

ONCOSEC MEDICAL Inc
 Form 424B4
 September 17, 2013
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 Registration No. 333-189516

ONCOSEC MEDICAL INCORPORATED

PROSPECTUS

47,792,000 Shares of Common Stock

Warrants to Purchase up to 23,896,000 Shares of Common Stock

23,896,000 Shares of Common Stock Underlying the Warrants

We are offering up to 47,792,000 shares of our common stock and warrants to purchase up to 23,896,000 shares of our common stock. Each share of common stock we sell in the offering will be accompanied by a warrant to purchase one-half of a share of common stock. Each share of common stock and warrant will be sold at a price of \$0.25. The common stock and warrants are immediately separable and will be issued separately. We are not required to sell any specific dollar amount or number of securities, but will use our best efforts to sell all of the securities being offered. This offering will terminate on October 13, 2013, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. The offering price for the common stock and warrants and the exercise price of the warrants will remain fixed for the duration of the offering. All costs associated with the registration will be borne by us.

Our common stock is traded on the OTC Markets Group Inc.'s OTCQB tier under the symbol "ONCS". We do not intend to apply for listing of the warrants on any securities exchange and we do not expect that the warrants will be quoted on the OTCQB marketplace. On September 13, 2013, the closing price of our common stock on the OTCQB marketplace was \$0.32 per share.

	Per Share (1)		Total
Offering Price	\$	0.250	\$ 11,948,000
Placement Agent's Fees (2)	\$	0.015	\$ 716,880
Offering Proceeds, Before Expenses	\$	0.235	\$ 11,231,120

(1) Per share price represents the offering price for a share of common stock and a warrant to purchase one-half of a share of common stock.

(2) In addition we have agreed to issue to the placement agent warrants to purchase up to an aggregate of 5% of the aggregate number of shares of common stock sold in this offering and to pay to the placement agent a non-accountable expense allowance equal to 1% of the aggregate gross proceeds raised in the offering.

H.C. Wainwright & Co., LLC has agreed to act as our lead placement agent in connection with this offering. The placement agent is not purchasing the securities offered by us, and is not required to sell any specific number or dollar amount of securities, but will use its best efforts to sell the securities offered. We have agreed to pay the placement agent a placement fee equal to 6% of the aggregate gross proceeds to us from the sale of the common stock in the offering. We may also choose to pay up to 40% of the amount of the cash fee and issue up to 40% of the placement agent warrants directly to one or more other broker-dealers acting as financial advisors in the offering. We have engaged Maxim Group LLC (Maxim) as financial advisor with respect to the offering, and has agreed to pay 20% of the placement agent fee and issue 20% of the placement agent warrants to Maxim in consideration for Maxim's financial advisory services. We estimate total expenses of this offering, excluding the placement agent fees, will be approximately \$118,000. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. See Plan of Distribution beginning on page 25 of this prospectus for more information on this offering and the placement agent arrangements.

Investing in our common stock involves a high degree of risk. Before making any investment in our common stock, you should read and carefully consider the risks described in this prospectus under Risk Factors beginning on page 6 of this prospectus.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

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.

This prospectus is dated September 17, 2013

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About This Prospectus

You should rely only on the information that we have provided or incorporated by reference in this prospectus and any applicable prospectus supplement. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus and any applicable prospectus supplement. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus and any applicable prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement, or any sale of a security.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading **Where You Can Find Additional Information**.

SUMMARY

This summary does not contain all of the information that should be considered before investing in our common stock and warrants. Investors should read the entire prospectus carefully, including the more detailed information regarding our business, the risks of purchasing our common stock and warrants discussed in this prospectus under **Risk Factors beginning on page 6 of this prospectus and our financial statements and the accompanying notes beginning on page F-1 of this prospectus.**

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 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 under the name **Netventory Solutions Inc.** Initially, we provided online inventory services to small and medium sized companies. On March 1, 2011, we changed our name 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.

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Our assets include intellectual property relating to certain delivery technologies, which we 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 and a DNA-based cytokine to treat solid tumors. These two different approaches represent unique therapeutic modalities, which we refer to as ImmunoPulse and NeoPulse. 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. Our NeoPulse approach 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,

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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 may be significant demand for our NeoPulse technology from patients, dermatologists and surgical oncologists.

Our 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. We are actively pursuing opportunities primarily focused in Europe, Asia and North America to partner NeoPulse for further clinical development and commercialization.

When detected early and still confined to a single location, cancer may be cured by surgery or radiation and potentially, by promising new technologies such as NeoPulse. However, neither surgery nor radiation 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, radiation, 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- α , have shown encouraging results. However, these agents often require frequent doses that may result in severe side effects.

Two 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.

In May 2013, two new drugs for metastatic melanoma were approved. Tafinlar[®] and Mekinist[®] are single-agent oral treatments for the treatment of unresectable metastatic melanoma. Like Zelboraf[®], both of these new agents interrupt a key process in melanoma growth by inhibiting the MAP Kinase signaling pathway. Also, like Zelboraf, these agents can cause significant side effects and long-term use may lead to drug resistance by tumor cells.

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 loco-regional immune response against the tumor, which potentially may result in a 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 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 United States Food and Drug Administration (the 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.

For more information regarding our business, see Management's Discussion and Analysis of Financial Condition and Results of Operations and Business, included elsewhere in this prospectus.

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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 9810 Summers Ridge Road, Suite 110, 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.

The Offering

Securities offered	Up to 47,792,000 shares of common stock
	Warrants to purchase up to 23,896,000 shares of common stock
	Up to 23,896,000 shares of common stock issuable upon exercise of the warrants
Common stock outstanding prior to offering	119,146,891(1)
Common stock to be outstanding after the offering	143,042,891(2)
Use of Proceeds	We expect to use the proceeds received from the offering to fund our clinical trials, for activities relating to execution of our development plan, and for working capital and general corporate purposes, including director and officer compensation. See Use of Proceeds for more information.
OTCQB Symbol	ONCS. There is no established trading market for the warrants and we do not expect a market to develop.
Risk Factors	See Risk Factors beginning on page 6 and other information in this prospectus for a discussion of the factors you should consider before you decide to invest in our common stock and warrants.

(1) Excludes (i) 9,000,000 shares of common stock reserved for future issuance under our 2011 Stock Incentive Plan, as amended (the 2011 Plan) and (ii) 56,511,609 shares of common stock issuable upon the exercise of outstanding warrants. As of August 13, 2013, there were (i) options to purchase 5,150,000 shares of our common stock outstanding under the 2011 Plan, with a weighted average exercise price of \$0.23 per share and (ii) 56,511,609 shares of common stock issuable upon the exercise of outstanding warrants with exercise prices ranging from \$0.26 to \$1.20 per share.

(2) Assumes the sale of all shares of common stock covered by this prospectus. Excludes (i) up to 23,896,000 shares of common stock that could be issued upon exercise of the warrants sold as part of this offering and (ii) the shares of common stock underlying the warrants issuable to the placement agent in connection with this offering.

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.

Risks Related to this Offering

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of up to 47,792,000 shares of common stock and warrants to purchase an additional 23,896,000 shares of our common stock, and after deducting placement agent commissions and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of \$0.15 per share, or 60%, at the public offering price, assuming no exercise of the warrants.

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Since inception we have funded our operations primarily through equity financings, including our June 2011 issuance of 4,000,000 shares of common stock and three series of warrants to purchase an aggregate of 12,000,000 shares of our common stock to two institutional investors for proceeds of \$3.0 million (the June 2011 Private Placement), our March 2012 issuance of 31,000,000 shares of common stock and warrants to purchase an aggregate of 31,000,000 shares of our common stock to investors in a public offering for proceeds of \$7.75 million (the March 2012 Public Offering), and our December 2012 issuance of 28,800,000 shares of common stock and warrants to purchase an aggregate of 14,400,000 shares of our common stock to investors in a public offering for proceeds of \$7.2 million (the December 2012 Public Offering). To the extent any of the warrants and options we have issued are exercised, you will sustain future dilution. We may also acquire or license other technologies or finance strategic alliances by issuing equity, which may result in additional dilution to our stockholders.

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, and may never generate, any cash from operations and must raise additional funds in order to continue operating our business. We estimate our cash requirements for the next 6 months to be approximately \$4.7 million, which is inclusive of our \$1 million payment to be made in December 2013 to Inovio Pharmaceuticals, Inc. (Inovio) under the Asset Purchase Agreement, as amended (the Asset Purchase Agreement). As of April 30, 2013, we had cash and cash equivalents of approximately \$7.3 million. We expect these funds to be sufficient to continue to operate our business through the remainder of our current 6 month period; however, we do not currently believe our existing cash resources are sufficient to meet our anticipated needs during the next twelve months. We will require additional financing to fund our planned future operations, including the continuation of our ongoing clinical trials, developing and commercializing our intellectual property, seeking to license or acquire new assets, and researching and developing any potential patents, the related compounds and any further intellectual property that we may acquire.

We have a history of raising funds through offerings of our common stock, and we may in the future raise additional funds through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. 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 our intellectual property, 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 will have immediate and broad discretion over the use of the net proceeds from this offering and we may use these proceeds in ways with which you may not agree.

We have considerable discretion in the application of the proceeds of this offering. We currently expect to use the net proceeds from this offering for our clinical development and for working capital and general corporate purposes. We may also use a portion of these proceeds for the potential acquisition of, or investment in, product candidates, technologies, formulations or companies that complement our business, although we have no current understandings, commitments, or agreements to do so. You must rely on our judgment regarding the application of the net proceeds of this offering. Our judgment may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial, or other information upon which we base our decisions.

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There is no public market for the warrants being offered in this offering.

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing the warrants on any securities exchange or expect the warrants to trade on the OTCQB marketplace. Without an active market, the liquidity of the warrants will be limited.

Risks Related to Our Business

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 nine month period ended April 30, 2013, we incurred a net loss of approximately \$5.4 million. From inception through April 30, 2013, we incurred an aggregate loss of approximately \$11.5 million. We expect that our operating expenses will continue to increase as we continue to pursue U.S. Food and Drug Administration (FDA) approval for our product candidates.

As of July 31, 2012, these circumstances raised 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 (Fiscal 2012), which is included in our Annual Report on Form 10-K for Fiscal 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.

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.

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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 have 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 acquired from Inovio related to certain non-DNA vaccine technology and intellectual property relating to selective electrochemical tumor ablation, which we 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.

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.

Certain of our intellectual property is licensed from Inovio pursuant to a non-exclusive license.

As we describe elsewhere in this prospectus, we have acquired certain technology and related assets from Inovio pursuant to the Asset Purchase Agreement. In connection with the closing of the Asset Purchase Agreement, we entered into a cross-license agreement with Inovio. Under the terms of the cross-license agreement, Inovio granted to us a non-exclusive, worldwide license to certain non-SECTA technology patents held by Inovio, and we granted to Inovio a limited, exclusive license to our acquired SECTA technology. While we do not currently rely on the intellectual property we have licensed from Inovio pursuant to this non-exclusive license, our product candidates may in the future utilize this intellectual property. Because the license is non-exclusive, Inovio may use its technology to compete with us. In addition, there are no restrictions on Inovio's ability to license their technology to others. As a result Inovio could license to others, including our competitors, the intellectual property rights covered by their license to us, including any of our improvements to the licensed intellectual property. In addition, either party may terminate the cross-license agreement with 30 days' notice if they no longer utilize or sublicense the patent rights they have acquired pursuant to the cross-license. If either party were to terminate the cross-license agreement, they would no longer have the right to use intellectual property that is subject to the cross license.

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

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 affect 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. We are continuing to analyze the available data from 214 patients treated in both Phase III studies. If we are unable to partner, 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 our 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 our 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;
- 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.

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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 must 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 currently rely 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.

We have in the past, and may in the future, participate in clinical trials 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, 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, our revenues 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