ONCOSEC MEDICAL Inc
Form 10-K
October 15, 2012
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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, 2012

OR

o **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 of incorporation or organization)	(I.R.S. Employer Identification Number)

4690 Executive Drive, Suite 250

San Diego, CA 92121

(Address of Principal Executive Offices)(Zip Code)

(855) 662-6732

(Registrant s telephone number, including area code)

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

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

Common Stock, par value $0.0001 per share

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o 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 o 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 o

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 o

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. x

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of January 31, 2012 totaled approximately $31,000,000 based on the closing price of $0.76. As of October 12, 2012, there were 87,856,000 shares of the Company s common stock ($0.0001 par value) outstanding.

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OncoSec Medical Incorporated has filed applications to register the following trademarks: ImmunoPulse and NeoPulse. Other registered trademarks used in this Annual Report are the property of their respective owners.

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PART I

ITEM 1. BUSINESS

The following discussion should be read in conjunction with our consolidated financial statements and the related notes and other financial information appearing elsewhere in this Form 10-K. This report contains forward-looking statements that involve risks, uncertainties and assumptions. In some cases, you can identify forward-looking statements by terminology such as may , should , expects , plans , anticipates , believes , estimates , predicts , potential or continue or the negative of these terms or other comparable terminology. All statements made in this Annual Report on Form 10-K other than statements of historical fact could be deemed forward-looking statements.

By their nature, forward-looking statements speak only as of the date they are made, are neither statements of historical fact nor guarantees of future performance and are subject to risks, uncertainties, assumptions and changes in circumstances that are difficult to predict or quantify. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks identified in the section entitled Risk Factors in Part I, Item IA of this Annual Report, and similar discussions in our other SEC filings. If such risks or uncertainties materialize or such assumptions prove incorrect, our results could differ materially from those expressed or implied by such forward-looking statements and assumptions. Risks that could cause actual results to differ from those contained in the forward-looking statements include but are not limited to risks related to: uncertainties inherent in pre-clinical studies and clinical trials; our need to raise additional capital and our ability to obtain financing; general economic and business conditions; our ability to continue as a going concern; our limited operating history; our ability to recruit and retain qualified personnel; our ability to manage future growth; our ability to develop our planned products; and our ability to protect our intellectual property.

You should not place undue reliance on forward-looking statements. Unless required to do so by law, we do not intend to update or revise any forward-looking statement, because of new information or future developments or otherwise.

As used in this Annual Report on Form 10-K and unless otherwise indicated, the terms the Company , we , us and our refer to OncoSec Medical Incorporated.

Overview

We are an emerging drug-medical device and therapeutic company focused on designing, developing and commercializing innovative and proprietary medical approaches for the treatment of solid tumors that have unmet medical needs or where currently approved therapies are inadequate based on their efficacy or side-effects. Our company was incorporated under the laws of Nevada on February 8, 2008 as Netventory Solutions Inc. Initially, we provided online inventory services to small and medium sized companies. On March 1, 2011, we changed our name from Netventory Solutions, Inc. to OncoSec Medical Incorporated . In March 2011, we acquired from Inovio Pharmaceuticals, Inc. (Inovio) certain assets related to the use of drug-medical device combination products for the treatment of various cancers. With this acquisition, we have abandoned our efforts in the online inventory services industry and are focusing our efforts in the biomedical industry.

Our Strategy

The assets we acquired from Inovio include intellectual property relating to certain delivery technologies, which we now refer to as the OncoSec Medical System (OMS), a therapeutic approach which is based on the use of an electroporation delivery device in combination with an approved chemotherapeutic drug or a DNA-based cytokine to treat solid tumors. These two different approaches represent unique therapeutic modalities, ImmunoPulse (formerly OMS ElectroImmunotherapy) and NeoPulse (formerly OMS ElectroChemotherapy). Our ImmunoPulse approach is based on the use of electroporation to enhance the local delivery of DNA plasmids which, upon uptake into cells, direct the production of immunostimulatory cytokines to generate a local, regional and systemic immune response for the treatment of various cutaneous cancers. NeoPulse utilizes our electroporation technologies for the local delivery of the chemotherapeutic drug bleomycin to treat solid tumors. OMS consists of an electrical pulse generator console and various disposable applicators specific to the individual tumor size, type and location and is designed to increase the permeability of cancer cell membranes and, as a result, increases the intracellular delivery of selected therapeutic agents. Using either ImmunoPulse, a DNA-based immunotherapy or NeoPulse, a therapy to treat solid tumors, our mission is to enable people with cancer to live longer with a better quality of life than otherwise possible or available with existing therapies.

Cancer is a disease of uncontrolled cell growth. The primary front line treatment of solid tumors involves surgical resection and/or radiation to eliminate or debulk tumor growth prior to initiating systemic therapy with chemotherapeutic agents. In the case of invasive surgical procedures, surgeons will often remove or resect an area outside of the obvious tumor mass to ensure that they have

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excised all of the cancerous tissue because of the difficulty in determining the border, or margin, between healthy and diseased tissue. This treatment can result in the loss of function and appearance of the surrounding tissues, significantly reducing the patient s quality of life. Although there have been recent advances in non-surgical forms of tumor ablation, such as cryoablation, stereotactic, microwave and high frequency radio ablation therapy, we believe they fail to fully satisfy the clinical need to preserve normal healthy tissue. Given the desire for improved outcomes in the surgical resection of solid tumors, we believe that there can be significant demand for our NeoPulse technology from patients, dermatologists and surgical oncologists.

The NeoPulse approach has been developed up to Phase III clinical trials in the United States for the treatment of recurrent head and neck cancer and Phase I/II for the treatment of recurrent breast cancer. NeoPulse has potential application in a wide range of solid tumors, including basal cell carcinoma, squamous cell carcinoma, melanoma, breast, prostate, and pancreatic cancers. In addition, Phase IV pre-marketing studies to support the commercialization of NeoPulse in Europe have also been performed for the treatment of primary and recurrent head and neck cancers and cutaneous skin cancers.

When detected early and still confined to a single location, cancer may be cured by surgery or irradiation and potentially, by promising new technologies such as NeoPulse. However, neither surgery nor irradiation can cure cancer that has spread throughout the body. Although chemotherapy can sometimes effectively treat cancer that has spread throughout the body, a number of non-cancerous cells, such as bone marrow cells, are also highly susceptible to chemotherapy. As a result, chemotherapy often has fairly significant side effects. In addition, it is common to see cancer return after apparently successful treatment by each of these means.

Immunotherapy, a process which uses the patient s own immune system to treat cancer, may have advantages over surgery, irradiation, and chemotherapy. Many cancers appear to have developed the ability to hide from the immune system. A treatment that can augment the immune response against tumor cells by making the cancer more visible to the immune system would likely represent a significant improvement in cancer therapy. Immune-enhancing proteins such as interleukin-2, or IL-2, and interferon-alpha, or IFN- , have shown encouraging results. However, these agents often require frequent doses that may result in severe side effects.

Two new drugs for metastatic melanoma were approved in 2011, both on the basis of increased survival. Yervoy ®, a monoclonal antibody marketed by Bristol-Myers Squibb Co., increases the effectiveness of T-cells that can seek out and destroy melanoma cells. Zelboraf ®, a B-Raf inhibitor marketed by Roche and Daiichi Sankyo, interrupts a key process in melanoma growth in patients with a particular melanoma mutation. Both drugs are associated with significant side effects, and neither is considered a cure for melanoma.

Our current ImmunoPulse clinical-stage approach consists of directly injecting solid tumors with a DNA plasmid which, upon uptake into cells, direct the production of the encoded immunostimulatory cytokine to generate a local, regional and systemic immune response. The ease of manufacture, convenience, and ability to repeat administration may offer advantages over current modalities of therapy. In addition, cancer therapies using non-viral DNA delivery may offer an added margin of safety compared with viral-based delivery, as no viral particles or other potentially infectious agents are contained in the formulation. A Phase I clinical trial using our ImmunoPulse approach has been completed and three Phase II clinical trials focused on melanoma, Merkel cell carcinoma and cutaneous T-cell lymphoma have been initiated.

Our business model is based on a commercialization strategy that leverages previous in-depth clinical experiences, previous approvals for the electroporation-based devices and late stage clinical studies in the United States and Europe. We may plan to seek regulatory approvals to initiate specific studies in target markets to collect clinical, reimbursement, and pharmacoeconomic data in order to advance our commercialization strategy. Our clinical development strategy includes completing the necessary additional clinical trials in accordance with FDA guidelines for cutaneous cancers including select rare cancers that have limited, adverse or no therapeutic alternatives. Our strategy also

includes expanding the applications of our technologies through strategic collaborations or evaluation of other opportunities such as in-licensing and strategic acquisitions. We may collaborate with major pharmaceutical and biotechnology companies and government agencies, providing us access to complementary technologies or greater resources. These business activities are intended to provide us with mutually beneficial opportunities to expand or advance our product pipeline and serve significant unmet medical needs. We may license our intellectual property to other companies to leverage our technologies for applications that may not be appropriate for our independent product development.

Asset Acquisition

On March 14, 2011, we entered into an Asset Purchase Agreement with Inovio to acquire certain assets from Inovio related to certain non-DNA vaccine technology and intellectual property relating to selective electrochemical tumor ablation (formerly referred to as SECTA, and which we now refer to as the OncoSec Medical System, or OMS). The asset purchase was completed on March 24, 2011. On September 28, 2011 and March 24, 2012, we entered into amendments to the Asset Purchase Agreement to

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amend certain of the payment terms. We acquired the following assets from Inovio in connection with this transaction: certain equipment, machinery, inventory and other tangible assets of Inovio related to the OMS technology; certain engineering and quality documentation related to the OMS technology; the assignment of certain contracts; and certain of Inovio s patents, including patent applications, and trademarks, and all goodwill associated therewith related to the OMS technology. We did not assume any of the liabilities of Inovio except with respect to all liabilities under the assigned contracts and assigned or acquired intellectual property arising after the closing of the acquisition.

Pursuant to a cross-license agreement with Inovio entered into in connection with the closing of the asset acquisition, we granted to Inovio a fully paid-up, exclusive, worldwide license to certain of the OMS technology patents in the field of gene or nucleic acids, outside of those encoding cytokines, delivered by electroporation. Inovio also granted us a non-exclusive, worldwide license to certain non-OMS technology patents in the OMS field for the following consideration: a fee for any sublicense of the Inovio technology; a royalty on net sales of any business we develop with the Inovio technology; and repayment of Inovio for any amount Inovio pays to the licensor of the Inovio technology that is a direct result of the license.

We are required to pay Inovio $3,000,000 in scheduled payments over a period of two years from the closing date and a royalty on commercial product sales related to the OMS technology. As we describe elsewhere in this filing, on March 18, 2011, we closed a private placement of 1,456,000 units at a purchase price of $0.75 per unit for gross proceeds of $1,092,000. Each unit consists of one share of our common stock and one share purchase warrant entitling the holder to acquire one share of common stock at a price of $1.00 per share for a period of five years from the closing of such private placement. We used $250,000 of the proceeds as the first payment to Inovio pursuant to the Asset Purchase Agreement. On September 28, 2011, we entered into a First Amendment to Asset Purchase Agreement (the First Amendment). The First Amendment modified the payment terms of the $750,000 due to Inovio by September 24, 2011, instead requiring us to make a payment of $100,000 to Inovio on September 30, 2011, with the remaining $650,000 to be paid to Inovio at the earlier of (a) 30 days following the receipt by us of aggregate net proceeds of more than $5,000,000 from one or more financings occurring on or after September 30, 2011, or (b) March 31, 2012. On March 24, 2012, we entered into a Second Amendment to Asset Purchase Agreement (the Second Amendment). The Second Amendment further modified the payment terms for the $1,150,000 scheduled payments due to Inovio in March 2012 by requiring us to make a payment of $150,000 on March 31, 2012, with the remaining $1,000,000 to be paid to Inovio on December 31, 2013. In consideration for the amendments, we issued to Inovio warrants to purchase 1,000,000 and 3,000,000 shares of our common stock, respectively. The warrants have an exercise price of $1.20 and $1.00 per share, respectively, are exercisable immediately upon issuance and have an exercise term of five years. The warrants also contain a mandatory exercise provision allowing us to request the exercise of the warrant in whole provided that our daily market price (as defined in the warrant) is equal to or greater than $2.40 for twenty consecutive trading days. Payment of the remaining amounts owed to Inovio are due on the following schedule: $500,000 eighteen months from the closing date, September 24, 2012; $1,000,000 on the second anniversary of the closing date, March 24, 2013; and $1,000,000 on December 31, 2013.

The OncoSec Medical System

Most drugs and DNA-based therapeutics must enter the target cell through its membrane in order to perform their intended function. However, the effectiveness of these medicines is limited as gaining entry into target cells through the outer membrane can be a significant challenge. 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. As a consequence, it was also demonstrated that there was a subsequent increase in the ability of both small and large molecules to move between the cell exterior and interior via the newly formed membrane pores.

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 OMS therapeutic approach. OMS consists of an electrical pulse generator console and various disposable applicators specific to the individual tumor size, type and location. While the extent of membrane permeabilization depends on various electrical, physical, chemical, and biological parameters, research with OMS has demonstrated an increase of cellular uptake of chemical

molecules from 6,000-8,000 fold above baseline. Once inside of the cell, the membrane permeability decreased thereby trapping the molecules within the cell and allowing them to perform their function. The enhanced delivery of these agents may result in the ability to not only improve cytotoxicity and therapeutic value but also to lower the required doses and thereby providing a potentially safer treatment.

DNA Delivery With Electroporation ImmunoPulse

The greatest obstacles to making conventional immunotherapy and DNA-based immunotherapies a reality has been the limited data supporting safe, efficient, and economical delivery and expression of plasmid-DNA constructs into the target cells. We are leveraging off the past history and experience of certain managers and advisors in developing the methods and devices that optimize the use of electroporation for the efficient and effective delivery of DNA-based therapeutics. The use of OMS in this

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approach has been validated from multiple clinical studies assessing DNA-based immunotherapies against cancers. Together with our partners and collaborators, we plan to be the leader in establishing electroporation-delivered DNA immunotherapies. We believe that electroporation should become the method of choice for plasmid-DNA delivery into cells in many clinical applications.

The immunotherapy approach of our OMS therapy uses an electroporation system that is calibrated and designed to create optimal conditions to deliver plasmid DNA encoding immunotherapeutic cytokines into tumor cells that in turn promote anti-cancer responses. The cytokine-encoding plasmid is first injected with a syringe/needle into the selected tumor. Using a remote control, the pulse generator is switched on and electrical pulses are generated and delivered through an attached electrical cord into the injected tissue through an electrode-needle array on the applicator. When DNA injection is followed by electroporation of the target tissue, transfection is significantly greater with resultant gene expression generally enhanced from 100 to 1000-fold. This increase makes many DNA-based candidates potentially feasible without unduly compromising safety or cost.

A Phase I clinical trial in metastatic melanoma has been completed using ImmunoPulse to deliver plasmid-DNA encoding for the IL-12 cytokine. The study was designed to assess both the adaptive and innate immunity responses from the targeted delivery of the IL-12 into melanoma tumor cells. Published data have suggested that gene transfer utilizing in vivo DNA electroporation in metastatic melanoma showed that it was safe, effective, reproducible, and titratable. The findings also demonstrated not only regression of treated melanoma skin lesions, but also regression of distant untreated lesions, suggesting a systemic immune response to the localized treatment. These results are of great significance and thus the Company is now planning the further development of OMS for the delivery of plasmid-DNA encoding for the IL-12 cytokine in a Phase II clinical trial that has been initiated.

Drug Delivery With Electroporation NeoPulse

The chemotherapeutic approach of our OMS ElectroOncology platform was formerly described as Selective Electrochemical Tumor Ablation (SECTA). OMS utilizes electroporation technologies for the local delivery of the chemotherapeutic drug bleomycin to treat solid tumors. The approach has demonstrated safety and efficacy in a wide range of solid tumors including, basal cell, squamous cell, melanoma, breast, prostate, and pancreatic. The OMS therapy has been developed up to Phase III clinical trials in the United States for the treatment of recurrent head and neck cancer and in Phase I/II for the treatment of recurrent breast cancer. In addition, Phase IV pre-marketing studies to support the commercialization of the OMS system in Europe were also performed for the treatment of primary and recurrent head and neck cancers and cutaneous skin cancers. The previous sponsor of these studies (Inovio Pharmaceuticals, Inc.) elected not to conclude the clinical testing but rather monetize certain SECTA assets in order to pursue a more focused strategy for development of DNA vaccines.

We believe that one of the distinctive features of the system is both the preservation of healthy tissue and killing of cancerous cells at the margins of the tumor. We anticipate the system may therefore afford advantages over surgery in preserving function and improving the quality of life for cancer patients who would otherwise face significant morbidity associated with cancer surgery or other methods of treatment. In addition, we believe that the OMS ElectroOncology approach will have pharmacoeconomic advantages over existing therapies and will be more readily accepted by both physicians and patients alike.

Clinical Program

We initiated three Phase II clinical trials to assess the cancer-destroying and tissue-sparing properties of the ImmunoPulse technology in patients with melanoma, Merkel cell carcinoma and cutaneous T-cell lymphoma during calendar year 2012. Our lead ImmunoPulse candidate for these trials is a DNA plasmid coding for IL-12 that is delivered using our OMS electroporation device. While the DNA IL-12 immunotherapy is administered locally, results from preclinical and Phase I clinical trials indicated that the therapy was safe and without toxic side effects. Although Phase I trials are designed to study only safety and tolerability, our Phase I melanoma trial suggested that our ImmunoPulse produced both a local and systemic effect against cancerous cells. All three Phase II clinical trials are currently physician-sponsored open label, multi-center trials. In the future we expect to transfer the physician sponsored Investigational New Drug (IND) applications for these current Phase II clinical trials to the Company.

Phase II Melanoma Trial (OMS-I100)

Our melanoma trial, entitled Phase II trial of intratumoral pIL-12 electroporation in advanced stage cutaneous and in transit malignant melanoma, is a single dose trial treating approximately 25 patients. The primary endpoint is the objective response rate (local and distant) at six months. Secondary trial endpoints include time to objective response (complete and partial responses), duration of distant response and overall survival. We are building on positive Phase I dose escalation trial results in 24 patients with metastatic melanoma treated with pIL-12 in combination with electroporation. That study established safety and tolerability and suggested a systemic objective response in more than half of the subjects; 15% of patients showed 100% clearance of distant, nontreated tumors. Based on historical data, less than 0.25% of patients would have been expected to see regression in their untreated tumors. Our melanoma study is currently a physician-sponsored trial that is led by the University of California at San Francisco.

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Phase II Merkel Cell Carcinoma Trial (OMS-I110)

Merkel cell carcinoma is a rare but lethal skin cancer affecting about 1,500 people each year with 33% mortality rate. Current outcomes to chemotherapy treatment have demonstrated short-lived responses with no clear impact on overall survival. Our clinical trial, entitled A Phase II study of intratumoral injection of interleukin-12 plasmid and in vivo electroporation in patients with Merkel cell carcinoma, is a single dose, open label trial in 15 patients. The study s endpoints are IL-12 gene expression in tumor tissue at three to four weeks post-treatment and objective response rates (both local and distant) at six months post-treatment. Secondary endpoints will evaluate time to relapse or progression and overall survival. This study will evaluate the safety and tolerability of DNA IL-12 as a treatment for Merkel cell carcinoma and aims to further validate the findings from the Phase I dose escalation trial carried out in 24 metastatic melanoma patients. This study is currently a physician-sponsored trial initiated at the University of Washington in collaboration with the University of California at San Francisco.

Phase II Cutaneous T-Cell Lymphoma (OMS-I120)

Cutaneous T-cell lymphoma, or CTCL, is a rare disease affecting approximately 3,000 people each year with current therapies requiring life-long management and treatment. Today s treatment methods delivered either locally or systemically all result in systemic toxicities. Cytokine therapies have shown some therapeutic benefit, however, the requirement for high dose systemic concentrations results in unwanted toxicities and eventual resistance to the therapy. In contrast, our ImmunoPulse treatment uses locally delivered low dose plasmid-DNA coding for IL-12, which induces a systemic immune response designed to target and destroy cancerous cells. A previous Phase I clinical trial in 24 melanoma patients demonstrated a strong safety profile for this mode of treatment. The planned clinical trial, entitled Phase II trial of intratumoral IL-12 plasmid electroporation in cutaneous lymphoma, is an open label, multi-center study and is expected to enroll 27 patients. The trial s primary endpoint is to assess the objective response rate (both local and distant) at six months post-treatment, with safety and progression-free survival as secondary endpoint measures. ImmunoPulse is a new treatment for patients suffering from CTCL, who currently have few options to treat this chronic life-altering disease. This study is currently a physician-sponsored trial led by the University of California at San Francisco.

Scientific Advisory Panel

We have consulted with senior and respected oncology researchers to provide counsel as part of our scientific advisory panel for our ImmunoPulse clinical program, each of whom is employed elsewhere on a full-time basis. As a result, they can only spend a limited amount of time on our affairs. We expect to access scientific and medical experts in academia, as needed, to support our scientific advisory panel. The scientific advisory panel assists us on issues related to potential product applications, product development and clinical testing.

Commercialization

Our business model is based on a partnering and commercialization strategy that leverages previous in-depth clinical experiences, and late stage clinical studies in the United States (Phase III) and Europe (Phase IV). Our near term plan will be to identify and engage potential partner(s) who are established industry leaders in the field of surgical oncology, or who are seeking to expand their portfolio into this space with the purpose of partnering the NeoPulse asset in select geographic regions, such as Eastern Europe and Asia. Once a partner is engaged, we may plan to seek regulatory approvals to initiate specific studies in target markets to collect clinical, reimbursement, and pharmacoeconomic data in order to advance a joint commercialization strategy.

We plan to continue our clinical development strategy for the ImmunoPulse program with Phase II and subsequent pivotal clinical trials focused on cutaneous cancers including select rare cancers that have limited, adverse or no therapeutic alternatives. We expect our current studies to validate data from previous Phase I clinical experience, which will be used to further develop the Company s commercialization strategy for this program.

Competition

We are in a highly competitive industry. We are in competition with traditional and alternative therapies for the indications we are targeting, as well as pharmaceutical and biotechnology companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of drugs and other therapies for these indications. Our competitors may succeed, and many have already succeeded, in developing competing products, obtaining FDA approval for products or gaining patient and physician acceptance of products before us for the same markets and indications that we are targeting. Many of these companies, and large pharmaceutical companies in particular, have greater research and development, regulatory, manufacturing, marketing, financial and managerial resources and experience than we have and many of these companies may have products and product candidates that are in a more advanced stage of development than our product candidates. If we are not first to market for a particular indication, it may be more difficult for us or our collaborators to effectively enter markets unless we can demonstrate our products are clearly superior to existing therapies (see also Intellectual Property below).

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Examples of competitive therapies include the following:

- Surgical Resection. In 90% of cases, the primary treatment for localized and operable tumors or lesions is surgical resection alone or in combination with other modalities such as radiation therapy. Given the ability to cut an appropriate margin around the tumor in order to avoid recurrence from microscopic disease populating the periphery of the tumor mass makes surgery highly effective for early stage cancers. Recent advances in robotic surgical technology have provided more minimally invasive surgical options. However, accessibility of a tumor at times prevents the use of surgery or limits the margin that can be removed especially at sites such as the tongue where the loss of tissue results in the loss of critical function such as speech. The drawback to resecting tissue is potential disfigurement or debilitating effects on organ function. Surgery also requires additional cost in the form of hospitalization and post-operative care.

- Radiation Therapy. Radiation therapy s high-energy rays generated by an external machine or by radioactive materials placed directly into or near the tumor are used to damage and stop growth of malignant cells, which are more sensitive to the effects of radiation. Radiation is often used in combination with surgery and chemotherapy. In cases where a tumor is inoperable or unresponsive to chemotherapy, radiation is often used palliatively to limit the complications of disease progression. Radiation therapy has a number of significant side effects, in that it damages healthy cells surrounding the target area and takes several weeks to administer. It may also be costly due to the number of procedures and cost of administration.

- Chemotherapy. Post-surgery or in cases where surgery is contraindicated, chemotherapy is often used to treat systemic disease and may frequently be combined with radiation therapy. Typically it is used under the following circumstances:

- When cancer is disseminated requiring treatment of systemic or metastatic disease;

- Where the prognosis for local regional disease is poor due to the likelihood of disease progression;

- Where surgery is contraindicated, e.g. certain liver or pancreatic carcinoma or as a result of the patient s overall health condition; and

- For palliation, to achieve tumor shrinkage to ameliorate tumor symptoms or complications.

The cytotoxicity of many existing anti-cancer drugs is well proven, but with many undesirable proven side effects including immunosuppression alopecia (loss of hair), nausea, vomiting, and in some cases drug resistance. Surgery and radiation cannot be used where treatment poses a risk to nearby nerves, blood vessels, or vital organs. All of these practices have limited efficacy in treating cancers of certain organs, such as the pancreas.

- Alternative treatments. Competitive therapies also include alternative treatments, such as radio frequency ablation, photodynamic therapy, cryoablation, brachytherapy and biologic or immunotherapy:

- Radio Frequency Ablation (RFA). This modality uses radio frequency energy to heat tissue to a high enough temperature to cause ablation or cell death. An RFA ablation probe is placed directly into the target tissue. An array of several small, curved electrodes is deployed from the end of the probe. Once sufficient temperatures are reached, the heat kills the target tissue within a few minutes. This treatment has been proven efficacious in treating some solid tumors but suffers from not being tumor specific by destroying healthy as well as malignant tissue.

- Photodynamic Therapy. Photodynamic therapy (PDT) uses intravenous administration of a light-activated drug that accumulates in malignant cells. A non-thermal laser is used to activate the drug, producing free radical oxygen molecules that destroy the cancer. PDT has low risk of damage to adjacent normal tissue, the ability to retreat, and can be used concurrently with other treatment modalities. A major side effect of PDT is patient photosensitivity that can last up to eight weeks. Other side effects include nausea and vomiting. This method is limited by the shallow depth of penetration of the laser light which makes it more applicable to surface lesions on the skin or esophagus.

- Cryoablation. Cryoablation is a technique being used to treat lesions in liver, kidney, prostate, and breast cancer. This method uses liquid nitrogen filled probes inserted into the tumor mass with image guided surgery to freeze cancer cells. Necrosis (cell death) occurs and the dead cells are naturally sloughed off into the body. Cryoablation has been most commonly adopted for use in treating prostate carcinoma where surgery can often lead to impotence. The technology is claimed to limit nerve damage in the prostate allowing for the retention of bladder and sexual function. Therefore, it may afford advantages over surgery and brachytherapy (see below).

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- Brachytherapy. Brachytherapy involves the local implantation of radioactive seeds into or near a tumor mass. It has been most widely used in prostate and breast carcinoma in situ. The seeds decay over time resulting in the local destruction of malignant cells. The difficulty with brachytherapy, in addition to the concomitant destruction of nascent healthy tissue, is the investment and training required to administer the therapy. Recent reports also suggest that the therapy may not produce durable responses (i.e. long term cures). Consequently, brachytherapy does not appear to be growing in acceptance in the marketplace.

- Biological and Immunotherapy. This therapeutic approach stimulates the patient s own immune system to attack malignant tumor cells, which have managed to circumvent the body s natural immune processes that would normally recognize and destroy these cells before they are able to form growing cancerous tumors. Several methods have been employed to evoke this immune response, including monoclonal antibodies and autologous cell-based vaccines, as well as viral and non-viral targeted delivery of immunotherapeutic agents.

Yervoy® is a monoclonal antibody that acts to block the CTLA-4 receptor (an immune checkpoint receptor) on T-cells. In the presence of CTLA-4 receptor it is believed tumors are able suppress the immune system from recognizing cancerous cells, however, blockade of this receptor with Yervoy® (an anti-CTLA-4 antibody) appears to allow the immune system to generate an antitumor T-cell response. Yervoy® was the first approved immunotherapy in melanoma, and current research is evaluating the use of other anti-checkpoint monoclonal antibodies. Despite these therapies showing benefit to some patients by extending life beyond traditional therapeutic options, safety and tolerance to these drugs, as well as ease of administration of the therapies, may be a deterrent for some patients. As a result, emerging therapies continue to be developed to improve upon the safety, efficacy and ease-of-use problems currently encountered by immunotherapies.

Like Provenge®, a product developed and marketed by Dendreon Corporation, many emerging therapies continue to employ an autologous cell-based mode of delivery, which involves the harvesting of a patients own cells, growing them in a lab, incubating with a vaccine or immune stimulating agent, and re-administering the resulting product to the patient. This autologous cell-based approach has shown safety and efficacy, however, the significant cost and time involved in preparing this therapeutic treatment for each individual patient has been unattractive for many patients and clinicians.

Viral vectors, such as adenoviruses and oncolytic viruses, have also been used to deliver immunotherapeutic payloads to fight against cancerous cells, either systemically or through direct injection into the tumor. Clinical trials for this therapeutic delivery method are on-going with no approved therapies yet to be available in the clinic, however, questions still remain about efficacy of viral vectors as a delivery method, since the patient may mobilize an immune reaction against the virus itself resulting in neutralization of the virus and clearance from the body before an effectual response is elicited. Since viral vectors are occasionally created from pathogenic viruses, involving a deletion of a part of the viral genome critical for viral replication, safety has also been a concern to avoid production of new virions.

Other non-viral vector methods, including liposome-based delivery systems, are also currently being developed and employed in on-going clinical trials. The impact of these emerging cancer immunotherapies will ultimately be determined by their ability to improve upon the safety, efficacy, utility and cost of currently available therapies.

- Vaccination. The use of vaccination has long held interest as another potential modality that could prove beneficial in treating and limiting systemic disease. The challenge has been that many tumors do not display antigens unique to the tumor cell that the immune system can use to specifically target for selective destruction of the malignant tissue. Even though tumors over-express normal cellular products that the immune system ignores, due to a process called tolerization, the immune system is educated not to recognize self antigens early in development.

As a result of the lack of immune system detection, it has proven difficult to use conventional vaccination strategies to break or overcome tolerance and generate immunity against tumor cells.

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Research and Development Expenditures

Prior to our acquisition of certain assets of Inovio in March 2011, we did not engage in any research and development activities. We incurred $648,314 in research and development expenses from March 2011 through the remainder of the fiscal year ended July 31, 2011, and $2,368,481 in research and development expenses during the fiscal year ended July 31, 2012. We expect research and development to account for a significant portion of our total expenses in the future as we continue to focus on designing and developing our therapies. Our expenditures will be primarily related to the advancement of three Phase II clinical trials to assess the ImmunoPulse technology in patients with melanoma, Merkel cell carcinoma and cutaneous T-cell lymphoma. Expenditures related to these studies began during calendar year 2011 and we expect to ramp up expenditures based on enrollment in the trials and subsequent analysis of patient data from the separate studies.

Employees

Concurrent with the asset acquisition, we assembled a senior management team with many years of experience and success in biotech/pharma operations, business and commercial development and capital markets. In addition, we have assembled a clinical and regulatory team that has had many years of experience in developing and advancing novel therapeutic approaches through clinical testing and regulatory approvals. As of October 12, 2012, we had a total of ten full-time employees.

We expect to hire additional staff and to engage consultants in regulatory, compliance, investor and public relations, and general administration as necessary. We also expect to engage experts in healthcare and in general business to advise us in various capacities.

Intellectual Property

Our success and ability to compete depends upon our intellectual property. We have acquired and have been issued 27 U.S. patents and have two U.S. patent applications pending. We expect to file additional patent applications. We have a total of 18 issued patents and patent applications in other jurisdictions. The bulk of our patents, including fundamental patents directed toward our proprietary technology, expire between 2014 and 2027. In addition, we have licensed intellectual property rights to use certain electroporation technology and intellectual property for delivering DNA-based cytokines as an immunotherapy.

Government Regulation

United States

In the United States, our product candidates are subject to extensive regulation by the Food and Drug Administration (the FDA). Federal and state statutes and regulations, many of which are administered by the FDA, govern, among other things, the research, development, testing,

manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, postapproval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA s refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

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

- completion of pre-clinical testing and formulation studies in compliance with the FDA s good laboratory practice regulations;

- submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must become 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 drug product for each intended use; and

- submission to the FDA of a new drug application, or NDA, which the FDA must review and approve.

The pre-clinical and clinical testing and approval process 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.

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

- *Phase I*: The drug is initially introduced into 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 effectiveness.

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

- *Phase IV*: In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor s agreement to conduct additional clinical trials to further assess the drug s safety and effectiveness after NDA approval.

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

Once the submission has been accepted for filing, the FDA begins an in-depth substantive review. Pursuant to the FDA s performance goals, NDA reviews are to be completed within ten months, subject to extensions by the FDA. Before approving an NDA, 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. If the FDA determines that the NDA is not acceptable, then the FDA may outline the deficiencies in the NDA and often will request additional information or additional clinical trials. 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.

Even if regulatory approval of a product candidate is obtained, such approval will usually entail limitations on the indicated uses for which the product may be marketed. Additionally, the FDA may require post-approval testing, such as Phase IV studies, or surveillance programs to monitor the effect of approved products, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

After FDA approval, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug/device listing, recordkeeping, periodic reporting, product sampling and distribution, manufacturing practices, labeling, advertising and promotion, and reporting of adverse experiences with the product. The FDA may withdraw its approval of a product if compliance with regulatory requirements and manufacturing standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: restrictions on the marketing or manufacturing of the product; complete withdrawal of the product from the market or product recalls; fines, warning letters or

holds on post-approval clinical trials; or injunctions or the imposition of civil or criminal penalties.