Celsion CORP
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Registration Statement No. 333-183286

PROSPECTUS SUPPLEMENT

(To Prospectus dated September 14, 2012)

6,264,492 Shares of Common Stock

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering 6,264,492 shares of our comment stock to certain institutional investors at a per share price of $1.57. Our common stock is listed on The NASDAQ Capital Market under the symbol “CLSN”. On May 29, 2013, the last reported closing bid price of our common stock on The NASDAQ Capital Market was $1.57 per share.

Investing in our securities involves a high degree of risk. Before making an investment decision, please read “Risk Factors” beginning on page S-6 of this prospectus supplement, page 8 of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We have retained H.C. Wainwright & Co., LLC to act as our exclusive placement agent in connection with the shares of common stock offered by this prospectus supplement. We have agreed to pay the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities we are offering. See “Plan of Distribution” beginning on page S-19 of this prospectus supplement for more information regarding this arrangement.

Total

	Per Share	
Public offering price of shares	$1.57	$9,835,252.44
Placement agent fees	$0.11775	$737,643.93
Proceeds, before expenses, to us	$1.45225	$9,097,608.51

Delivery of the shares of common stock will take place on or about June 3, 2013, subject to the satisfaction of certain conditions.

H.C. Wainwright & Co., LLC

This prospectus supplement is dated May 30, 2013

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a "shelf" registration statement on Form S-3 (File No. 333-183286) that we filed with the Securities and Exchange Commission on August 20, 2012 and that was declared effective on September 14, 2012.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part is the accompanying prospectus, which gives more general information about the shares of our common stock and other securities we may offer from time to time under our shelf registration statement, some of which does not apply to the securities offered by this prospectus supplement. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference herein or therein, on the other hand, you should rely on the information in this prospectus supplement.

You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering before making an investment decision. You should also read and consider the information in the documents referred to in the sections of this prospectus supplement entitled "Where You Can Find More Information" and "Incorporation of Certain Documents by Reference."

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it.

We are not making an offer to sell the securities covered by this prospectus supplement in any jurisdiction where the offer or sale is not permitted.

The information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of its respective date, regardless of the time of delivery of the respective document or of any sale of securities covered by this prospectus supplement. You should not assume that the information contained in or incorporated by reference in this prospectus supplement or the accompanying prospectus, or in any free writing prospectus that we have authorized for use in connection with this

offering, is accurate as of any date other than the respective dates thereof.

In this prospectus supplement, the terms “Celsion Corporation,” “Company,” “we,” “us,” “our” and similar terms refer to Celsi
Corporation, a Delaware corporation, unless the context otherwise requires.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement and the accompanying 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 supplement. 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 supplement and the accompanying prospectus, including the information incorporated by reference in this prospectus supplement and the accompanying prospectus and the information included in any free writing prospectus that we have authorized for use in connection with this offering, including the information referred to under the heading "Risk Factors" in this prospectus supplement beginning on page S-6.

Our Company

Celsion Corporation is an oncology drug development company focused on the development of treatments 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. We project our unaudited cash and investment balance to be approximately $50 million as of the closing of this offering on or about June 3, 2013, including the net proceeds from this offering of approximately $9.1 million.

Overview

Our lead product ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the HEAT study) and a Phase II clinical trial 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 heat at mild hyperthermia temperatures (greater than 39.5 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

The HEAT Study for Primary Liver Cancer

The HEAT study for ThermoDox®, in combination with radiofrequency ablation (RFA), was conducted under a Special Protocol Assessment agreed to with the U.S. Food and Drug Administration (FDA). The Special Protocol

Assessment agreed to with the FDA specified Progression Free Survival (PFS) as the HEAT study's primary endpoint. We scheduled a meeting with the HEAT study independent Data Monitoring Committee (DMC) on January 30, 2013 in order to conduct an analysis of the HEAT study's PFS. Following review by the DMC, on January 31, 2013, we announced that ThermoDox® in combination with RFA did not meet the primary endpoint of the HEAT study in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer. Specifically, we determined, after conferring with the DMC, that the HEAT study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval in the population chosen for the HEAT study. The HEAT study was designed to show a 33 percent improvement in PFS with 80 percent power and a p-value = 0.05. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. We will continue to follow the patients enrolled in the HEAT study to the secondary endpoint, Overall Survival (OS). We are also conducting additional analyses of the data from the HEAT study to assess the future strategic value of ThermoDox®.

Following the announcement of the HEAT study results, we have conducted a comprehensive analysis of the clinical data with key principal investigators, data experts and liver cancer experts. Emerging data from the HEAT study post hoc analysis demonstrates that ThermoDox® markedly improves PFS and OS in patients who had optimal RFA. The post hoc analysis indicates that if patients' lesions undergo RFA for 45 minutes or more, they clearly benefited from ThermoDox®. These findings apply to HCC lesions from both size cohorts of the HEAT study (3-5 cm and 5-7 cm) and represent a sizable subgroup of approximately 300 patients. This data is subject to further verification and review by the HEAT Study Steering Committee.

Prior to the HEAT study results announced on January 31, 2013, and consistent with our global regulatory strategy, we announced on April 23, 2012 that randomization of at least 200 patients in the People's Republic of China (PRC), a requirement for registrational filing in the PRC, had been completed. The HEAT study had already enrolled a sufficient number to support registrational filings in South Korea and Taiwan, two important markets for ThermoDox®. The future of these activities will be part of our strategic planning as we analyze the data announced on January 31, 2013 and may affect our partnership with Zhejiang Hisun Pharmaceutical Co., Ltd. (Hisun) described below.

On May 6, 2012, we entered into a long term commercial supply agreement with Hisun for the production of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Hisun will be responsible for providing all of the technical and regulatory support services for the manufacture of ThermoDox® in the China territory and we will repay Hisun for the aggregate amount of these development costs and fees, which we expect to be approximately $2.0 million in total, commencing on the successful completion of three registrational batches of ThermoDox®. As of March 31, 2013, we have incurred approximately $326,000 in costs to be reimbursed to Hisun. On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of $5.0 million to support our development of ThermoDox® and we will provide research data and other technical support in relation to a regulatory filing by Hisun for approval of ThermoDox® for manufacturing and sale in the China territory. Following our announcement on January 31, 2013 that ThermoDox® in combination with RFA failed to meet its primary endpoint, Hisun and Celsion have agreed that the technology development contract will remain in effect while the parties continue to collaborate and are evaluating next steps in relation to ThermoDox®, which include the sub-group analysis of patients in the HEAT study and other activities to further the development of ThermoDox® for the China territory.

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As part of the analysis of the HEAT study results, we are also assessing our product pipeline and research and development priorities. In April 2013, we announced the elimination of approximately one-third of our workforce and the deferral of expenses associated with the Phase II clinical trial for colorectal liver metastasis (the ABLATE study) until such time as we finalize our plans for the continuation of its development program with ThermoDox® in HCC.

In April 2013, we engaged Cantor Fitzgerald & Co. to conduct a comprehensive review of merger and acquisition opportunities with the goal of identifying novel products with high potential, or companies, for us to acquire. Strategic alternatives we may pursue could include, but are not limited to, continuing our current operating plan, partnering or other collaboration agreements, acquisition of another company's business or assets, or a merger or other strategic transaction. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

ThermoDox® in Relation to Cancers other than Primary Liver Cancer

In 2009, we formed a joint research agreement with Philips Healthcare, a division of Royal Philips Electronics, 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. As a result of our progress to clinical development status, we are currently negotiating a new agreement with Philips. In August 2012, we announced FDA clearance to commence a Phase II study of ThermoDox® and Philip's Sonalleve® MR-Guided HIFU technology for the palliation of painful metastases to the bone caused by lung, prostate or breast cancers.

In June 2012, we announced a collaboration with the University of Oxford to begin a clinical study of ThermoDox® plus HIFU in the treatment of metastatic liver cancer. The trial, which is supported by the National Institute for Health Research Oxford Biomedical Research Centre, will be carried out as a multidisciplinary collaboration between us, the Oxford University Institute of Biomedical Engineering and the Oxford University Hospitals NHS Trust. This early phase clinical study is being finalized and will require approval from a local ethics committee. Treatment of the first patient is targeted for 2013.

We are also working with the Focused Ultrasound Foundation in preclinical studies designed to explore the use of ThermoDox® in combination with MR-guided HIFU for the treatment of pancreatic cancer. The studies are being conducted at the University of Washington (UW) School of Medicine. The UW research is expected to include animal models to confirm the ability of HIFU to target high concentrations of doxorubicin in proprietary pancreatic cancer cell lines and in vivo studies to assess the response to these tumors treated using ThermoDox® with and without HIFU-induced hyperthermia. We believe that these collaborations are just the beginning for combining important device technologies such as HIFU with our low heat activated liposomal technology.

In addition to the HEAT study and the collaborations outlined above, ThermoDox® is being evaluated in a Phase II study of ThermoDox® in combination with hyperthermia for the treatment of recurrent chest wall (RCW) breast cancer (the DIGNITY study). The DIGNITY study has opened for enrollment with the activation of three clinical sites. The primary study endpoint of the DIGNITY study is bioequivalence of the drug supplied by our second U.S. manufacturing site, with the secondary endpoint of tumor response based on RECIST criteria. ThermoDox® had been evaluated in a Phase II study in combination with RFA for the treatment of colorectal liver metastases (the ABLATE study) before we decided in April 2013 to defer expenses associated with the ABLATE study until such time as we finalize our plans for the continuation of its development program with ThermoDox® in HCC. The primary study endpoint for the ABLATE study is based on one year local tumor recurrence, with secondary endpoint of time to progression and overall survival.

Business Strategy

An element of our business strategy has been to pursue, as resources permit, the research and development of a range of product candidates for a variety of indications. We may also evaluate licensing cancer products from third parties for cancer treatments to expand our product pipeline. This is intended to allow us to diversify the risks associated with our research and development expenditures. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates would increase and results such as those announced in relation to the HEAT study on January 31, 2013 will have a more significant impact on our financial prospects, financial condition and market value. We will assess our product pipeline and research and development priorities. We may also consider and evaluate strategic alternatives, including investment in, or acquisition of, complementary businesses, technologies or products. As demonstrated by the Heat study results, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval. The timing and the outcome of clinical results is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, financial condition and market value.

Our current business strategy includes the possibility of entering into collaborative arrangements with third parties to complete the development and commercialization of our product candidates. In the event that third parties take over the clinical trial process for one or more of our product candidates, the estimated completion date would largely be under the control of that third party rather than us. We cannot predict with any degree of certainty which proprietary products or indications, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our development plan or capital requirements. We may also apply for subsidies, grants or government or agency-sponsored studies that could reduce our development costs.

As a result of the uncertainties discussed above, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or to obtain positive results in our clinical trials, as well as any failure to enter into collaborative agreements when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research, development and clinical trials or whether we are in a position to pursue manufacturing or commercialization activities, it is clear we will need significant additional capital to develop our product candidates through clinical development, manufacturing and commercialization. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

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 997 Lenox Drive, Suite 100, Lawrenceville, New Jersey 08648. Our telephone number is (609) 896-9100 and our website is www.celsion.com. The information available on or through our website is not part of, nor incorporated by reference into, this prospectus supplement or the accompanying prospectus and should not be relied upon.

THE OFFERING

Common stock offered by us	6,264,492 shares of common stock.
Common stock to be outstanding before this offering	50,835,477 shares (as more fully described in the notes following this table).
Common stock to be outstanding after this offering	57,099,969 shares (as more fully described in the notes following this table).
Manner of offering	Registered direct offering. See “Plan of Distribution” on page S-19 of this prospectus supplement.
Use of proceeds	We currently intend to use the net proceeds from this offering, if any, for general corporate purposes, including research and development activities, capital expenditures and working capital. We may also use all or a portion of the net proceeds from this offering to fund possible investments in, or acquisitions of, complementary businesses, technologies or products, but we currently have no agreements or commitments with respect to any investment or acquisition. See “Use of Proceeds” on page S-16 of this prospectus supplement.
NASDAQ Capital Market symbol	“CLSN”.
Risk factors	Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page S-6 of this prospectus supplement.
Waiver of rights with respect to warrants	Each investor participating in the offering that holds outstanding common stock purchase warrants previously issued by us agrees to waive its rights to purchase an aggregate of 6,264,492 shares of common stock that would otherwise be purchasable upon exercise of such warrants, and with respect to which the applicable prospectus supplements previously filed by us for the issuance of such warrants are not available for use, until we have obtained our stockholders’ approval of increase in the number of authorized shares of our common stock to 75,000,000 in conjunction with a reverse split of the outstanding shares of our common stock.

The number of shares of our common stock shown above outstanding immediately before and after this offering is based on 50,835,477 shares outstanding as of March 31, 2013, and excludes, as of such date:

3,246,618 shares of our common stock subject to outstanding options having a weighted average exercise price of $3.25 per share and restricted stock awards;

4,054,326 shares of our common stock reserved for issuance pursuant to the conversion of 5,037 shares of preferred stock;

2,142,304 shares of our common stock reserved for future issuance pursuant to our existing stock incentive plans;

13,818,772 shares of our common stock reserved for issuance upon exercise of outstanding warrants having a weighted average exercise price of $2.42 per share; and

662,379 shares of our common stock held as treasury stock.

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 18 under Part I, Item IA of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the Securities and Exchange Commission on March 18, 2013, and any subsequent Quarterly Report on Form 10-Q, which are incorporated by reference into this prospectus supplement and the accompanying prospectus, as well as the other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference and in any free writing prospectus that we have authorized for use in connection with this offering. If any of the identified risks actually 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 have a history of significant losses from continuing operations and expect to continue such losses for the foreseeable future.

Since our inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of $156 million at March 31, 2013. Because we presently have no product revenues and we are committed to continuing our product research, development and commercialization programs, we will continue to experience significant operating losses unless and until we complete the development of ThermoDox® and other new products and these products have been clinically tested, approved by the U.S. Food and Drug Administration (FDA) and successfully marketed.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Our lead drug candidate failed to meets its primary endpoint in the Phase III HEAT study.

We have a number of drug candidates in research and development ranging from the early discovery research phase through preclinical testing and clinical trials. Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. Drug development is very risky. It will take us several years to complete clinical trials. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our

own financial constraints.

On January 31, 2013, we announced that our lead product ThermoDox® in combination with radiofrequency ablation failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer (the HEAT study). We have not completed our final analysis of the data and do not know the extent to which, if any, the failure of ThermoDox® to meet its primary endpoint in the Phase III trial could impact our other ongoing studies of ThermoDox®. ThermoDox® is also being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies. Even with success in preclinical testing and previously completed clinical trials, the risk of clinical failure for any drug candidate remains high prior to regulatory approval. Even if ThermoDox® has positive results in its Phase II clinical trials, there is a substantial risk that it will fail to have sufficiently positive results in Phase III clinical trials with regard to efficacy, safety or other clinical outcomes. One or more of our clinical studies could fail at any time, as evidenced by the failure of ThermoDox® to meet its primary endpoint in the HEAT study. The failure of one or more of our drug candidates or development programs could have a material adverse effect on our business, financial condition and results of operations.

If we do not obtain or maintain FDA and foreign regulatory approvals for our drug candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, we will be unable to sell those products and our business, results of operations and financial condition will be negatively affected.

To obtain regulatory approvals from the FDA and foreign 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 foreign regulatory agencies may require us to perform additional trials beyond those we planned. This process generally takes a number of years and requires the expenditure of substantial resources. The time required for completing testing and obtaining approvals is uncertain, and the FDA and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. In addition, undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

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

We have devoted our resources to developing a new generation of products and will not be able to market these products until we have completed clinical trials and obtain all necessary governmental approvals. Our lead product candidate, ThermoDox®, is still in various stages of development and trials and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Following our announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint of progression free survival, we will continue to follow the patients enrolled in the Heat study to the secondary endpoint, overall survival. ThermoDox® is currently also being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies. We do not expect to realize any revenues from product sales in the next several years, if at all. Accordingly, our revenue sources are, and will remain, extremely limited until our product candidates are clinically tested, approved by the FDA or foreign regulatory agencies and successfully marketed. We cannot guarantee that any of our product candidates will be successfully tested, approved by the FDA or foreign regulatory agency or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

We will need to raise substantial additional capital to fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates.

As of March 31, 2013, we had approximately $45.9 million in cash, cash equivalents and short-term investments. We have substantial future capital requirements to continue our research and development activities and advance our drug candidates through various development stages. For example, ThermoDox® is being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies. We will conduct additional analyses of the data from the HEAT study to assess the future strategic value of ThermoDox® and are performing sub-group analysis of the Chinese cohort of patients in the HEAT study and other activities for further development of ThermoDox® for mainland China, Hong Kong and Macau. To complete the development and commercialization of our product candidates, we will need to raise substantial amounts of additional capital to fund our operations. We do not have any committed sources of financing and cannot assure you that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, convertible debt or other convertible or exercisable securities. Such dilutive equity financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders.

If we cannot raise additional capital, we may be required to delay, reduce 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 have no internal sales or marketing capability. If we are unable to create sales, marketing and distribution capabilities or enter into alliances with others possessing such capabilities to perform these functions, we will not be able to commercialize our products successfully.

We currently have no sales, marketing or distribution capabilities. We intend to market our products, if and when such products are approved for commercialization by the FDA and foreign regulatory agencies, either directly or through other strategic alliances and distribution arrangements with third parties. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products, we will need to establish and maintain partnership arrangements, and there can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on acceptable 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 and there can be no assurance that 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 a 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. Additionally, we have a joint research agreement with Philips Healthcare, a division of Royal Philips Electronics, 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. If we breach any provisions of the license and research agreements, we may 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 may be required to alter any of our potential products or processes, or enter into a license and pay licensing fees to a third party or cease certain activities. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. If a license is not available on commercially reasonable terms or at all, our business, results of operations, and financial condition could be significantly harmed and we may be prevented from developing and commercializing the product. 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 rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.

We rely on trade secrets and confidential information that we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We cannot assure you that these agreements are adequate to protect our trade secrets and confidential information or will not be breached or, if breached, we will have adequate remedies. Furthermore, others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

Our products may 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 currently are not involved in any material litigation involving patents, a third party patent holder may 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.

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 expect to significantly increase our personnel in the foreseeable future and may 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 significantly 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.

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, or those of our vendors and suppliers, 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 the 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 may do business, or in which our products may be sold, if at all, 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 healthcare 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 whether or when any legislative proposals will be adopted or what actions federal, state, or private payors for health care treatment and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect healthcare 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. health care system.

The success of our products may be harmed if the government, private health insurers and other third-party payers 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 healthcare 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.

The commercial success of our products will depend upon their acceptance by the medical community and third-party payers as clinically useful, cost effective and safe. Any or our drug candidates 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 clinical 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, which would have an adverse effect on our business, financial condition and results of operations.

The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.

It is very difficult to predict the commercial potential of product candidates due to important factors such as safety and efficacy compared to other available treatments, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payor reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful product candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the revenue potential for such drug candidate and would adversely affect our business, financial condition and results of operations.