Celsion CORP Form 424B3 September 28, 2011

Filed pursuant to Rule 424(b)(3)

Under the Securities Act of 1933 in connection with Registration Statement No. 333-176486 PROSPECTUS

1,793,443 Shares

Celsion Corporation

Common Stock

This prospectus relates to the sale or other disposition from time to time of up to 1,793,443 shares of our common stock, which includes 512,412 shares of our common stock issuable upon the exercise of warrants, which are held by the selling stockholder named in this prospectus. The shares of common stock covered by this prospectus were previously issued by us to the selling stockholders in a private placement that closed on July 25, 2011, or underlie certain common stock purchase warrants that were previously issued by us to the selling stockholders in this prospectus. We are not selling any shares of common stock under this prospectus and will not receive any of the proceeds from the sale of shares of common stock by the selling stockholders. However, we will receive the proceeds of any cash exercise of the warrants.

The selling stockholders may sell or otherwise dispose of the shares of common stock covered by this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell or otherwise dispose of their shares of common stock in the section entitled "Plan of Distribution" on page 24. The selling shareholders will pay all brokerage fees and commissions and similar expenses. We will pay all expenses (except brokerage fees and commissions and similar expenses) relating to the registration of the shares with the Securities and Exchange Commission.

Our common stock is listed on The NASDAQ Capital Market under the symbol "CLSN." On September 13, 2011, the last reported sale price of our common stock on The NASDAQ Capital Market was \$3.35.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 3 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 passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is September 22, 2011

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in or incorporated by reference into this prospectus, as supplemented and amended. We have not, and the selling stockholders have not, authorized anyone to provide you with different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. You should not assume that the information we have included in this prospectus is accurate as of any date other than the date of this prospectus or that any information we have incorporated by reference is accurate as of any date other than the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since that date. This document may only be used where it is legal to sell these securities.

We urge you to read carefully this prospectus, as supplemented and amended, together with the information incorporated herein by reference as described under the heading "Information Incorporated by Reference", before deciding whether to invest in any of the common stock being offered.

Unless the context indicates otherwise, as used in this prospectus, the terms "Celsion", "the Company", "we", "us" and "our" refer to Celsion Corporation, a Delaware corporation. The Celsion brand and product names, including but not limited to Celsion®, contained in this document are trademarks, registered trademarks or service marks of Celsion Corporation in the United States (U.S.) and certain other countries. This document may also contain references to trademarks and service marks of other companies that are the property of their respective owners.

PROSPECTUS SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in the securities covered by this prospectus. For a more complete understanding of Celsion and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus, including the information incorporated by reference in this prospectus, including the information referred to under the heading "Risk Factors" in this prospectus beginning on page 3.

Celsion Corporation

Overview

We are an innovative oncology drug development company focused on the development of therapeutics for those suffering with difficult to treat forms of cancer. We are working to develop and commercialize more efficient, effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. The promise of this drug technology is to maximize efficacy while minimizing side effects common to cancer treatments.

Our lead product, ThermoDox®, is being evaluated in a Phase III clinical trial, which we refer to as the HEAT study, for primary liver cancer and a Phase I/II study for recurrent chest wall breast cancer. ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized mild hyperthermia (greater than 40 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in the region of the tumor target.

We have also demonstrated feasibility for a product pipeline of cancer drugs that employ our heat activated liposomal technology in combination with known chemotherapeutics, including docetaxel and carboplatin. We believe that our technology can improve efficacy and safety of anticancer agents whose mechanism of action and safety profile are well understood by the medical and regulatory communities. Our approach provides a comparatively cost effective, low risk approval pathway. Additionally, we have formed a joint research agreement with Philips Healthcare to evaluate the combination of Philips' high intensity focused ultrasound (HIFU) with ThermoDox® to determine the potential of this combination to treat a broad range of cancers.

For certain markets, we may seek licensing partners to share in the development and commercialization costs. We will also evaluate licensing cancer products from third parties for cancer treatments to expand our development pipeline.

In the fourth quarter of 2008, we entered into a development, product supply and commercialization agreement with Yakult Honsha under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. We were paid a \$2.5 million up-front licensing fee and we have the potential to receive additional payments from Yakult upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare as well as upon the achievement of certain levels of sales and approval for new indications. We will receive double digit escalating royalties on the sale of ThermoDox® in Japan, when and if any such sales occur. We also will be the exclusive supplier of ThermoDox® to Yakult.

Concurrent with a preferred equity financing in January 2011, we amended our development, product supply and commercialization agreement with Yakult to provide for up to \$4.0 million in an accelerated partial payment to us of a future drug approval milestone. The terms of the agreement with Yakult provided for the payment to us of \$2.0

million upon the closing of the preferred equity financing and an additional \$2.0 million conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the HEAT study. In consideration of these accelerated milestone payments from Yakult, we have agreed to reduce future drug approval milestone payments by approximately forty percent (40%). All other milestone payments are unaffected.

Corporate Information

We were founded in 1982 and are a Delaware corporation. Our shares of common stock trade on The NASDAQ Capital Market under the symbol "CLSN." Our principal executive offices are located at 10220-L Old Columbia Road, Columbia, Maryland 21046-2364. Our telephone number is (410) 290-5390 and our website is www.celsion.com. The information available on or through our website is not part of this prospectus and should not be relied upon.

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The Offering

The following is a brief summary of the offering. You should read the entire prospectus carefully, including "Risk Factors" beginning on page 3, and the information, including financial information, included in our filings with the Securities and Exchange Commission and incorporated in this document by reference.

Common stock to be offered by the selling stockholders	1,793,443 shares
Use of proceeds	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus. However, we will receive the proceeds of any cash exercise of the warrants.
NASDAQ Capital Market Symbol	CLSN
Dividends	We have never declared or paid any cash dividends on our common stock and do not currently anticipate paying cash dividends in the foreseeable future.
Risk Factors	See "Risk Factors" beginning on page 3 of this prospectus and other information included in this prospectus for a discussion of the factors you should consider before deciding to invest in shares of our common stock.

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RISK FACTORS

An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks discussed below, together with the risks under the heading "Risk Factors" beginning on page 10 under Part I, Item IA of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the SEC on March 28, 2011, on page 21 of our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2011, filed with the SEC on May 12, 2011, and on page 27 of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2011, filed with the Securities and Exchange Commission (SEC) on August 9, 2011, as well as the other information in this prospectus, as amended or supplemented, and the information and documents incorporated by reference. If any of the identified risks occur, they could materially adversely affect our business, financial condition, operating results or prospects and the trading price of our securities. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also impair our business, financial condition, operating results and prospects and the trading price of our securities.

RISKS RELATED TO OUR BUSINESS

We do not generate operating income and will require additional financing in the future. If additional capital is not available, we may have to curtail or cease operations.

Our business currently does not generate the cash necessary to finance our operations. Since our inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$101 million at December 31, 2010. We incurred a net loss of \$18.8 million for the year ended December 31, 2010 and a net loss of \$10.7 million for the six months ended June 30, 2011. We presently have no product revenue. We may need to raise additional capital to fund research and development and to develop and commercialize our products. Our future capital needs depend on many factors, including the scope, duration and expenditures associated with our clinical trials, the outcome of potential licensing transactions, if any, competing technological developments and the regulatory approval process for our products.

We may seek to raise necessary funds through public or private equity offerings, debt financings or additional strategic alliances and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets. We may be required to relinquish rights to our technologies or products, or grant licenses on terms that are not favorable to us, in order to raise additional funds through alliance, joint venture or licensing arrangements. If adequate funds are not available, we may have to delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expense. Such events could cause our independent registered public accounting firm to indicate that there may be substantial doubt about our ability to continue as a going concern in future periods.

If our products fail in clinical trials, we will be unable to obtain or maintain FDA and international regulatory approvals and will be unable to sell those products.

To obtain regulatory approvals from the U.S. Food and Drug Administration (FDA) and international regulatory agencies, we must conduct clinical trials demonstrating that our products are safe and effective. We may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful.

We do not expect to generate significant revenue for the foreseeable future.

We have devoted our resources to developing a new generation of products but will not be able to market these products until we have completed clinical testing and obtain all necessary governmental approvals. In addition, our products are still in various stages of development and testing and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Accordingly, our revenue sources are, and will remain, extremely limited until our products are clinically tested, approved by the FDA and successfully marketed. We cannot guarantee that any or all of our products will be successfully tested, approved by the FDA or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

If we do not raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates.

As of June 30, 2011, we had approximately \$5.5 million in cash and short term investments. Subsequent to June 30, 2011, we completed three equity offerings with gross proceeds totaling approximately \$25 million in the aggregate. To complete the development and commercialization of our products, we will need to raise substantial amounts of additional capital. We do not have any committed sources of financing and cannot offer any assurances that alternate funding will be available in a timely manner, on acceptable terms or at all.

In the event we can not raise additional capital, we may be required to delay, scale back or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force us to relinquish rights to certain of our technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

We may experience limitations on the utilization of our net operating loss carry forwards.

As of December 31, 2010, we had net operating loss carry forwards for income tax reporting purposes of approximately \$81.1 million, which represented a deferred tax asset of approximately \$31.3 million. These net operating loss carry forwards begin to expire in 2022. We continue to evaluate our net operating losses and currently maintain a valuation allowance equal to the deferred tax asset, thereby recognizing a net deferred tax asset of zero. Net operating losses are subject to the ownership change limitations of the Internal Revenue Code Section 382 (Section 382), under which if we have a greater than 50% ownership change (as defined by Section 382), our net operating losses may be limited for purposes of offsetting future taxable income. In connection with our recent financings, we are currently evaluating if a Sec 382 change in control has occurred. We cannot assure these net operating losses will not be subject to Section 382 limitations.

We have no internal sales or marketing capability and must enter into alliances with others possessing such capabilities to commercialize our products successfully.

We intend to market our products, if and when such products are approved for commercialization by the FDA, either directly or through other strategic alliances and distribution arrangements with third parties. There can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on advantageous terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense. There can be no assurance that, to the extent that we sell products directly or we enter into any commercialization arrangements with third parties, such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services.

Our business depends on license agreements with third parties to permit us to use patented technologies. The loss of any of our rights under these agreements could impair our ability to develop and market our products.

Our success will depend, in substantial part, on our ability to maintain our rights under license agreements granting us rights to use patented technologies. We have entered into license agreements with Duke University, under which we have exclusive rights to commercialize medical treatment products and procedures based on Duke's thermo-sensitive liposome technology. The Duke University license agreement contains a license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that we must meet by certain deadlines. If we were to breach these or other provisions of the license and research agreements, we could lose our ability to use the subject technology, as well as compensation for our efforts in developing or exploiting the technology. Any such loss of rights and access to technology could have a material adverse effect on our business.

Further, we cannot guarantee that any patent or other technology rights licensed to us by others will not be challenged or circumvented successfully by third parties, or that the rights granted will provide adequate protection. We are aware of published patent applications and issued patents belonging to others, and it is not clear whether any of these patents or applications, or other patent applications of which we may not have any knowledge, will require us to alter any of our potential products or processes, pay licensing fees to others or cease certain activities. Litigation, which could result in substantial costs, may also be necessary to enforce any patents issued to or licensed by us or to determine the scope and validity of others' claimed proprietary rights. We also rely on trade secrets and confidential information that we seek to protect, in part, by confidentiality agreements will not be breached, that, even if not breached, that they are adequate to protect our trade secrets, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known to, or will not be discovered independently by, competitors.

Our products could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.

Our commercial success depends on our ability to operate without infringing the patents and other proprietary rights of third parties. There may be third party patents that relate to our products and technology. We may unintentionally infringe upon valid patent rights of third parties. Although we are currently not involved in any material litigation involving patents, a third party patent holder could assert a claim of patent infringement against us in the future. Alternatively, we may initiate litigation against the third party patent holder to request that a court declare that we are not infringing the third party's patent and/or that the third party's patent is invalid or unenforceable. If a claim of infringement is asserted against us and is successful, and therefore we are found to infringe, we could be required to pay damages for infringement, including treble damages if it is determined that we knew or became aware of such a patent and we failed to exercise due care in determining whether or not we infringed the patent. If we have supplied infringing products to third parties or have licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for damages they may be required to pay to the patent holder and for

any losses they may sustain. We can also be prevented from selling or commercializing any of our products that use the infringing technology in the future, unless we obtain a license from such third party. A license may not be available from such third party on commercially reasonable terms, or may not be available at all. Any modification to include a non-infringing technology may not be possible or if possible may be difficult or time-consuming to develop, and require revalidation, which could delay our ability to commercialize our products. Any infringement action asserted against us, even if we are ultimately successful in defending against such action, would likely delay the regulatory approval process of our products, harm our competitive position, be expensive and require the time and attention of our key management and technical personnel.

We rely on third parties to conduct all of our clinical trials. If these third parties are unable to carry out their contractual duties in a manner that is consistent with our expectations, comply with budgets and other financial obligations or meet expected deadlines, we may not receive certain development milestone payments or be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner.

As of June 30, 2011, we had 16 full-time employees. We rely, and expect to continue to rely, on third-party Clinical Research Organizations to conduct our clinical trials. Because we do not conduct our own clinical trials, we must rely on the efforts of others and cannot always control or predict accurately the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on third parties to conduct all of our future clinical trials. If these third parties are unable to carry out their contractual duties or obligations in a manner that is consistent with our expectations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, we may not receive development milestone payments when expected or at all, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. At this time, the Company is unable to determine what, if any, effect the catastrophic events resulting from the March 11, 2011 earthquake and Tsunami in Japan will have on the conduct or timeframe of clinical trials for our Phase III HEAT study at sites in Japan. In addition, enrollment of additional patients at clinical sites in Japan for our Phase III HEAT study is currently on hold pending the DMC's ongoing review of safety and efficacy data in accordance with the PMDA in Japan and the DMC's charter. A failure to resume patient enrollment at clinical trial sites in Japan could have a material adverse affect on our financial condition as the resumption of patient enrollment is a condition to our receipt of an accelerated \$2 million development milestone payment under our agreement with Yakult and is a mandatory conversion event of our 8% redeemable convertible preferred stock.

Our business is subject to numerous and evolving state, federal and foreign regulations and we may not be able to secure the government approvals needed to develop and market our products.

Our research and development activities, pre-clinical tests and clinical trials, and ultimately the manufacturing, marketing and labeling of our products, are all subject to extensive regulation by the FDA and foreign regulatory agencies. Pre-clinical testing and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would adversely affect our ability to commercialize any product candidates and our ability to generate product revenues or royalties.

The FDA and foreign regulatory agencies require that the safety and efficacy of product candidates be supported through adequate and well-controlled clinical trials. If the results of pivotal clinical trials do not establish the safety and efficacy of our product candidates to the satisfaction of the FDA and other foreign regulatory agencies, we will not receive the approvals necessary to market such product candidates. Even if regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed.

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate FDA regulations. FDA guidelines specify that a warning letter is issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on the Company.

We are also subject to recordkeeping and reporting regulations. These regulations require, among other things, the reporting to the FDA of adverse events alleged to have been associated with the use of a product or in connection with certain product failures.

Labeling and promotional activities also are regulated by the FDA. We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our products. The FDA can impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise.

Many states in which we do, or in the future, may do business, or in which our products may be sold, impose licensing, labeling or certification requirements that are in addition to those imposed by the FDA. There can be no assurance that one or more states will not impose regulations or requirements that have a material adverse effect on our ability to sell our products.

In many of the foreign countries in which we may do business or in which our products may be sold, we will be subject to regulation by national governments and supranational agencies as well as by local agencies affecting,

among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. There can be no assurance that one or more countries or agencies will not impose regulations or requirements that could have a material adverse effect on our ability to sell our products.

Legislative and regulatory changes affecting the heath care industry could adversely affect our business.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. There have been a number of government and private sector initiatives during the last few years to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements. It is uncertain which legislative proposals, if any, will be adopted (or when) or what actions federal, state, or private payors for health care treatment and services may take in response to any health care reform proposals or legislation. We cannot predict the effect health care reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business. These actual and potential changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. In addition, uncertainty remains regarding proposed significant reforms to the U.S. healthcare system.

The success of our products may be harmed if the government, private health insurers and other third-party payors do not provide sufficient coverage or reimbursement.

Our ability to commercialize our new cancer treatment systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. The reimbursement status of newly approved medical products is subject to significant uncertainty. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

Our products may not achieve sufficient acceptance by the medical community to sustain our business.

Our cancer treatment development projects using ThermoDox® plus RFA or microwave heating, are currently in clinical trials. Any or all of these projects may prove not to be effective in practice. If testing and clinical practice do not confirm the safety and efficacy of our product candidates or, even if further testing and practice produce positive results but the medical community does not view these new forms of treatment as effective and desirable, our efforts to market our new products may fail, with material adverse consequences to our business.

Technologies for the treatment of cancer are subject to rapid change, and the development of treatment strategies that are more effective than our technologies could render our technologies obsolete.

Various methods for treating cancer currently are, and in the future are expected to be, the subject of extensive research and development. Many possible treatments that are being researched, if successfully developed, may not require, or may supplant, the use of our technologies. The successful development and acceptance of any one or more of these alternative forms of treatment could render our technology obsolete as a cancer treatment method.

We may not be able to hire or retain key officers or employees that we need to implement our business strategy and develop or products and business.

Our success depends significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, and on our ability to attract additional personnel as we seek to implement our business strategy and develop our products and businesses. During our operating history, we have assigned many essential responsibilities to a relatively small number of individuals. However, as our business and the demands on our key employees expand, we have been, and will continue to be, required to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel or our inability to attract additional personnel to fill critical positions could adversely affect our business. Further, we do not carry "key man" insurance on any of our personnel. Therefore, loss of the services of key personnel would not be ameliorated by the receipt of the proceeds from such insurance.

Our success depends in part on our ability to grow and diversify, which in turn will require that we manage and control our growth effectively.

Our business strategy contemplates growth and diversification. Our ability to manage growth effectively will require that we continue to expend funds to improve our operational, financial and management controls, reporting systems and procedures. In addition, we must effectively expand, train and manage our employees. We will be unable to manage our business effectively if we are unable to alleviate the strain on resources caused by growth in a timely and successful manner. There can be no assurance that we will be able to manage our growth and a failure to do so could have a material adverse effect on our business.

We face intense competition and the failure to compete effectively could adversely affect our ability to develop and market our products.

There are many companies and other institutions engaged in research and development of various technologies for cancer treatment products that seek treatment outcomes similar to those that we are pursuing. We believe that the level of interest by others in investigating the potential of possible competitive treatments and alternative technologies will continue and may increase. Potential competitors engaged in all areas of cancer treatment research in the United States and other countries include, among others, major pharmaceutical, specialized technology companies, and universities and other research institutions. Most of our current and potential competitors have substantially greater financial, technical, human and other resources, and may also have far greater experience than do we, both in pre-clinical testing and human clinical trials of new products and in obtaining FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

We may be subject to significant product liability claims and litigation.

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10 million per incident and \$10 million annually. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a material adverse effect on our business. In addition, liability or alleged liability could harm the business by diverting the attention and resources of our management and by damaging our reputation.

RISKS RELATED TO OUR COMMON STOCK

Our stockholders may experience significant dilution as a result of future equity offerings and exercise of outstanding options and warrants.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering. In addition, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 8,369,539 shares of common stock issuable upon exercise of outstanding warrants as of August 22, 2011. As of August 22, 2011, 561,124 shares of common stock were reserved for future issuance under our stock incentive plan. As of that date, there were also options outstanding to purchase 2,893,764 shares of our common stock. You will incur dilution upon exercise of any outstanding stock options or warrants. The issuance of additional shares as a result of any such exercise, or the subsequent sale of securities, could adversely affect the price of our common stock.

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of August 22, 2011, we had 26,632,062 shares of common stock outstanding, all of which shares, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144 promulgated under the Securities Act of 1933, as amended, including the volume limitations and manner of sale requirements. In addition, all of the shares of common stock issuable upon conversion of our preferred stock or exercise of warrants will be freely tradable without restriction or further registration upon issuance.

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors and subject us to securities class action litigation.

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospects. It is impossible to assure you that the market price of our shares of common stock will not fall in the future. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

fluctuations in our quarterly operating results or the operating results of our competitors;

variance in our financial performance from the expectations of investors;

changes in the estimation of the future size and growth rate of our markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;

failure of our products to achieve or maintain market acceptance or commercial success;

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

changes in our pricing policies or the pricing policies of our competitors;

announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;

changes in legislation or regulatory policies, practices, or actions;

the commencement or outcome of litigation involving our company, our general industry or both;

recruitment or departure of key personnel;

changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;

actual or expected sales of our common stock by our stockholders; and

the trading volume of our common stock.

In addition, the stock market in general, The NASDAQ Capital Market and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

We may be unable to maintain compliance with NASDAQ Marketplace Rules which could cause our common stock to be delisted from The NASDAQ Capital Market. This could result in the lack of a market for our common stock, cause a decrease in the value of an investment in us, and adversely affect our business, financial condition and results of operations.