ONCOSEC MEDICAL Inc
Form POS AM
October 31, 2012
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AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON OCTOBER 31, 2012

Registration No. 333-179146

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Post-Effective Amendment No. 1

to

FORM S-1

on

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ONCOSEC MEDICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Nevada	**98-0573252**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4690 Executive Drive, Suite 250

San Diego, California 92121

(855) 662-6732

(Address, including zip code and telephone number, including area code, of

registrant s principal executive offices)

Punit Dhillon

President and Chief Executive Officer

4690 Executive Drive, Suite 250

San Diego, California 92121

(855) 662-6732

(Address, including zip code and telephone number,

including area code, of agent for service)

Copy to:

Steven G. Rowles, Esq.

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Morrison & Foerster LLP

12531 High Bluff Drive, Suite 100

San Diego, California 92130

(858) 720-5100

(858) 720-5125 (fax)

Approximate date of commencement of proposed sale of the securities to the public: From time to time, after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

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 (do not check if a smaller reporting company) o	Smaller reporting company x

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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EXPLANATORY NOTE

On January 24, 2012, OncoSec Medical Incorporated (the Company) filed with the Securities and Exchange Commission (the Commission) a registration statement on Form S-1 (File No. 333-179146) (as amended, the Initial Registration Statement) registering the offer and sale of up to 40,000,000 shares of the Company s common stock, warrants to purchase up to 40,000,000 shares of common stock, and up to 40,000,000 shares of common stock underlying the warrants. The Registration Statement was declared effective by the Commission on March 23, 2012. The Company sold an aggregate of 31,000,000 shares of common stock and warrants to purchase 31,000,000 shares of common stock pursuant to the Initial Registration Statement.

This Post-Effective Amendment No. 1 to Form S-1 on Form S-3 (this Post-Effective Amendment) is being filed to (i) deregister certain securities, (ii) convert the Form S-1 into a registration statement on Form S-3, and (iii) register only the 31,000,000 shares of common stock issuable upon the exercise of the already issued warrants. No further offering will be made pursuant to this Post-Effective Amendment. All filing fees payable in connection with the registration of the securities were previously paid by the registrant in connection with the filing of the Initial Registration Statement.

Deregistration of Unsold Securities

Pursuant to the Company s undertakings in Part II, Item 17 of the Initial Registration Statement, the Company hereby removes from registration the securities registered under the Initial Registration Statement that remained unsold at the termination of the offering, or an aggregate amount of 9,000,000 shares of common stock, warrants to purchase 9,000,000 shares of common stock and 9,000,000 shares issuable upon exercise of the warrants. The Company is requesting the removal from registration of these securities as the offering of the securities terminated on March 30, 2012.

Registration of Common Stock upon Exercise of Warrants

This Post-Effective Amendment also contains an updated prospectus relating to an aggregate of 31,000,000 shares of common stock issuable upon the exercise of warrants previously issued to investors in connection with the offering of the securities, which closed on March 28, 2012. This Post-Effective Amendment is being filed in compliance with Section 10(a)(3) of the Securities Act of 1933, as amended.

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THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES NOR IS IT AN INVITATION FOR OFFERS TO BUY THESE SECURITIES IN ANY STATE OR JURISDICTION WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED OCTOBER 31, 2012

PROSPECTUS

OncoSec Medical Incorporated

Up to 31,000,000 Shares of Common Stock Issuable Upon Exercise of Warrants

This prospectus relates to the issuance of up to 31,000,000 shares of our common stock upon the exercise of outstanding warrants with an exercise price of $0.35 per share, which were issued by us as part of an offering that closed on March 28, 2012.

Our common stock is listed on the OTC Bulletin Board under the symbol ONCS.OB. On October 26, 2012, the last reported sales price of our common stock was $0.29 per share.

The shares may be sold or otherwise disposed of from time to time. We may receive proceeds in connection with the exercise of the warrants.

Investing in our securities involves risks. You should review carefully the risks and uncertainties described under the heading Risk Factors beginning on page 4 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is .

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ABOUT THIS PROSPECTUS

You should rely only on the information provided in this prospectus, in any prospectus supplement, including the information incorporated by reference. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus or any supplement to this prospectus is accurate at any date other than the date indicated on the cover page of these documents or the date of the statement contained in any incorporated documents, respectively. This prospectus is not an offer to sell or a solicitation of an offer to buy any securities other than the securities referred to in the prospectus supplement. This prospectus is not an offer to sell or a solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should not interpret the delivery of this prospectus, or any sale of securities, as an indication that there has been no change in our affairs since the date of this prospectus. You should also be aware that information in this prospectus may change after this date. The information contained in this prospectus or a prospectus supplement or amendment, or incorporated herein or therein by reference, is accurate only as of the date of this prospectus or prospectus supplement or amendment, as applicable, regardless of the time of delivery of this prospectus or prospectus supplement or amendment, as applicable, or of any sale of the shares.

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PROSPECTUS SUMMARY

This summary does not contain all of the information that should be considered before investing in our common stock. Investors should read the entire prospectus carefully, including the more detailed information regarding our business, the risks of purchasing our common stock discussed in this prospectus under Risk Factors .

As used in this prospectus, unless the context requires otherwise, the Company , we , us , and our refer to OncoSec Medical Incorporated, a Nevada corporation, and its consolidated subsidiary.

Our Company

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.

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 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.

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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.

Corporate Information

We were incorporated under the laws of the State of Nevada on February 8, 2008 under the name Netventory Solutions Inc. to pursue the business of inventory management solutions. Effective March 1, 2011, we completed a merger with our subsidiary, OncoSec Medical Incorporated, a Nevada corporation which was incorporated solely to effect a change in our name. As a result, we have changed our name from Netventory Solutions Inc. to OncoSec Medical Incorporated . Our principal executive offices are located at 4690 Executive Drive, Suite #250, San Diego, CA 92121. 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 deemed part of this prospectus.

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THE OFFERING

Securities offered	Up to 31,000,000 shares of common stock (warrant shares) issuable upon the exercise of outstanding warrants with an exercise price of $0.35 per share, which were issued by us as part of an offering that closed on March 28, 2012.
Common stock outstanding as of October 26, 2012	88,159,000(1)
Common stock outstanding following the issuance of all warrant shares covered by this prospectus	119,159,000(1)
Use of Proceeds	We expect to use proceeds received from the exercise of the warrants for working capital and general corporate purposes. However, the warrant holders may choose not to exercise their warrants, and we may never receive any proceeds from their exercise. See Use of Proceeds for more information.
OTC Bulletin Board Symbol	ONCS.OB

(1) Excludes (i) 5,200,000 shares of common stock reserved for future issuance under our 2011 Stock Incentive Plan (the 2011 Plan) and (ii) 10,943,000 shares of common stock issuable upon the exercise of outstanding warrants that are not being registered pursuant to the registration statement of which this prospectus forms a part. As of October 26, 2012, there were (i) options to purchase 4,525,000 shares of our common stock outstanding under the 2011 Plan, with a weighted average exercise price of $0.22 per share and (ii) 41,943,000 shares of common stock issuable upon the exercise of outstanding warrants with exercise prices ranging from $0.3125 to $1.20 per share.

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RISK FACTORS

The following risk factors should be considered carefully in addition to the other information contained in this prospectus. This prospectus contains forward-looking statements. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks. Additional risks not presently known to us or that we currently deem immaterial may also impair our business financial condition, results of operations and stock price.

We must raise additional capital in order to continue operating our business, and such additional funds may not be available on acceptable terms or at all.

We do not generate any cash from operations and must raise additional funds in order to continue operating our business. We expect our cash requirements over the annual fiscal period ending July 31, 2013, including our mandatory payments to Inovio under the Asset Purchase Agreement, to be approximately $6,400,000. As of July 31, 2012, we had cash and cash equivalents of $5,141,509.

We expect to continue to fund our operations primarily through equity and debt financings in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely. We will require additional financing to fund our planned operations, including developing and commercializing the assets obtained under the Asset Purchase Agreement with Inovio, seeking to license or acquire new assets, researching and developing any potential patents, related compounds and other intellectual property, funding potential acquisitions, and supporting clinical trials and seeking regulatory approval relating to our assets and any assets we may acquire in the future. Additional financing may not be available to us when needed or, if available, may not be available on commercially reasonable terms. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments.

We may not be able to obtain additional financing if the volatile conditions in the capital and financial markets, and more particularly the market for early development stage biomedical company stocks, persist. Weak economic and capital markets conditions could result in increased difficulties in raising capital for our operations. We may not be able to raise money through the sale of our equity securities or through borrowing funds on terms we find acceptable. If we cannot raise the funds that we need, we will be unable to continue our operations, and our stockholders could lose their entire investment in our company.

We have never generated revenue from our operations and our independent auditors have expressed substantial doubt about our ability to continue as a going concern.

We have not generated any revenue from operations since our inception. During the annual period ended July 31, 2012, we incurred a net loss of $2,364,852. From inception through July 31, 2012, we incurred an aggregate loss of $6,200,728. We expect that our operating expenses will increase substantially over the 2013 fiscal year as we continue to pursue U.S. Food and Drug Administration (FDA) approval for our product candidates. We expect our expenses during our fiscal year ending July 31, 2013 to be approximately $6,400,000, including general and

administrative expenses and our mandatory payments to Inovio but excluding the cost of any future acquisitions and development activities. As of July 31, 2012, we had cash and cash equivalents of $5,141,509.

In order to fund our anticipated budget through the end of our fiscal year ending July 31, 2013, including payments owing to Inovio under the Asset Purchase Agreement, we believe that we will need to raise approximately $1.3 million in additional funds. This amount could increase if we encounter unanticipated difficulties. In addition, our estimates of the amount of cash necessary to fund our business and development and commercialization activities may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these were to occur, there is a substantial risk that our business would fail.

These circumstances raise substantial doubt about our ability to continue as a going concern, as described in the explanatory paragraph to our independent auditors report on our financial statements for the year ended July 31, 2012, which is included in our Annual Report on Form 10-K for the fiscal year ended July 31, 2012, filed with the Securities and Exchange Commission (the SEC) on October 15, 2012. Although our financial statements raise substantial doubt about our ability to continue as a going concern, they do not reflect any adjustments that might result if we are unable to continue our business. Our financial statements contain additional note disclosures describing the circumstances that lead to this disclosure by our independent auditors.

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We are an early-stage company with a limited operating history, which may hinder our ability to successfully meet our objectives.

We are an early-stage 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. Only recently have we explored opportunities in the biomedical industry. As a result, the revenue and income potential of our business is unproven. In addition, because of our limited operating history, we have limited insight into trends that may emerge and affect our business. Errors may be made in predicting and reacting to relevant business trends and we will be subject to the risks, uncertainties and difficulties frequently encountered by early-stage companies in evolving markets. We may not be able to successfully address any or all of these risks and uncertainties. Failure to adequately do so could cause our business, results of operations and financial condition to suffer or fail.

We have not commercialized any of our potential product candidates and we cannot predict if or when we will become profitable.

We have not commercialized any product candidate relating to our current assets in the biomedical industry. Our ability to generate revenues from any of our product candidates will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and negotiate arrangements with third parties to help finance the development of, and market and distribute, any product candidate that receives regulatory approval. In addition, we will be subject to the risk that the marketplace will not accept our products.

Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict the extent of our future losses or when or if we will become profitable, and it is possible we will never commercialize any of our product candidates or become profitable. Our failure to obtain regulatory approval and successfully commercialize any of our product candidates 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.

If we are unable to successfully recruit and retain qualified personnel, we may not be able to continue our operations.

In order to successfully implement and manage our business plan, we will depend upon, among other things, successfully recruiting and retaining qualified personnel having experience in the biomedical industry. Competition for qualified individuals is intense. If we are not able to find, attract and retain qualified personnel on acceptable terms, our business operations could suffer.

Additionally, although we have employment agreements with each of our executive officers, these agreements are terminable by them at will and we may not be able to retain their services. The loss of the services of any members of our senior management team could delay or prevent the development and commercialization of any other product candidates and our business could be harmed to the extent that we are not able to find suitable replacements.

Future growth could strain our resources, and if we are unable to manage our growth, we may not be able to successfully implement our business plan.

We hope to experience rapid growth in our operations, which will place a significant strain on our management, administrative, operational and financial infrastructure. Our future success will depend in part upon the ability of our executive officers to manage growth effectively. This will require that we hire and train additional personnel to manage our expanding operations. In addition, we must continue to improve our operational, financial and management controls and our reporting systems and procedures. If we fail to successfully manage our growth, we may be unable to execute upon our business plan.

We may be unable to successfully develop and commercialize the assets we recently acquired, or acquire, or develop and commercialize new assets and product candidates.

Our future results of operations will depend to a significant extent upon our ability to successfully develop and commercialize in a timely manner the assets we recently acquired from Inovio related to certain non-DNA vaccine technology and intellectual property relating to selective electrochemical tumor ablation, which we now refer to as the OncoSec Medical System (OMS). In addition, we may acquire new assets or product candidates in the future. There are numerous difficulties inherent in acquiring, developing and commercializing new products and product candidates, including difficulties related to:

- successfully identifying potential product candidates;
- developing potential product candidates;
- difficulties in conducting or completing clinical trials, including receiving incomplete, unconvincing or equivocal clinical trials data;
- obtaining requisite regulatory approvals for such products in a timely manner or at all;
- acquiring, developing, testing and manufacturing products in compliance with regulatory standards in a timely manner or at all;
- being subject to legal actions brought by our competitors, which may delay or prevent the development and commercialization of new products;
- delays or unanticipated costs; and
- significant and unpredictable changes in the payer landscape, coverage and reimbursement for any products we develop.

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As a result of these and other difficulties, we may be unable to develop potential product candidates using our intellectual property, and potential products in development by us may not receive timely regulatory approvals, or approvals at all, necessary for marketing by us or our third-party partners. If we do not acquire or develop product candidates, any of our product candidates are not approved in a timely fashion or at all or, when acquired or developed and approved, cannot be successfully manufactured and commercialized, our operating results would be adversely affected. In addition, we may not recoup our investment in developing products, even if we are successful in commercializing those products. Our business expenditures may not result in the successful acquisition, development or commercialization of products that will prove to be commercially successful or result in the long-term profitability of our business.

Regulatory authorities may not approve our product candidates or the approvals may be too limited for us to earn sufficient revenues.

The United States Food and Drug Administration (the FDA) and other foreign regulatory agencies can delay approval of or refuse to approve our product candidates for a variety of reasons, including failure to meet safety and efficacy endpoints in our clinical trials. Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. Clinical trials of our product candidates may not demonstrate that they are safe and effective to the extent necessary to obtain regulatory approvals. We have initiated three Phase II clinical trials to assess our ImmunoPulse technology in patients with metastatic melanoma, Merkel cell carcinoma and cutaneous T-cell lymphoma. If we cannot adequately demonstrate through the clinical trial process that a therapeutic product we are developing is safe and effective, regulatory approval of that product would be delayed or prevented, which would impair our reputation, increase our costs and prevent us from earning revenues. 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 would have an adverse effect on our business, reputation and results of operations.

Acquisition of the OMS technology included an extensive clinical database from two Phase III clinical trials that were halted before enrollment was completed. In 2007, these two Phase III clinical trials, HNBE-01 and HNBE-02, which were designed to evaluate the use of the NeoPulse technology as a treatment for resectable recurrent and second primary squamous cell carcinomas of the head and neck were halted as a result of a recommendation from the Data Monitoring Committee (DMC). The DMC cited concerns regarding efficacy and safety, including mortality rates and enrollment futility. In the DMC s opinion, although no single parameter was sufficient to warrant recommending a review of the trial, the totality of data for these recurrent head and neck cancer studies suggested an unfavorable benefit-to-risk profile for the NeoPulse arm relative to the surgery arm. Without conducting further analysis, enrollment for both studies were halted, however the treated patients were followed up to two years to further evaluate safety and efficacy, as per the protocol, and the clinical trials were not reinitiated. Upon acquisition of the OMS technology, OncoSec has since carried out extensive analysis of the available data from 214 patients treated in both Phase III studies, which indicated that there were no statistically significant differences between time to death or duration of local control between the control or experimental arms, or the combined groups across studies. Furthermore, none of the other parameters examined, including demographics, time since original diagnosis, prior therapies or tumor stage, showed any significant statistical difference between these parameters. OncoSec is continuing to evaluate this data, however if we are unable to initiate or complete new Phase III or pivotal clinical studies, we will be unable to commercialize the NeoPulse technology.

Delays in the commencement or completion of clinical testing for product candidates based on the OMS technology could result in increased costs to us and delay or limit our ability to pursue regulatory approval or generate revenues.

Clinical trials are very expensive, time consuming and difficult to design and implement. Even if the results of our proposed clinical trials are favorable, clinical trials for product candidates based on the OMS technology will continue for several years and may take significantly longer than expected to complete. Delays in the commencement or completion of clinical testing could significantly affect our product development

costs and business plan. We do not know whether our Phase II clinical trials will be completed on schedule, if at all. In addition, we do not know whether any other pre-clinical or clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining clearance from the FDA or respective international regulatory equivalent 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, approval to initiate and conduct a clinical trial at a prospective site;

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- identifying, recruiting and training suitable clinical investigators;

- identifying, recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for similar indications; and

- 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, or for any other reason they choose, or who are lost to further follow-up.

We believe that we have planned and designed an adequate clinical trial program for our product candidates based on our OMS technology. However, the FDA could determine that it is not satisfied with our plan or the details of our pivotal clinical trial protocols and designs.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our product candidates may be harmed, which may have a material adverse effect on our business, results of operations, financial condition and prospects.

We expect to rely on third parties to conduct our clinical trials. 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 expect to enter into agreements with third-party CROs to conduct our planned clinical trials and anticipate that we may enter into other such agreements in the future regarding any future product candidates. We rely heavily on these parties for the execution of our clinical and pre-clinical studies, and control only certain aspects of their activities. We, and our CROs, are required to comply with the current FDA Code of Federal Regulations for Conducting Clinical Trials and GCP and ICH guidelines. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators, CRO trial sites, laboratories, and any entity having to do with the completion of the study protocol and processing of data. If we, or our CROs, fail to comply with applicable GCP regulations, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA and similar foreign regulators may determine that our clinical trials are not compliant with GCP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate additional revenues could be delayed.

We may participate in clinical trials conducted under an approved investigator sponsored investigational new drug (IND) application and correspondence and communication with the FDA pertaining to these trials will strictly be between the investigator and the FDA.

Currently, our three Phase II clinical trials, for metastatic melanoma, Merkel cell carcinoma and cutaneous T-cell lymphoma, are being conducted under an approved investigator sponsored investigational new drug (IND) application. 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 agency as it pertains to safety of the treatment. This communication can be relayed to the agency in the form of safety reports, annual reports or verbal communication at the request of the FDA. Accordingly, since the IND applications under which each of our three clinical trials will be conducted is held by the investigators, it is the responsibility of each investigator (as the sponsor of the trial) to be the point of contact with the FDA. The communication and information provided by the investigator may not be appropriate and accurate, and the investigator has the ultimate responsibility and final decision-making authority with respect to submissions to the FDA. This may result in reviews, audits, delays or clinical holds by the FDA ultimately affecting the timelines for these studies and potentially risking the completion of these trials.

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

The FDA provides guidelines with respect to appropriate product promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General: U.S. Department of Health and Human Services may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management s attention could be diverted and our reputation could be damaged.

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We have limited experience in manufacturing our product candidates in quantities required to conduct our clinical trials, and if our products are eventually approved for sale by the FDA, in manufacturing commercial quantities. We may not be able to comply with applicable manufacturing regulations or produce sufficient product for contract, clinical trial or commercial purposes.

The commercial manufacturing of DNA based cytokines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA s current Good Manufacturing Practices, or cGMP, regulations. We may not be able to comply with the cGMP regulations, and our manufacturing process may be subject to delays, disruptions or quality control problems. In addition, we may need to complete the installation and validation of additional large-scale fermentation and related purification equipment to produce the quantities of product expected to be required for clinical trials, and if our products are eventually approved for sale by the FDA, for commercial purposes. We have limited experience in manufacturing at this scale. Noncompliance with the cGMP regulations, the inability to complete the installation or validation of additional large-scale equipment, or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates, and cause us to breach our contract manufacturing service arrangements.

If any product candidate for which we receive regulatory approval does not achieve broad market acceptance or coverage by third- party payors, the revenues that we generate may be limited.

The commercial success of any potential product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our approved product by third-party payors is also necessary for commercial success. The degree of market acceptance of any potential product candidates for which we may receive regulatory approval will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the prevalence and severity of adverse side effects;
- limitations or warnings contained in a product s FDA-approved labeling;
- the clinical indications for which the product is approved;
- availability and perceived advantages of alternative treatments;

- any negative publicity related to our or our competitors products;
- the effectiveness of our or any current or future collaborators sales, marketing and distribution strategies;
- pricing and cost effectiveness;
- our ability to obtain sufficient third-party payor coverage or reimbursement; and
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage.

Our efforts to educate the medical community and third-party payors on the benefits of any of our potential product candidates for which we obtain marketing approval from the FDA or other regulatory authorities may require significant resources and may never be successful. If our potential products do not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenue from these products to become or remain profitable.

We may not be successful in executing our strategy for the commercialization of our product candidates. If we are unable to successfully execute our commercialization strategy, we may not be able to generate significant revenue.

We intend to advance a commercialization strategy that leverages previous in-depth clinical experiences, previous CE (Conformité Européene) approvals for the electroporation-based devices and late stage clinical studies in the United States (Phase III) and Europe (Phase IV). This strategy includes seeking approval from the FDA to initiate pivotal registration studies in the United States for select rare cancers that have limited, adverse or no therapeutic alternatives. This strategy also includes expanding the addressable markets for the OMS therapies through the addition of relevant indications. Our commercialization plan also includes partnering and/or co-developing OMS in developing geographic locations, such as Eastern Europe and Asia, where local resources are best leveraged and appropriate collaborators can be secured.

We may not be able to implement our commercialization strategy as we have planned. Further, we have little experience and have not proven our ability to succeed in the biomedical industry and are not certain that our implementation strategy, if implemented correctly, would lead to significant revenue. If we are unable to successfully implement our commercialization plans and drive adoption by patients and physicians of our potential future products through our sales, marketing and commercialization efforts, then we will not be able to generate significant revenue which will have a material adverse effect on our business, results of operations, financial condition and prospects.

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In order to market our proprietary products, we may choose to establish our own sales, marketing and distribution capabilities. We have no experience in these areas, and if we have problems establishing these capabilities, the commercialization of our products would be impaired.

We may choose to establish our own sales, marketing and distribution capabilities to market products to our target markets. We have no experience in these areas, and developing these capabilities will require significant expenditures on personnel and infrastructure. While we intend to market products that are aimed at a small patient population, we may not be able to create an effective sales force around even a niche market. In addition, some of our product candidates may require a large sales force to call on, educate and support physicians and patients. We may desire in the future to enter into collaborations with one or more pharmaceutical companies to sell, market and distribute such products, but we may not be able to enter into any such arrangement on acceptable terms, if at all. Any collaboration we do enter into may not be effective in generating meaningful product royalties or other revenues for us.

Our success depends in part on our ability to protect our intellectual property. Because of the difficulties of protecting our proprietary rights and technology, we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our product candidates and their respective components, formulations, manufacturing methods and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The coverage claimed in a patent application typically is significantly reduced before a patent is issued, either in the United States or abroad. Consequently, any of our pending or future patent applications may not result in the issuance of patents and any patents issued may be subjected to further proceedings limiting their scope and may in any event not contain claims broad enough to provide meaningful protection. Any patents that are issued to us or our future collaborators may not provide significant proprietary protection or competitive advantage, and may be circumvented or invalidated. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. Further, because development and commercialization of our potential product candidates can be subject to substantial delays, our patents may expire and provide only a short period of protection, if any, following any future commercialization of products. Moreover, obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. If any of our patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products.

We may incur substantial costs as a result of litigation or other proceedings relating to protection of our patent and other intellectual property rights, and we may be unable to successfully protect our rights to our potential products and technology.