ImmunoPulse® IL-12, is a drug-device combination. The drug consists of a plasmid construct called tavo, which encodes IL-12, which is delivered into a tumor using our proprietary electroporation device. A Phase I clinical trial in metastatic melanoma using electroporation to deliver plasmid-DNA encoding for IL-12 was completed in 2008. The data from this trial indicated that the in vivo gene transfer of IL-12 DNA using electroporation in metastatic melanoma was well-tolerated. In addition, anti-tumor activity was observed after a single cycle of treatment, including two complete responses. Importantly, regression in distant, non-injected/non-electroporated lesions was also observed, suggesting that local treatment with ImmunoPulse® IL-12 may lead to a systemic anti-tumor immune response.

In February 2017, we received Fast Track designation from the FDA for ImmunoPulse® IL-12. The Fast Track program was established to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. Drugs that receive this designation benefit from more frequent communications and meetings with the FDA to review the drug’s development plan, including the design of proposed clinical trials and the extent of data needed for approval. Fast Track designated drugs may also qualify for expedited FDA review and a rolling Biologics License Application, or BLA, review, if certain criteria are met.

Clinical Programs

All of our ongoing and planned clinical programs relate to our lead product candidate, ImmunoPulse® IL-12. Our current primary focus is to pursue our planned Phase II registration-directed study of ImmunoPulse® IL-12 in combination with Merck & Co., Inc.’s, or Merck’s, approved anti-PD-1 antibody KEYTRUDA® in patients with advanced, metastatic (stage 3-4) melanoma who have shown resistance to or relapse from an anti-PD-1 therapy (OMS-I103). We refer to this study as PISCES.

In addition, we have two ongoing clinical trials related to ImmunoPulse® IL-12, although we are not currently actively pursuing these trials: A pilot trial of ImmunoPulse® IL-12 monotherapy in patients with triple negative breast cancer (OMS-I140); a Phase II investigator-sponsored trial with ImmunoPulse® IL-12 plus pembrolizumab in patients with advanced, metastatic melanoma (OMS-I102); and a Phase II trial of ImmunoPulse® IL-12 as a monotherapy in patients with metastatic melanoma (OMS-I100).

OMS-I103: The PISCES Study: An Open-Label Phase II Trial of Intratumoral pIL-12 plus Electroporation in Combination with Intravenous Pembrolizumab in Patients with Stage 3-4 Melanoma who are Progressing on either Pembrolizumab or Nivolumab Treatment

Melanoma is a deadly form of skin cancer with rapidly rising incidences both in the U.S. and internationally. The National Cancer Institute Surveillance, Epidemiology and End Results Program estimates that over 75,000 new melanoma cases were diagnosed in 2016, representing 4.5% of all new cancer cases in the U.S. Overall, the five-year survival rate for melanoma, regardless of disease stage, is over 90%; however, for patients who present with metastatic disease and receive systemic treatment, the five-year survival rate is considerably lower at less than 18%. Despite recent advances in therapy, advanced metastatic melanoma continues to present significant morbidity and mortality.

The PISCES study is a Phase II, 2-stage, open-label, single-arm, multi-center study of ImmunoPulse® IL-12 in combination with an intravenous anti-PD-1 antibody, Merck's KEYTRUDA®, in patients with histological diagnosis of melanoma with progressive locally advanced or metastatic disease defined as stage 3 or 4.

Patients in the study must be refractory to certain anti-PD-1 monoclonal antibodies, namely pembrolizumab (KEYTRUDA®) or nivolumab, as either monotherapy or in combination with other approved checkpoint inhibitors or targeted therapies according to their approved label, or relapsed as documented disease progression within 24 weeks of the last dose of anti-PD1 monoclonal antibodies. The primary endpoint of the study is to assess efficacy over 24 weeks of intratumoral pIL-12-EP in combination with pembrolizumab in patients with unresectable or metastatic melanoma who previously have progressed on certain approved anti-PD-1 antibodies (either as monotherapy or in combination with other approved checkpoint inhibitors).

In May 2017, we submitted to the FDA an investigational new drug application, or IND, for the PISCES study, which, in general, must become accepted and effective before any human clinical trials may begin in the United States. Additionally, in May 2017, we entered into a clinical trial collaboration and supply agreement with a subsidiary of Merck in connection with the PISCES study, in which we have agreed to sponsor and fund the study and Merck has agreed to manufacture and supply KEYTRUDA® for use in the study. The PISCES study opened for enrollment in October 2017.

OMS-I140: Biomarker-Focused Pilot Study of ImmunoPulse® IL-12 in Patients with Triple Negative Breast Cancer

Worldwide, approximately 170,000 new cases of triple negative breast cancer, or TNBC, are diagnosed each year, accounting for approximately 15% of all breast cancer. TNBC frequently affects younger women (less than 40 years old) and is characterized by higher relapse rates than estrogen receptor positive breast cancers. TNBC is also associated with an increased risk of recurrence, both locally and in distant sites including the lungs and brain. Advanced TNBC remains a significant area of unmet medical need and there is no established standard-of-care. Treatment generally includes chemotherapy, with or without radiation and/or surgery, but no treatment regimen has demonstrated clear superiority.

In January 2017, we amended the clinical protocol for our biomarker-focused pilot study of ImmunoPulse® IL-12 in patients with TNBC to improve the enrollment rate, as it had been slow to enroll, and in September 2017, we enrolled half the patients needed for the study. The study is now open for enrollment and is ongoing. The primary objective of the study is to evaluate the potential of ImmunoPulse® IL-12 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 is being conducted at Stanford University and is designed to assess whether ImmunoPulse® IL-12 increases TNBC tumor

immunogenicity by driving a pro-inflammatory cascade that leads to increases in cytotoxic TILs. The presence and number of TILs is thought to be a key requirement for promoting the anti-tumor activity of monoclonal antibodies, such as anti-PD-1. By driving cytotoxic immune cells into the tumor, ImmunoPulse® IL-12 could be used in combination with checkpoint blockade therapies, which have reported some, but limited, activity in TNBC.

OMS-I102: An Open-Label Phase II Trial of ImmunoPulse® IL-12 plus Pembrolizumab in Patients with Advanced, Metastatic Melanoma

In August 2015, we enrolled the first patient in our Phase II investigator-sponsored clinical trial led by the clinicians at the University of California, San Francisco, or UCSF. The primary endpoint of this study is to assess the anti-tumor efficacy of the combination of intratumoral pIL-12 by electroporation and Merck's KEYTRUDA® in patients with melanoma who are progressing or have progressed on anti-PD-1 therapy. The primary endpoint of the study is the best overall response rate of the combination regimen in patients whose tumors are characterized by low numbers of TILs. Recent data suggest that patients whose tumors are not associated with TILs or CD8+ T-cells at the tumor margin are unlikely to respond to anti-PD-1 therapies such as KEYTRUDA®, while those who are CTLA-4 and PD-L1 positive and have increased TILs are more likely to have a clinical benefit. Therefore, therapies that promote TIL generation and PD-L1 positivity may play an important role in augmenting the clinical efficacy of the anti-PD1/PD-L1 agents.

This hypothesis is being tested in this trial by enrolling a low-TIL metastatic melanoma patient population. Initial data was presented in February 2017 and the trial stopped enrolling patients in September 2017. The overall response rate in the 22-patient population was 43% at week 24 (best overall response rate was 48%), with one significant adverse Grade-3 event and one Grade-2 event, both of which were resolved with antibiotics or over-the-counter medicines. Based on these results, we believe the combination therapy studied in the trial was well-tolerated. Ongoing analysis of days to best overall response, duration of response and progression free survival are underway as the existing patients are followed on a long-term basis.

OMS-I100: An Open-Label Phase II Trial of ImmunoPulse® IL-12 Monotherapy in Patients with Metastatic Melanoma

On December 5, 2014, we released top-line six-month data from a Phase II repeat dose trial of tavo in patients with stage 3 and 4 metastatic melanoma. In this study, which was conducted at UCSF, 30 patients with stage 3 and 4 melanoma received up to four cycles of tavo delivered by electroporation on days one, five and eight of each 12-week cycle. Of the 29 patients in the study who were evaluable, an objective response rate of 31% (9/29) was observed, with 14% (4/29) of patients having a complete response and 17% (5/29) of patients having a partial response. Regression of distant lesions was seen in 50% (13/26) of patients with evaluable non-injected, non-electroporated lesions. Clinical endpoints included objective response rate, local and distant lesion regression, duration of response, overall survival and safety. We believe the results of this study demonstrated that multiple treatment cycles of ImmunoPulse® IL-12 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; however, five patients experienced at least one serious adverse event, four of which were not related to study treatment and one of which was assessed as definitely related to the combination of pIL-12 + electroporation but unlikely to be related to the individual components of the study treatment. No adverse events led to permanent discontinuation of study treatment, and no adverse events resulted in death.

In order to continue to acquire clinical and immune correlational data on melanoma patients treated with ImmunoPulse® IL-12, the protocol of the OMS-I100 study was amended in February 2014 to enroll up to 30 patients. Enrollment in OMS-I100 Addendum was completed in March 2016, the data base is locked and the clinical study report is pending.

Following participation in this trial, some patients participated in a separate study in which they received an anti-PD-1/PD-L1 therapy. Long-term, follow-up data regarding these patients suggest that ImmunoPulse® IL-12 may prime and enhance response rates to PD-1/PD-L1 blockade. Of the 29 patients who completed ImmunoPulse® IL-12, 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%. 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 ImmunoPulse® IL-12 prior to anti-PD-1/PD-L1 therapy.

Other Trials and Studies

In addition to the trials and studies described above, we have also pursued and closed Phase II clinical trials in patients with Merkel cell carcinoma, head and neck cancer and cutaneous T-cell lymphoma, although we are no longer pursuing any of these clinical programs.

Our ImmunoPulse® Platform

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

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

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

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

Our ImmunoPulse® platform employs an electroporation system designed to create favorable conditions to deliver plasmid DNA encoding immunotherapeutic cytokines directly into cells of the tumor microenvironment. The cytokine-encoding plasmid is first injected into the tumor. A needle-electrode array then delivers the electrical pulses produced in the pulse generator. In addition, we are continuing to advance the field of electroporation by developing our tissue-based real-time adaptive control electroporation, or TRACE, technology. The TRACE technology uses electrochemical impedance spectroscopy, or EIS, to continuously evaluate the electrical properties of the tissue. By doing so, TRACE has the ability to modulate the electric field in real-time, thus optimizing the electroporation conditions and improving the transfection of the DNA into the cells.

Our lead product candidate, ImmunoPulse® IL-12, consists of a plasmid construct encoding the proinflammatory cytokine IL-12 that is delivered into the tumor through in vivo electroporation using our ImmunoPulse® technology. We are also researching other DNA-encoded, immunologically-active molecules, with an aim of developing additional immunotherapeutic drugs that, when delivered through electroporation using our ImmunoPulse® platform, may be capable of breaking the immune system's tolerance to cancer.

Commercialization

Strategy

Our primary focus is to continue our clinical development strategy for ImmunoPulse® IL-12, including our currently planned and ongoing Phase II clinical trials discussed under "Clinical Programs" above and potentially other Phase II or subsequent trials we may pursue in the future, which may include trials focused on cancers that have demonstrated a response to anti-PD-1/PD-L1 checkpoint therapies, such as metastatic melanoma.

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 or government agencies 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 development.

Manufacturing and Supply

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

We rely upon a small number of suppliers and manufacturers for our clinical activities, including distributors such as Cryosite, Sherpa, as well as manufacturers such as Richter Helm, VGXI and SGS, which collectively account for 100% of clinical materials; and Minnetronix, which accounts for 50% of electroporation systems support and materials. We believe there are alternate sources of raw material supply and finished goods manufacturing to satisfy our requirements, although transitioning to other vendors, if necessary, could result in significant delay or material additional costs. In addition, for combination trials, we typically rely exclusively on one supplier of the non-company-owned product used in the trial, such as our reliance upon Merck for the supply of KEYTRUDA® in the PISCES study.

We are certified by all appropriate standards and authorities for the limited assembly and manufacture activities we conduct, and we and 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 recently announced development strategies similar to our current focus on our PISCES study, namely the combination of IL-12 and a checkpoint inhibitor to improve response rates in patients who are refractory or who have relapsed on anti-PD-1 therapies either alone or in combination with other therapies, and we view these companies as our most relevant current competitors. These companies include, among others, Bristol Myers-Squibb, Iovance Therapeutics, Syndax, Dynavax Technologies and Idera Pharmaceuticals. In addition, we also compete with other early-stage biotechnology companies for funding and support from healthcare and other investors and potential collaboration relationships with larger pharmaceutical or other companies, as well as for personnel with expertise in our industry. We are smaller, less experienced and less well-funded than many of our competitors, and we have a shorter and less proven operating history and a less recognizable and established brand name than many of our competitors. In addition, some of our competitors have commercially available products, which provide them with operating revenue and other competitive advantages. Furthermore, recent trends in the biotechnology industry are for large drug companies to acquire smaller outfits and consolidate into a smaller number of very large entities, which further concentrates financial, technical and market strength and increases competitive pressure in the industry.

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

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

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 2017, we owned 28 U.S. patents and several patents in foreign jurisdictions, and we are currently prosecuting several pending patent applications in various jurisdictions. In addition, we have licensed intellectual property rights that allow us to use certain electroporation technology to deliver DNA-based cytokines as an immunotherapy, as well as catheter-based delivery devices. From these in-licensed portfolios, we have access to five issued U.S. patents, one pending U.S. patent application, and several pending patent applications in foreign jurisdictions. 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 2017 and 2030. Importantly, although we have previously obtained patent protection, through an asset purchase agreement, covering our ImmunoPulse® clinical device, the primary U.S. patent providing such protection expired in September 2017 and our international patent providing such protection will expire in 2018.

In addition, we have entered into a cross-license agreement for certain electroporation technology with Inovio Pharmaceuticals, Inc., or Inovio, including our patent protection for our ImmunoPulse® clinical device (some of which, as noted above, has recently expired or will expire in 2018). Under the terms of the agreement, Inovio has granted us a non-exclusive, worldwide license under certain of its electroporation patents, and in exchange, we have

granted to Inovio an exclusive license to certain of our purchased technology in a limited field of use.

Research and Development

We recognized $12.0 million and $14.7 million in research and development expenses in our fiscal years ended July 31, 2017 and 2016, respectively. From our inception through July 31, 2017, we have incurred an aggregate of approximately $51.7 million of research and development expenses, the significant majority of which relate to our development of immuno-oncology therapeutic product candidates with the use of an electroporation device.

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 administered by the FDA and, to a lesser extent, by the U.S. Drug Enforcement Agency, or DEA, and comparable state government agencies, and outside the United States, these regulations are typically administered by various regulatory agencies comparable to the FDA in foreign countries where products or product candidates are researched, tested, manufactured and/or marketed.

United States

General

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

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 pre-clinical chemistry, manufacturing, and control testing, commonly known as CMC;
- submission to the FDA of an 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 medical device, submission to the FDA of a premarket approval application or 510(k) premarket notification, which the FDA must review and approve; and
- for a therapeutic, submission to the FDA of a new drug application, or NDA, or biologic license application, 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 time, effort and financial resources, and the receipt and timing of approval, if any, is highly uncertain. The results of pre-clinical tests, together with certain manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Once an IND is in effect, the protocol for each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

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

Phase I: 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 II: 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 II clinical trials may be conducted.

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

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

Once the NDA or BLA submission has been accepted, the FDA begins an in-depth substantive review. Pursuant to the FDA's performance goals, NDA and BLA reviews are to be completed within 10 months, subject to extensions by the FDA. Before approving an NDA or BLA, the FDA often inspects the facility or facilities where the product is manufactured and will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with good manufacturing practices. Additionally, the FDA will typically inspect one or more clinical sites to assure compliance with good clinical practices before approving an NDA or BLA. If the FDA determines that an NDA or BLA is not acceptable, 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 usually impose limitations on 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 IV clinical trials, or surveillance programs to monitor the effect of any approved products, and the 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 tests and 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 foreign jurisdictions before we could commence clinical trials or marketing of our product candidates in these jurisdictions. In addition, we would become subject to a variety of foreign regulations regarding safety and efficacy of our product candidates and governing, among other things, clinical trials, commercial activities, manufacture and distribution of our product candidates. The requirements to obtain product approvals vary widely from country to country, and the FDA's approval requirements, review procedures and timelines may not be the same as or even similar to the requirements or a comparable foreign regulator. As a result, even if we obtain regulatory approval for a product candidate in one country, we may be required to undertake additional clinical trials or studies, submit additional information, wait for longer review periods or make other efforts in order to obtain regulatory approvals in other desirable geographic markets.

Healthcare Laws and Regulations

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

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

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

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

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

the federal Health Insurance Portability and Accountability Act of 1986, or HIPAA, as amended by the federal Health Information Technology for Economic and Clinical Health Act, or HITECH, which, in general and among other things, establish comprehensive federal standards with respect to the privacy, security and transmission of

individually identifiable health information and impose requirements for the use of standardized electronic transactions with respect to transmission of such information; and

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

Additionally, the healthcare compliance environment is continuously changing, with proposed revisions to or replacement of the Affordable Care Act at the federal level and with some states mandating implementation of compliance programs, compliance with industry ethics codes, spending limits and reporting to state governments of gifts, compensation and other remuneration to physicians. Further, 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, 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

We have assembled a senior management team with many years of experience and 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 ImmunoPulse® 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, 2017, we had a total of 35 employees, including 34 full-time employees and one part-time employee. None of our employees is represented by a labor union or covered by a collective bargaining agreement, and we believe that our relations with our employees are good.

Corporate Information

We were incorporated under the laws of the State of Nevada in February 2008 under the name Netventory Solutions Inc. to pursue the business of inventory management solutions. In March 2011, we completed a merger with our subsidiary to change our name to "OncoSec Medical Incorporated," and we commenced operations as a biotechnology company upon our acquisition of assets from Inovio related to the use of drug-medical device combination products for the treatment of various cancers. Our principal executive offices are located at 5820 Nancy Ridge Drive, San Diego, California 92121, and the telephone number at our principal executive office is (855) 662-6732. Our website address is www.oncosec.com. Information contained on our website is not, and should not be considered, part of this report.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business

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

We have not generated any revenue from our operations since our inception, and we do not anticipate generating meaningful, or any, revenue in the near term. During our fiscal year ended July 31, 2017, we incurred a net loss of approximately $21.4 million, and from inception through July 31, 2017, we have incurred an aggregate net loss of approximately $94.9 million. We will need significant additional funding to continue our operations and pursue our strategic plans, including continued development of ImmunoPulse® IL-12. Although we have been and expect to continue to tightly manage our operating expenses, we expect our cumulative operating expenses will continue to increase as we further our development activities and pursue FDA approval for one or more of our product candidates.

Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, many of which are discussed in these risk factors, we are unable to predict the extent of our future losses or

when or if we will generate meaningful revenue or become profitable, and it is possible we will never achieve these goals. Our failure to develop our investments in our proprietary technologies and product candidates into revenue-generating operations would have a material adverse effect on our business, results of operations, financial condition, and prospects and could result in our inability to continue operations.

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

We anticipate that, based on the amount of cash we have on hand (taking into account the expected aggregate net proceeds from our October 2017 equity financings) and our current rate of cash consumption, we could continue operations to the third calendar quarter of 2018 without a significant change in our business plan or reduction in spending. However, we will need additional capital after that time to maintain our current level of operations or before that time to ramp up development or other efforts. As a result, our ability to continue as a going concern will depend upon the availability and terms of future funding.

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

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

As of July 31, 2017, we had cash and cash equivalents of approximately $11.4 million and, as of that date, we estimated our cash requirements for the following 12 months to be approximately $21.0 million. As a result, even taking into account the expected aggregate net proceeds from our October 2017 equity financings, we do not believe we have sufficient cash on-hand to support our operations for the next 12 months, and we expect that we will require additional funding by the third calendar quarter of 2018. We do not generate any cash from our operations, and we do not currently have any firm commitments for future capital. Consequently, we will need significant additional capital to continue operating our business and fund our planned operations.

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

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

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

We are an early-stage, pre-commercial company with a limited operating history and no commercially available or approved products, which makes assessment of our future viability difficult and which may hinder our ability to

generate revenue and meet our other objectives.

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

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

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

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

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

- our ability to conduct and complete pre-clinical and clinical studies and trials, including the time, costs and uncertainties associated with all aspects of these trials;
- the data we obtain from pre-clinical and clinical testing of the product candidates, including data demonstrating the required level of safety and efficacy of the product candidates (for example, the data we obtain from the PISCES study will be a key factor in determining whether we are able to successfully develop and commercialize our ImmunoPulse® IL-2 platform in melanoma);
- the regulatory approval pathway we choose to pursue for our product candidates in the United States or any other jurisdiction;
- our ability to obtain required regulatory approvals for one or more of our product candidates in the United States and in other jurisdictions, and the time required to obtain these approvals;
- the manufacturing arrangements we are able to establish with third-party manufacturers, both for the manufacture of the product candidates for clinical trial use and for the manufacture of products, if and when approved, on a commercial basis;
- our ability to build an infrastructure capable of supporting product sales, marketing and distribution of any approved products in territories where we pursue commercialization directly;
- our ability to establish commercial distribution agreements with third-party distributors for any approved products in territories where we do not pursue commercialization directly;
- the labeling requirements for any product candidates that are approved, including obtaining sufficiently broad labels that would not unduly restrict patient access;
- acceptance of our products, if and when approved, by patients and the medical community;
- the ability of our products, if and when approved, to effectively compete with other cancer treatments;

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

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

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

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

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

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

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

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

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

- the severity of the disease under investigation;
- the design of the study protocol;
- the eligibility criteria for the study;
- the perceived risks, benefits and convenience of administration of the product candidate being studied;
- the competitive disease space with many trials for patients to select from;
- the patient referral practices of physicians; and
- the proximity and availability of clinical trial sites to prospective patients.

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

Physicians, patients, and third-party payors may be less accepting of product candidates based on our ImmunoPulse® technology platform due to certain characteristics of this platform. For example, these parties may have concerns about the complexity inherent in a combination therapy approach or the clinical application of electroporation

technology, which is less prevalent in the United States than in certain foreign markets. Moreover, our efforts to educate the medical community and third-party payors about the benefits of any of our technologies and product candidates may require significant resources and may never be successful. As a result, even if any of our product candidates achieve regulatory approval, a lack of acceptance by physicians, third-party payors and patients of the products or underlying technologies could prevent their successful commercialization and could materially limit our revenue potential.

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

Clinical trials are very expensive, time-consuming, unpredictable and difficult to design and implement. Even if we are able to complete our ongoing and currently proposed clinical trials and assuming the results are favorable, clinical trials for product candidates based on our technology will continue for several years and may take significantly longer than expected to complete. Even with the Fast Track designation we received from the FDA for ImmunoPulse® IL-12 in February 2017, Phase II and Phase III clinical trials, which can take many years to complete, are still required.

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

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

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

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

harmed, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

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

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

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

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

We have participated in, and continue to participate in, clinical trials conducted under an approved investigator-sponsored IND application, including our melanoma combination investigator-sponsored Phase II clinical trial led by the University of California, San Francisco. In investigator-initiated trials, the investigator typically designs and implements the study and the investigator or its institution acts as the sponsor of the trial. This trial sponsor has control over the design, conduct and timing of the trial, and as a result, we have limited or no control over the commencement, conduct and completion of these investigator-initiated trials. In addition, regulations and guidelines imposed by the FDA with respect to IND applications include a requirement that the sponsor of a clinical

trial provide ongoing communication with the FDA as it pertains to the safety of the treatment being tested. It is the responsibility of the investigator, as the sponsor of the trial, to be the sole point of contact with the FDA for these communications and to exercise all decision-making authority regarding these or other submissions to the FDA about the trial. Consequently, we have little or no control over the content or timing of these communications, including whether they are timely, accurate or complete. Any failures by the investigator sponsoring these trials could result in reviews, audits, delays or clinical holds by the FDA that could negatively affect the timelines for these trials or jeopardize their completion. As a result, our lack of control over the conduct and timing of, and communications with the FDA regarding, these investigator-sponsored trials exposes us to additional risks, many of which our outside our control and the occurrence of which could severely harm our performance and the commercial prospects for our product candidates.

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

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

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

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

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

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

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

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

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

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

These risks of third parties' infringement of our intellectual property rights may increase if we engage in discussions, collaborations or other strategic arrangements with third parties. Also, new challenges could arise if and to the extent we pursue engagements with third parties located outside the United States. These factors could increase the risks and costs associated with building and protecting our intellectual property portfolio and could adversely affect our

performance and our business prospects.

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

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