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As filed with the Securities and Exchange Commission on April 6, 2010

Registration No. 333-163957

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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AMENDMENT NO. 3  
TO  
**FORM S-1**  
**REGISTRATION STATEMENT**

UNDER  
*THE SECURITIES ACT OF 1933*

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**SurgiVision, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**3841**  
(Primary Standard Industrial  
Classification Code Number)  
  
SurgiVision, Inc.  
One Commerce Square, Suite 2550  
Memphis, TN 38103  
(901) 522-9300

**58-2394628**  
(I.R.S. Employer  
Identification No.)

(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

---

Kimble L. Jenkins  
Chief Executive Officer  
SurgiVision, Inc.  
One Commerce Square, Suite 2550  
Memphis, TN 38103  
(901) 522-9300

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. "

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

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

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

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

Large Accelerated filer                    "

Accelerated filer                                 "

Non-accelerated filer             (Do not check if a smaller reporting company)

Smaller reporting company                                 "

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

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION, DATED APRIL 6, 2010



Shares

**SurgiVision, Inc.**

**Common Stock**

This is the initial public offering of shares of common stock of SurgiVision, Inc. We are offering \_\_\_\_\_ shares of our common stock.

No public market currently exists for our common stock. We estimate that the initial public offering price will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share. We intend to apply for the quotation of our common stock on the Nasdaq Capital Market under the symbol "SRGV".

*Investing in our common stock involves risk. See "[Risk Factors](#)" on page 7 to read about factors you should consider before buying shares of our common stock.*

**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.**

	<u>Per Share</u>	<u>Total</u>
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

To the extent that the underwriters sell more than \_\_\_\_\_ shares of our common stock, the underwriters have the option to purchase up to an additional \_\_\_\_\_ shares from us at the initial public offering price less the underwriting discount and commissions.

In connection with this offering, we have also agreed to issue to the underwriters warrants to purchase up to an aggregate of \_\_\_\_\_ shares of our common stock at an exercise price of \$ \_\_\_\_\_ per share. These warrants are exercisable commencing on the first anniversary of the date of this prospectus and ending on the fifth anniversary of the date of this prospectus.

The underwriters expect to deliver the shares on or about \_\_\_\_\_, 2010.

**Canaccord Adams**

**Rodman & Renshaw,  
LLC**

Prospectus dated \_\_\_\_\_, 2010



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No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside the United States.

**Dealer Prospectus Delivery Obligation**

Through and including \_\_\_\_\_, 2010 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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### **Trademarks, Trade Names and Service Marks**

*ClearConnect™*, *ClearPoint™*, *ClearTrace™*, *SmartFrame™* and *SmartGrid™* are trademarks of SurgiVision, Inc. All other trademarks, trade names and service marks referred to in this prospectus are the property of their respective owners. Siemens refers to Siemens Aktiengesellschaft, Healthcare Sector. Boston Scientific refers to Boston Scientific Corporation and its affiliates.

### **Industry and Market Data**

The market data and other statistical information used throughout this prospectus are based on independent industry publications, government publications, reports by market research firms and other published independent sources. Some data is also based on our good faith estimates, which are derived from other relevant statistical information, as well as the independent sources listed above. Although we believe these sources are reliable, we have not independently verified the information.



## PROSPECTUS SUMMARY

*This summary highlights the information contained elsewhere in this prospectus. Because this is only a summary, it does not contain all of the information that may be important to you. Before investing in our common stock, you should read this entire prospectus, including the information set forth under the heading “Risk Factors” and the financial statements and the notes thereto.*

*Unless the context otherwise requires, references in this prospectus to “SurgiVision,” “we,” “our,” “us” and the “company” refer to SurgiVision, Inc. and, where appropriate, its consolidated subsidiary. The historical financial statements and financial data included in this prospectus are those of SurgiVision and its consolidated subsidiary.*

### **Our Business**

We are a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain and heart using direct, intra-procedural magnetic resonance imaging, or MRI, guidance while performing minimally invasive procedures. We believe that our product candidates will deliver better patient outcomes in shorter procedure times, enhance revenue potential for both physicians and hospitals, and reduce costs to the healthcare system. For the year ended December 31, 2009, we generated revenues of approximately \$2,600,000 and incurred a net loss of approximately \$7,159,000.

Millions of people suffer from brain and heart diseases and disorders. While some patients can be treated with medication, others require surgery. Current surgical interventions include both open and minimally invasive procedures. Given the option, patients, physicians and hospitals prefer minimally invasive procedures over open procedures. However, because of restricted visibility of the patient’s anatomy, surgical field and instruments, minimally invasive alternatives for some procedures in the brain and heart are either unavailable or exceedingly complex.

Based on our years of experience in the interventional MRI field, we have designed two innovative platforms, the ClearPoint system and the ClearTrace system, that address these issues. By combining the continuous, high resolution imaging capabilities of MRI with minimally invasive techniques, these two platforms, subject to appropriate regulatory clearance or approval, will enable physicians to:

- *Guide* a surgical instrument within the patient as it is advanced towards the therapeutic target;
- *Deliver* a planned therapy with precise visualization of a patient’s anatomy, the surgical field and instruments;
- *Monitor* for adverse events during and immediately after the administration of the therapy; and
- *Confirm* the desired results of a procedure.

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<b>Our Product Candidates</b>			
<b>Product Candidates</b>	<b>Regulatory Status</b>	<b>Target Market</b>	<b>Development Partner</b>
ClearPoint Neuro Intervention System	510(k) Clearance Pending	Initial target market is general neurological interventions, such as biopsies and catheter and electrode insertion. Subsequent target markets may include deep brain stimulation lead placement and precision delivery of drugs and biologics.	Developed Internally
ClearTrace Cardiac Intervention System	Development Stage	Initial target market is catheter-based cardiac ablation to treat atrial fibrillation. Subsequent target markets may include precision delivery of drugs and biologics.	Siemens
SafeLead Development Program	Development Stage	Target market is implantable leads for cardiac and neurological applications.	Boston Scientific

Our first product candidate is our ClearPoint system, which is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. Our ClearPoint system is an integrated system of reusable hardware components, disposable hardware components and intuitive, menu-driven software. Using our ClearPoint system, a physician sees and selects a neurological target, aims our targeting device and watches as the surgical instrument is advanced to the target, significantly reducing the time and complexity of the interventional procedure. Millions of people suffer from neurological disorders or diseases. Performing minimally invasive procedures in the brain presents special challenges, including a need to reach small therapeutic targets often located deep within the brain. We believe that our ClearPoint system addresses these challenges and can become the platform-of-choice for performing the next generation of minimally invasive procedures in the brain.

Our second product candidate is the ClearTrace system, which is designed to allow catheter-based minimally invasive procedures in the heart to be performed using continuous, intra-procedural MRI guidance. We are developing the hardware and MRI software for the ClearTrace system with Siemens, the global market leader in MRI scanners. The ClearTrace system is an integrated system of reusable hardware components, disposable catheters and intuitive, menu-driven software. The ClearTrace system will offer a novel, comprehensive solution for the planning, delivery and intra-procedural assessment of catheter-based cardiac interventions. We expect that the ClearTrace system’s initial application will be catheter-based cardiac ablation to treat atrial fibrillation. During cardiac ablation, a physician attempts to restore a normal heart rhythm by destroying small areas of heart tissue to block irregular electrical impulses that cause an irregular heartbeat, or arrhythmia. Atrial fibrillation is the most common cardiac arrhythmia, affecting over three million people in the United States alone.

Our third area of activity is referred to as the SafeLead Development Program. Over the last ten years, we have pioneered several technologies that improve the MRI-safety profile of implantable medical leads. These leads are thin, insulated wires that are connected to implantable generators, such as a pacemaker or neurostimulator, and deliver electrical pulses or stimulation to a specific area of the body, such as the heart or the brain. During an MRI scan, these leads are susceptible to heating, which could burn and destroy adjacent tissue. Our technologies address this issue by maintaining lead temperatures well within safe levels during an MRI scan. We are working with Boston Scientific to incorporate our MRI-safety technologies into Boston Scientific’s implantable leads for cardiac and neurological applications. Boston Scientific paid us licensing fees of \$13,000,000 in 2008 relating to implantable cardiac leads. In addition, under our agreements Boston Scientific has agreed to pay us up to \$21,600,000 in future milestone-based payments as well as royalties on net sales of products that are covered by a licensed patent. We believe that our MRI-safety technologies, when integrated into Boston Scientific’s implantable leads, could represent a meaningful market differentiator over existing implantable lead designs.

### **Licenses and Collaborative Relationships**

In addition to our internally-developed technologies and devices, we have established and intend to continue to pursue licensing and collaborative relationships with medical device companies and academic institutions to further the development and commercialization of our core technologies and product platforms. Our most significant licensing and collaborative relationships are summarized below:

- *Siemens.* We have entered into an agreement with Siemens to develop the hardware and MRI software systems for MRI-guided, catheter-based cardiac ablation to treat atrial fibrillation and other cardiac arrhythmias. Under this agreement, Siemens will develop the software and we will develop the catheters and other hardware, other than the MRI scanner and workstation. The agreement contains exclusivity provisions in the area of MRI-guided, catheter-based cardiac ablation. These provisions prohibit Siemens from marketing or offering software intended to work with other manufacturers' catheters. These provisions also prohibit us from selling or offering catheters intended to work with other manufacturers' MRI scanners.
- *Boston Scientific.* We have entered into a series of agreements with Boston Scientific with respect to our MRI-safety technologies. Under these agreements, Boston Scientific has the exclusive, worldwide right, but not the obligation, to use the licensed technologies in Boston Scientific's implantable leads for cardiac and neurological applications. We are working jointly with Boston Scientific to assess the potential use of our MRI-safety technologies in Boston Scientific's lead designs.
- *University of California, San Francisco.* We have entered into a research agreement with the University of California, San Francisco in the field of interventional MRI. Under our agreement, university personnel are assessing the safety and clinical efficacy of interventional MRI guidance for the performance of certain minimally invasive neurological procedures.
- *The University of Utah.* We have established a collaboration with The University of Utah, under which university personnel are conducting research activities and experiments to develop knowledge, techniques, methods and technologies related to MRI-guided cardiac ablation, including a specific focus on MRI-guided cardiac ablation to treat atrial fibrillation.
- *The Johns Hopkins University.* We have several license agreements with The Johns Hopkins University under which we have obtained exclusive licenses for various technologies relating to devices, systems and methods for performing MRI-guided interventions and MRI-safety.

### **Our Business Model and Strategy**

Our business model is focused on producing recurring revenue from the sale of the disposable components of both the ClearPoint and ClearTrace systems. Our disposable and reusable components are tightly integrated, which allows us to leverage each new installation of a ClearPoint or ClearTrace system to generate recurring sales of our disposable products. We anticipate that recurring revenues will constitute an increasing percentage of our total revenues as our installed base grows.

The key elements of our business strategy are obtaining regulatory clearance of our ClearPoint system, maximizing installation and adoption of our ClearPoint system, continuing development of the ClearTrace system with Siemens, pursuing the SafeLead Development Program with Boston Scientific, and building upon our core technologies to continue to develop MRI-based products.

SurgiVision has a significant intellectual property portfolio in the field of MRI-guided interventions. As of March 31, 2010, our portfolio included 36 patents and 116 patent applications, both US and foreign, which we wholly-own, co-own or have licensed. In addition, we have meaningful collaborations with major industry participants and renowned academic institutions. Our technologies have been the subject of numerous peer-

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reviewed articles in medical and scientific journals. As a result of our intellectual property and collaborative relationships, we believe that we are well positioned to remain on the forefront of the emerging market for MRI-guided minimally invasive procedures.

**Risks Related to Our Business**

We are subject to a number of risks of which you should be aware before you decide to buy our common stock. These risks are discussed more fully in the “Risk Factors” section of this prospectus beginning on page 7 and should be read in their entirety. In general, we face risks associated with the following:

- our limited operating history;
- the net losses that we have incurred in each year since our inception and expect to continue as we develop our business;
- our auditors have included an explanatory paragraph regarding the uncertainty of our ability to continue operations as a going concern in their report on our financial statements for the year ended December 31, 2009;
- there is no guarantee that we will achieve the milestones under our agreements with Boston Scientific or be entitled to the milestone payments, and, if some of the milestones relating to neurological applications are not met by December 31, 2012, we will be required to repay to Boston Scientific amounts specified in the related development agreement;
- obtaining FDA or other regulatory approvals or clearances of our product candidates;
- convincing physicians and hospitals to use our products and achieving market acceptance for our products;
- any failure to comply with rigorous FDA and other government regulations; and
- securing and maintaining patent or other intellectual property protection covering our products.

**Recent Developments**

In March 2010, we issued 10% senior unsecured convertible notes, or the bridge notes, in the aggregate principal amount of approximately \$4.1 million in a private placement, or the bridge financing. Upon consummation of this offering, the bridge notes will automatically convert into shares of our common stock at the lesser of \$2.00 per share or 80% of the public offering price of our common stock in this offering. The bridge notes mature two years from the date of issuance, unless earlier converted, and accrue interest at the rate of 10% per annum. All accrued interest will be paid in cash and will not be converted into shares of our common stock. We incurred approximately \$300,000 of expenses related to the bridge financing, including legal fees and placement agent fees. In addition, we issued to our placement agent a warrant, or the placement agent warrant, to purchase 101,775 shares of our common stock at an exercise price equal to the lesser of \$2.00 per share or 80% of the public offering price of our common stock in this offering. We intend to use the proceeds of the bridge financing for working capital and general corporate purposes.

**Corporate Information**

We were incorporated in Delaware in 1998 under the name Surgi-Vision, Inc. On November 12, 2008, we changed our name to SurgiVision, Inc. We operate in only one business segment. Our principal executive office is located at One Commerce Square, Suite 2550, Memphis, TN 38103, and our telephone number is (901) 522-9300. Our website address is [www.surgivision.com](http://www.surgivision.com). We do not incorporate the information on our website into this prospectus, and you should not consider it part of this prospectus.

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**Summary of the Offering**

Common stock offered by us	shares
Common stock to be outstanding after the offering	shares
Proposed Nasdaq Capital Market symbol	SRGV
Use of proceeds	We expect to use the net proceeds from this offering to fund our research and development activities, sales and marketing activities and for working capital and other general corporate purposes.

The number of shares of common stock to be outstanding after this offering is based on the number of shares outstanding as of March 31, 2010 and excludes:

- 2,402,500 shares of common stock issuable upon exercise of options issued under our stock option plans, at a weighted average exercise price of \$0.92 per share;
- 266,608 shares of common stock issuable upon the exercise of an option not issued under our stock option plans, at an exercise price of \$2.41 per share;
- 1,642,167 shares of common stock issuable upon exercise of warrants, at a weighted average exercise price of \$0.75 per share;
- 1,820,137 shares of common stock issuable upon the conversion of \$3,640,274 in principal amount of, and interest on, convertible promissory notes, at a conversion price of \$2.00 per share;
- \_\_\_\_\_ shares of our common stock that may be issued to the underwriters, upon exercise of warrants, at an exercise price of \$ \_\_\_\_\_ per share;
- 101,775 shares of common stock that may be issued pursuant to the placement agent warrant, at an exercise price of \$ \_\_\_\_\_ per share; and
- 5,000,000 shares of common stock reserved for future issuance under our 2010 Incentive Compensation Plan, which we plan to adopt before the completion of this offering.

Except as otherwise noted, all information in this prospectus:

- assumes no exercise of the underwriters' over-allotment option; and
- gives effect to the 1-for \_\_\_\_\_ reverse stock split and conversion into common stock of all outstanding shares of our preferred stock and the bridge notes.

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**Summary Financial Information**

The summary financial information below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements, notes thereto and other financial information included elsewhere in this prospectus. The summary financial information for the fiscal years ended December 31, 2009, 2008 and 2007 has been derived from our audited financial statements and the notes thereto included elsewhere in this prospectus.

	Year Ended December 31,		
	2009	2008	2007
<b>Statement of Operations Data:</b>			
Related party license revenue	\$ 2,600,000	\$ 1,950,000	\$ —
Operating costs and expenses:			
Research and development costs	6,067,617	4,258,492	2,098,672
General and administrative expenses	3,595,917	2,920,311	1,413,369
Total operating costs and expenses	9,663,534	7,178,803	3,512,041
Other income:			
Interest expense, net	(46,276)	(200,982)	(185,096)
Net loss	<u>\$ (7,159,060)</u>	<u>\$ (5,429,785)</u>	<u>\$ (3,697,137)</u>
Net loss per share attributable to common stockholders:			
Basic and Diluted	<u>\$ (0.34)</u>	<u>\$ (0.26)</u>	<u>\$ (0.18)</u>
Weighted average shares outstanding:			
Basic and Diluted	<u>21,346,533</u>	<u>20,980,324</u>	<u>20,098,058</u>

The following table presents a summary of our balance sheet as of December 31, 2009:

- on an actual basis;
- on a pro forma basis to reflect a 1-for- reverse stock split and the conversion into common stock of all outstanding shares of our preferred stock and the bridge notes; and
- on a pro forma as adjusted basis to reflect the pro forma adjustments reflected above and the sale in this offering of shares of common stock at an assumed initial offering price of \$ per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of December 31, 2009		
	Actual	Pro Forma	Pro Forma As Adjusted
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 2,569,129	\$	\$
Total assets	4,673,688		
Related party convertible notes payable, net of \$1,129,000 unamortized discount	2,371,000		
Convertible preferred stock	7,965,000		
Common stock, \$0.01 par value	218,205		
Additional paid-in capital	25,631,208		
Treasury stock	(1,679,234)		
Accumulated deficit	(42,022,964)		
Total stockholders’ equity (deficit)	(9,887,785)		

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**RISK FACTORS**

*Any investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below and all information contained in this prospectus, before you decide whether to purchase our common stock. If any of the following risks or uncertainties actually occurs, our business, financial condition, results of operations and prospects would likely suffer, possibly materially. In addition, the trading price of our common stock could decline due to any of these risks or uncertainties, and you may lose part or all of your investment.*

**Risks Related to Our Business**

***We are an early-stage medical device company and our business may not become profitable.***

We are an early-stage medical device company with a limited operating history upon which you can evaluate our business. We have not commercialized any of our current product candidates. The future success of our business depends on our ability to obtain regulatory clearances or approvals for our product candidates, which we may be unable to do in a timely manner, if at all. There is no assurance that we will succeed in bringing any of our product candidates to market.

Even if we obtain regulatory clearances or approvals for our product candidates, we face significant challenges with physician and hospital adoption of our products. We believe the market for our ClearPoint system is fairly concentrated among a few hundred hospitals. Failure to achieve significant penetration within these hospitals will negatively affect our business.

To succeed in our commercialization efforts, we must execute effectively on all elements of our business plan, including developing and testing products, obtaining regulatory clearances and approvals, expanding our sales and marketing capabilities and obtaining commercial-scale production capabilities through third parties. If we fail in any of these endeavors, or experience delays in pursuing them, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

***Our success depends substantially on our ability to obtain regulatory clearances or approvals for our current product candidates. We cannot be certain that we will be able to do so in a timely fashion or at all.***

We do not have the necessary regulatory clearances or approvals to market either our ClearPoint system or the ClearTrace system in the United States or in any foreign market. In the United States, without Food and Drug Administration, or FDA, clearances or approvals, we can not market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, unless an exemption applies. To obtain FDA clearance or approval, we must first receive either premarket clearance under Section 510(k) of the federal Food, Drug, and Cosmetic Act or approval of a premarket approval application, or PMA, from the FDA.

In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology, safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The 510(k) clearance process generally takes three to twelve months from submission, but can take significantly longer.

The process of obtaining PMA approval is much more costly and uncertain than the 510(k) clearance process. The PMA approval process can be lengthy and expensive and requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on data obtained in clinical trials. The PMA process generally takes one to three years, or even longer, from the time the PMA application is submitted to the FDA until an approval is obtained.

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The regulatory status of our current product candidates are as follows:

- *ClearPoint System.* We originally submitted five Section 510(k) premarket notifications to the FDA in the first and second calendar quarters of 2009 seeking marketing clearance for the individual devices comprising our ClearPoint system. Based on discussions with the FDA, we consolidated two of the devices into one 510(k) to obtain clearance of these devices as a system. We have obtained 510(k) clearance with respect to the devices addressed in three of those submissions. The final 510(k) submission for our ClearPoint system remains under review by the FDA. In the pending 510(k) submission, we are seeking 510(k) clearance to market the device for use in general neurological interventional procedures. If 510(k) clearance of this general neurological intervention claim is received, our ClearPoint system will initially be marketed to provide guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. Our ClearPoint system is intended as an integral part of procedures, such as biopsies and catheter and electrode insertion, that have traditionally used other methods. Until 510(k) clearance is obtained for all components of our ClearPoint system, we cannot market our ClearPoint system.
- *ClearTrace System.* We are still in the early stages of the development of the ClearTrace system and have not made any regulatory filings with the FDA with respect to that system. The ClearTrace system consists of several components, including an ablation catheter. The FDA has determined that ablation catheters require the submission of a PMA. Therefore, we will be required to pursue the PMA process for this component. As part of the PMA process, we will be required to conduct a clinical trial regarding the safety and effectiveness of our ablation catheter. We expect to commence enrollment in the clinical trial in the second half of 2011. With the exception of the ClearTrace ablation catheter, we plan to seek FDA clearance through the 510(k) process for the other ClearTrace system components.
- *SafeLead Development Program.* We are still in the early stages of the SafeLead Development Program. Boston Scientific is responsible for making any regulatory filings with the FDA with respect to its products that incorporate our MRI-safety technologies. Boston Scientific will control the timing and manner of any regulatory filing, and will be responsible for the costs associated with any regulatory filing. We do not anticipate that we will be able to influence the process or timing in any meaningful way. No regulatory filings have been made with the FDA to date.

The FDA may not act favorably or quickly in its review of our pending 510(k) submission for our ClearPoint system or any other 510(k) or PMA that, we, or Boston Scientific in connection with the SafeLead Development Program, may file. Additionally, we may encounter significant difficulties and costs in our efforts to obtain FDA clearances or approvals. If we are unable to use the 510(k) clearance process or are unable to obtain 510(k) clearance for any of our product candidates, or otherwise experience delays in obtaining or fail to obtain regulatory clearances, the commercialization of our product candidates will be delayed or prevented, which will adversely affect our ability to generate revenues. Such delay may also result in the loss of potential competitive advantages that we might otherwise attain by bringing our products to market earlier than our competitors. Any of these contingencies could adversely affect our business. Even if cleared or approved, our product candidates may not be cleared or approved for the indications that are necessary or desirable for successful commercialization.

***There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products and claims. Failure to obtain necessary clearances or approvals for our future product candidates and claims would adversely affect our ability to expand the utilization of our technologies, which may affect our ability to grow our business.***

In the future, we may seek to obtain additional, more specific indications for use of our ClearPoint system beyond the general neurological intervention claim, such as a specific claim for use in deep brain stimulation lead



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placement. In addition, we must seek to obtain clearance and approval of our other product candidates, any product candidates we may develop in the future, and expanded claims for any cleared or approved product. Some of these expanded claims and future products may require FDA clearance of a 510(k). Other claims and future products may require FDA approval of a PMA. Moreover, some specific ClearPoint system claims we may seek and some future products may require clinical trials to support regulatory clearance or approval, and we may not successfully complete or have the funds to initiate these clinical trials. The FDA may not clear or approve these future claims or products, or future generations of our ClearPoint system for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA approval. Failure to receive clearance or approval for additional claims for our ClearPoint system, or for our future products, would have an adverse effect on our ability to expand our business.

***Clinical trials necessary to support 510(k) clearance or PMA approval for our product candidates or new indications for use will be expensive and may require the enrollment of large numbers of suitable patients, who may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new product candidates and will adversely affect our business, operating results and prospects.***

Initiating and completing clinical trials necessary to support a PMA for the ClearTrace system or any other product candidates that we may develop, or additional safety and efficacy data that the FDA may require for 510(k) clearance or PMA approval for new specific indications of our ClearPoint system will be time consuming and expensive with an uncertain outcome. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, the proximity to clinical sites of patients that are able to comply with the eligibility and exclusion criteria for participation in the clinical trial, and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to our product candidates.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy will be required and we may not adequately develop such protocols to support clearance or approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our product candidates or result in the failure of the clinical trial. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

***If the third parties on which we may need to rely to conduct any clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our product candidates.***

We do not have the independent ability to conduct pre-clinical and clinical trials for our product candidates and to the extent we will need to conduct such trials, we will need to rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials.

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If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, a product candidate on a timely basis, if at all. As such, our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

***The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.***

Even if any clinical trial that we need to undertake is completed as planned, we cannot be certain that its results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. The clinical trial process may fail to demonstrate that a product candidate is safe and effective for the proposed indicated use, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize a product candidate and generate revenue. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

***Even if we succeed in obtaining FDA clearances and/or approvals for our product candidates within the time frames we anticipate, our products may not be commercially successful.***

Even if we receive regulatory clearances or approvals for our product candidates, our product candidates may not gain market acceptance unless we convince physicians, hospitals and patients of the benefits of our products. Moreover, even if physicians and hospitals understand the benefits of our products, they still may elect not to use our products for a variety of reasons, including:

- the shift in location of the procedure to the MRI suite;
- the hospital's ability and willingness to satisfy the increased demand for the MRI suite;
- the cost to the hospital to purchase or otherwise use our products;
- the lack of supporting clinical data;
- the physician's familiarity and having achieved successful results with the existing devices, approaches and methodologies; and
- for the ClearTrace system, a hospital may be required to purchase a new MRI scanner.

If physicians and hospitals do not perceive our products as attractive alternatives to existing products and procedures, we will not be able to generate significant revenue, if any.

***If hospitals and physicians are unable to obtain adequate coverage and reimbursement from third-party payors for procedures utilizing any products that we commercialize, our revenue and prospects for profitability will suffer.***

We anticipate that our products will be purchased primarily by hospitals, which bill various third-party payors, including governmental healthcare programs, such as Medicare, and private insurance plans, for procedures in which our products will be used. Reimbursement is a significant factor considered by hospitals in determining whether to acquire new medical devices such as our product candidates. Therefore, our ability to successfully commercialize products depends significantly on the availability of coverage and reimbursement from these third-party payors.

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Medicare pays acute care hospitals a prospectively determined amount for inpatient operating costs. The prospective payment for a patient's stay is determined by the patient's condition and other patient data and procedures performed during the inpatient stay using a classification system known as Medical Severity Diagnosis Related Groups, or MS-DRGs. Medicare pays a fixed amount to the hospital based on the MS-DRG into which the patient's stay is assigned, regardless of the actual cost to the hospital of furnishing the procedures, items and services provided. Therefore, a hospital must absorb the cost of our products as part of the payment it receives for the procedure in which the product is used. In addition, physicians that perform procedures in hospitals are paid a set amount by Medicare for performing such services under the Medicare physician fee schedule. Medicare payment rates for both systems are established annually. To the extent that payment reform initiatives result in more coordination between hospitals and physicians with respect to controlling supply costs, we anticipate more restrictions on physician choice and consolidation of medical device suppliers used by hospital purchasers, which could adversely affect our financial results and business.

At this time, we do not know if hospitals will consider third-party reimbursement levels adequate to cover the cost of our products. Furthermore, we do not know if physicians will consider third-party reimbursement levels adequate to compensate them for performing the procedures in which our products will be used. Failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used will deter them from purchasing or using our products and limit our sales growth.

***If there are changes in coverage or reimbursement from third-party payors, our revenues and prospects for profitability will suffer.***

We anticipate that existing billing codes would apply to procedures using our products. Reimbursement levels for procedures using our products could be decreased or eliminated as a result of future legislation, regulation, or reimbursement policies of third-party payors. Any such decrease or elimination would adversely affect the demand for our products and our ability to sell products on a profitable basis. For example, on July 30, 2008, Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers the Medicare Program, released a list of potential topics for national coverage determinations. This list included ablation for atrial fibrillation and specifically asked whether the evidence was adequate to demonstrate health benefits in patients who receive the procedure. On October 21, 2009, the Medicare Evidence Development and Coverage Advisory Committee held a meeting on the adequacy of the available evidence for catheter ablation for the treatment of atrial fibrillation. Although CMS has not formally opened a national coverage analysis on this topic, the agency has shown that it is interested in the clinical evidence of atrial fibrillation treatments and any national coverage decisions it makes could have a material effect on our potential business in this area. Furthermore, if procedures using our products gain market acceptance and the number of these procedures increases, CMS and other public or private payors may establish new billing codes for those procedures that provide for a lower reimbursement amount than traditional approaches, which could adversely affect our financial results and business.

On March 30, 2010, President Obama signed into law H.R. 4872, the Health Care and Education Reconciliation Act of 2010, which amends the broader Patient Protection and Affordable Care Act enacted on March 23, 2010 (collectively, the Health Care Reform Law). Among other things, the Health Care Reform Law will ultimately increase the overall pool of persons with access to health insurance in the United States. Although such an increase in covered lives should ultimately benefit hospitals, other changes in the Health Care Reform Law, such as a productivity adjustment to the market basket update and reduction of disproportionate share payments, could adversely impact the operations and finances of hospitals reducing their ability to purchase medical devices such as our products. Further, the fact that the Health Care Reform Law did not address pending reductions of Medicare physician payment rates under the sustainable growth rate formula could result in an overall reduction of physicians willing to participate in Medicare. Either of these events could adversely affect our business and financial results.

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***If third-party payors deny coverage or reimbursement for procedures using our products, our revenues and prospects for profitability will suffer.***

Notwithstanding regulatory clearances or approvals, if obtained, third-party payors may deny coverage or reimbursement if the payor determines that use of our product is unnecessary, inappropriate, experimental, not cost-effective, or is used for a non-approved indication. In addition, no uniform policy of coverage and reimbursement for medical technology exists among third-party payors. Therefore, coverage and reimbursement for medical technology can differ significantly from payor to payor.

***The Health Care Reform Law and other payment and policy changes may have a material adverse effect on us.***

In addition to reimbursement changes discussed above, the Health Care Reform Law will also impose a 2.3% excise tax on the sale of any taxable human medical devices after December 31, 2012, subject to certain exclusions, by the manufacturer, producer or importer of such devices. Further, the Health Care Reform Law encourages hospitals and physicians to work collaboratively through shared savings programs, such as accountable care organizations, which may ultimately result in the reduction of medical device acquisitions and the consolidation of medical device suppliers used by hospital purchasers. While passage of the Health Care Reform Law may ultimately expand the pool of potential end-users of our products, the above-discussed changes could adversely affect our financial results and business.

Further, with the increase in demand for healthcare services, we expect both a strain on the capacity of the healthcare system and more proposals by legislators, regulators and third-party payors to keep healthcare costs down. Certain proposals, if passed, could impose limitations on the prices we will be able to charge for our products, or the amounts of reimbursement available for our products from governmental agencies or third-party payors. These limitations could have a material adverse effect on our financial position and results of operations.

Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government's role in the United States healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially.

***The markets for medical devices, such as our product candidates, are highly competitive and we may not be able to compete effectively against the larger, well-established companies in our markets or emerging and small innovative companies that may seek to obtain or increase their share of the market.***

We will face competition from products and techniques already in existence in the marketplace. The markets for our product candidates are intensely competitive, and many of our competitors are much larger and have substantially more financial and human resources than we do. Many have long histories and strong reputations within the industry, and a relatively small number of companies dominate these markets. Examples of such large, well-known companies include Biosense Webster Inc., a division of Johnson & Johnson, Medtronic, Inc. and St. Jude Medical Inc.

These companies enjoy significant competitive advantages over us, including:

- broad product offerings, which address the needs of physicians and hospitals in a wide range of procedures;
- greater experience in, and resources for, launching, marketing, distributing and selling products, including strong sales forces and established distribution networks;
- existing relationships with physicians and hospitals;
- more extensive intellectual property portfolios and resources for patent protection;
- greater financial and other resources for product research and development;

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- greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements;
- established manufacturing operations and contract manufacturing relationships; and
- significantly greater name recognition and more recognizable trademarks.

Even if we successfully introduce our product candidates to market, we may not succeed in overcoming the competitive advantages of these large and established companies. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may introduce products that compete effectively against our products in terms of performance, price or both.

***We could become subject to product liability claims that could be expensive, divert management's attention and harm our business.***

Our business exposes us to potential product liability risks that are inherent in the manufacturing, marketing and sale of medical devices. We may be held liable if our products cause injury or death or are found otherwise unsuitable or defective during usage. Our ClearPoint system and the ClearTrace system incorporate mechanical and electrical parts, complex computer software and other sophisticated components, any of which can have defective or inferior parts or contain defects, errors or failures. Complex computer software is particularly vulnerable to errors and failures, especially when first introduced.

Because our ClearPoint system and the ClearTrace system are designed to be used to perform complex surgical procedures, defects could result in a number of complications, some of which could be serious and could harm or kill patients. The adverse publicity resulting from any of these events could cause physicians or hospitals to review and potentially terminate their relationships with us.

The medical device industry has historically been subject to extensive litigation over product liability claims. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Although we maintain product liability insurance, the coverage is subject to deductibles and limitations, and may not be adequate to cover future claims. Additionally, we may be unable to maintain our existing product liability insurance in the future at satisfactory rates or in adequate amounts. A product liability claim, regardless of its merit or eventual outcome could result in:

- decreased demand for our products;
- injury to our reputation;
- diversion of management's attention;
- significant costs of related litigation;
- payment of substantial monetary awards by us;
- product recalls or market withdrawals;
- a change in the design, manufacturing process or the indications for which our products may be used;
- loss of revenue; and
- an inability to commercialize product candidates.

***If we are unable to expand our sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate material product revenue.***

We do not have experience in the sales, marketing and distribution of medical devices. In order to commercialize any products that we develop, we must expand our present sales, marketing and distribution capabilities or make arrangements with a third party to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we will not be able to generate material product revenue and will not likely become profitable.

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If our ClearPoint system is cleared or approved for commercial sale, we currently plan to establish an internal sales force to market our product to physicians and hospitals in the United States. Although we anticipate a small sales force will be sufficient to cover the United States market, developing that sales force could prove time-consuming and expensive and could delay a wide product launch. We might not be able to develop our sales and marketing and distribution capabilities. If we are unable to establish these capabilities, we will need to contract with third parties to market and sell our products. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell our products ourselves.

***We may not realize the anticipated benefits from our collaborative agreements with Boston Scientific regarding the SafeLead Development Program.***

We entered into license and development agreements with Boston Scientific with respect to our MRI-safety technologies. We are working with Boston Scientific to incorporate our MRI-safety technologies into Boston Scientific's implantable medical leads for cardiac and neurological applications. There is no assurance that our joint development efforts will be successful or that patents will issue on any patent applications we licensed to Boston Scientific, in which case we would not receive future milestone payments or royalties provided for under our agreements with Boston Scientific. Further, Boston Scientific has no obligation to include our licensed intellectual property in its product candidates. Even if Boston Scientific incorporates our licensed intellectual property into its product candidates, Boston Scientific may be unable to obtain regulatory clearance or approval or successfully commercialize the related products, in which case we would not receive royalties in the amounts that we currently anticipate.

***We may be required to pay amounts to Boston Scientific under our development agreement in the neurological field if all of our development milestones under that agreement are not met by December 31, 2012.***

Our development agreement with Boston Scientific in the neurological field requires specified milestones in the development of an MRI-safe implantable lead to be achieved by December 31, 2012. If the milestones are not achieved by that date, and this failure is not the result of Boston Scientific's failure to reasonably cooperate with us in pursuing the milestones, we will be required to pay Boston Scientific a sum of money equal to all milestone payments previously paid to us by Boston Scientific under the development agreement, all development expense reimbursements previously paid to us by Boston Scientific under the development agreement, and all patent prosecution costs incurred by Boston Scientific with respect to the intellectual property licensed under the related license agreement. As of December 31, 2009, the potential obligation to Boston Scientific was approximately \$750,000, plus costs incurred by Boston Scientific in prosecuting the licensed intellectual property. Our potential payment obligation to Boston Scientific under the neuro development agreement does not apply to any amounts we receive under our agreements in the cardiac field, including the \$13 million of upfront licensing fees and any development milestone payments. Our agreements with Boston Scientific in the cardiac field do not impose a payment obligation on us for failure to achieve development milestones.

***Boston Scientific has the right to terminate our development agreement for implantable cardiac leads under specified circumstances.***

Boston Scientific has the one-time option, within 60 days after successful completion of the first lead feasibility study for cardiac applications, to cease further development work and to terminate the development agreement. If Boston Scientific elects to exercise its termination option under the development agreement, the license we granted to Boston Scientific in that field of use will automatically become non-exclusive with respect to some intellectual property; other intellectual property will be removed from the scope of the license and all rights will revert to us; and Boston Scientific will not be obligated to pay us any future royalties based on sales of its products containing our intellectual property that remains subject to the non-exclusive license.

***We may not realize the anticipated benefits from our collaborative agreement with Siemens regarding the ClearTrace system.***

We have entered into a co-development agreement with Siemens to develop the hardware and MRI software necessary for the ClearTrace system. There can be no assurance that our co-development efforts will be

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successful or that we will complete development of the ClearTrace system hardware and MRI software. Under our agreement, Siemens is responsible for developing the software for the ClearTrace system, and we are responsible for developing the catheters and other hardware, other than the MRI scanner and workstation. We are obligated to pay Siemens up to approximately \$2,500,000 in milestone payments associated with Siemens' successful development of the software in accordance with our specifications. We started making these payments in the second quarter of 2009 and will continue through the third quarter of 2011. Once the software for the ClearTrace system is commercially available, Siemens is obligated to pay us a fixed amount for each software license sold by Siemens until we recoup our investment in the software. However, if Siemens does not successfully commercialize the software, or if our agreement with Siemens is terminated, we may not recover our investment in the software.

***If we fail to obtain regulatory approval in foreign jurisdictions, we will not be able to expand the commercialization of our products abroad.***

Currently, our targeted geographic market for our ClearPoint system is the United States. We may, however, look to sell our ClearPoint system or our other product candidates in foreign jurisdictions in the future. It is anticipated that our initial market for the ClearTrace system will be in Europe. To sell our product candidates in foreign jurisdictions, we will have to obtain separate regulatory approvals from those foreign jurisdictions. The regulatory approval process varies among jurisdictions and can involve substantial additional testing. Clearance or approval by the FDA does not ensure clearance or approval by regulatory authorities in other jurisdictions, and clearance or approval by one foreign regulatory authority does not ensure clearance or approval by regulatory authorities in other foreign jurisdictions or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA clearance or approval in addition to other risks. In addition, the time required to obtain foreign clearance or approval may differ from that required to obtain FDA clearance or approval and we may not obtain foreign regulatory clearances or approvals on a timely basis, if at all. We may not be able to file for regulatory clearance or approval and may not receive necessary clearance or approval to commercialize our product candidates in any foreign market, either of which would preclude sale of our products in foreign jurisdictions.

To market a product in the European Union, we must be entitled to affix a CE mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. A CE Certification would enable us to market a product in all of the countries of the European Union, as well as in other countries, such as Switzerland and Israel, that have mutual recognition agreements with the European Union or have adopted the European Union's regulatory standards. There can be no assurance that we will receive CE Certifications for any of our product candidates.

***Our reliance on single source suppliers could harm our ability to meet demand for our ClearPoint system in a timely manner or within budget.***

Many of the components and subparts of our ClearPoint system are currently provided to us by single-sourced suppliers. We generally purchase components and component assemblies through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. While alternative suppliers exist and have been identified, the disruption or termination of the supply of components and component assemblies could cause a significant increase in the costs of these components, which could affect our operating results. Our dependence on a limited number of third-party suppliers and the challenges we may face in obtaining adequate supplies involve several risks, including limited control over pricing, availability, quality and delivery schedules. If we receive regulatory clearance to sell our ClearPoint system, a disruption or termination in the supply of components could also result in our inability to meet demand for our ClearPoint system, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the supplier of a key component or subpart of our product candidates, we may be required to verify that the new supplier maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new supplier could delay our ability to manufacture our ClearPoint system in a timely manner or within budget.

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**Risks Related to our Need for Financing**

*We have incurred significant losses since our inception and anticipate that we may continue to incur significant losses.*

As of December 31, 2009, we had an accumulated deficit of approximately \$42,023,000. The accumulated deficit has resulted principally from costs incurred in our research and development efforts and general operating expenses. We have incurred significant losses in each year since our inception in 1998. Net losses were approximately \$7,159,000 for the year ended December 31, 2009, approximately \$5,430,000 for the year ended December 31, 2008, and approximately \$3,697,000 for the year ended December 31, 2007. We expect to continue to incur significant operating losses as we continue to invest capital in the development of our product candidates and our business generally. We also expect that our general and administrative expenses will increase due to additional operational and regulatory burdens associated with operating as a public company. Because of the numerous risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Any failure to achieve and maintain profitability would continue to have an adverse effect on our stockholders' equity and working capital and could result in a decline in our stock price or cause us to cease operations.

*We may not be able to continue operations as a going concern and our stockholders may lose their entire investment in us.*

As discussed in note 3 to our financial statements included elsewhere in this prospectus, at December 31, 2009 we had cash and cash equivalents of approximately \$2,569,000 and stockholders' deficit of approximately \$9,888,000. In addition, we had a net loss for the year ended December 31, 2009 of approximately \$7,159,000.

These factors raise substantial doubt that we will be able to continue operations as a going concern. Our independent auditors included an explanatory paragraph regarding the uncertainty of whether we will be able to continue operations as a going concern in their report on our financial statements for the year ended December 31, 2009. Our ability to continue as a going concern is dependent upon us generating cash flow sufficient to fund operations and reducing operating expenses. Our business plans may not be successful in addressing these issues. If we cannot continue as a going concern, our stockholders may lose their entire investment in us.

*We may need additional funding to complete the development and commercialization of our product candidates and may not be able to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.*

We will require substantial future capital in order to continue to conduct the research and development and regulatory clearance and approval activities necessary to bring our product candidates to market and to establish effective marketing and sales capabilities. If we are unable to generate revenue, we do not expect our existing capital resources and the net proceeds from this offering to be sufficient to enable us to fund the completion of the development and commercialization of all of our product candidates. We believe that the net proceeds from this offering, our existing cash resources and interest on these funds will be sufficient to meet our projected operating requirements through the end of 2011. However, our operating plans may change, and we may need additional funds sooner than anticipated to meet our operational needs and capital requirements for product development, clinical trials, regulatory clearances and approvals, and product commercialization.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may terminate or delay the development of one or more of our product candidates, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our product candidates successfully.



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Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our research and development activities;
- the achievement of milestone events under, and other matters related to, our agreements with Boston Scientific and Siemens;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the cost and timing of clinical trials;
- the cost and timing of regulatory filings, clearances and approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities and other corporate infrastructure;
- the cost of establishing product inventories;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

***Raising additional capital by issuing securities or through collaborative or licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or products or grant licenses on terms that are not favorable to us. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

#### **Risks Related to our Intellectual Property**

***If we, or the third parties from whom we license intellectual property, are unable to secure and maintain patent or other intellectual property protection for the intellectual property covering our products, our ability to compete will be harmed.***

Our commercial success depends, in part, on obtaining patent and other intellectual property protection for the technologies contained in our products. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. Our patent position is uncertain and complex, in part, because of our dependence on intellectual property that we license from others. If we, or the third parties from whom we license intellectual property, fail to obtain adequate patent or other intellectual property protection for intellectual property covering our products, or if any protection is reduced or eliminated, others could use the intellectual property covering our products, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not provide us with a competitive advantage against competitors that devise ways of making competitive products without infringing any patents that we own or have rights to.

As of March 31, 2010, our portfolio included seven wholly-owned issued United States patents, 25 wholly-owned pending United States patent applications (including provisional applications), four co-owned issued United States patents, nine co-owned pending United States patent applications, one wholly-owned issued foreign patent, 38 wholly-owned pending foreign patent applications, one co-owned issued foreign patent and 22 co-owned pending foreign patent applications. In addition, as of March 31, 2010, we had licensed rights to 11

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United States and 12 foreign third-party issued patents, and we had licensed rights to eight United States and 14 foreign third-party pending patent applications. United States patents and patent applications may be subject to interference proceedings and United States patents may be subject to re-issue and reexamination proceedings in the United States Patent and Trademark Office. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. Changes in either patent laws or in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our protection. Interference, reexamination and opposition proceedings may be costly and time consuming, and we, or the third parties from whom we license intellectual property, may be unsuccessful in such proceedings. Thus, any patents that we own or license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may not result in patents being issued or may have claims that do not cover our products. Even if any of our pending or future patent applications are issued, they may not provide us with adequate protection or any competitive advantages. Our ability to develop additional patentable technology is also uncertain.

Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may also result in the loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical devices and procedures.

***Others may assert that our products infringe their intellectual property rights, which may cause us to engage in costly disputes and, if we are not successful in defending ourselves, could also cause us to pay substantial damages and prohibit us from selling our products.***

There may be United States and foreign patents issued to third parties that relate to our business, including MRI-guided intervention systems and the components and methods and processes related to these systems. Some of these patents may be broad enough to cover one or more aspects of our present technologies and/or may cover aspects of our future technologies. We do not know whether any of these patents, if asserted, would be held valid, enforceable and infringed.

We cannot assure that a court or administrative body would agree with any arguments or defenses we may have concerning invalidity, unenforceability or non-infringement of any third-party patent. In addition, other parties may have filed or may in the future file patent applications for products that are similar or identical to ours. We cannot assure that any patents issuing from applications filed by a third party will not cover our products or will not have priority over our patents or patent applications.

The medical device industry has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights, and companies have employed such actions to gain a competitive advantage. If third parties assert infringement or other intellectual property claims against us, our technical and management personnel will experience a significant diversion of time and effort and we will incur large expenses defending our company. If third parties in any patent action are successful, our patent portfolio may be damaged, we may have to pay substantial damages and we may be required to stop selling our products or obtain a license which, if available at all, may require us to pay substantial royalties. We cannot be certain that we will have the financial resources or the substantive arguments to defend our products from infringement or our patents from claims of invalidity or unenforceability, or to defend our products against allegations of infringement of third-party patents. In addition, any public announcements related to litigation or administrative proceedings initiated by us, or initiated or threatened against us, could cause our stock price to decline.

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***If we lose access to critical third-party software which is integrated into our ClearPoint system software, our costs could increase and sales of our ClearPoint system could be delayed, potentially hurting our competitive position.***

We license software from a third party that is integrated into the software component of our ClearPoint system. Our license continues through July 2015. If we are unable to continue to license this third-party software, we would not be able to continue to commercialize our ClearPoint system until equivalent software could be identified, licensed or developed, and integrated into the software component of our ClearPoint system. These delays, if they occur, could harm our business, operating results and financial condition.

***We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets or other proprietary information of their former employers.***

Many of our employees were previously employed at universities or other medical device companies, including competitors or potential competitors. In the future, we could be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending against such claims, a court could order us to pay substantial damages and prohibit us from using technologies or features that are essential to our products and processes, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. In addition, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, such litigation could result in substantial costs and be a distraction to our employees and management.

***If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, our ability to commercialize our products will be harmed, and we may not be able to operate our business profitably.***

Our success and ability to compete is dependent, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright, trademark and trade secret law and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties to protect our intellectual property. There can be no assurance that we will be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights. Litigation to enforce our intellectual property rights in patents, copyrights or trademarks is highly unpredictable, expensive and time consuming and would divert human and monetary resources away from managing our business, all of which could have a material adverse effect on our financial condition and results of operations even if we were to prevail in such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, or that they are invalid or unenforceable, and could award attorney fees.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technologies or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technologies or other information that we regard as proprietary. Additionally, third parties may be able to design around our patents. Furthermore, the laws of foreign countries may not protect

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our proprietary rights to the same extent as the laws of the United States. Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technologies, which could substantially impair our ability to compete.

We have entered into confidentiality and intellectual property assignment agreements with our employees and consultants as one of the ways we seek to protect our intellectual property and other proprietary technologies. However, these agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

Our employees, consultants and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our proprietary know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect know-how than courts in the United States. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain intellectual property protection could adversely affect our competitive business position.

*We may be dependent upon one of our licenses from The Johns Hopkins University to develop and commercialize some components of the ClearTrace system.*

We have entered into exclusive license agreements with The Johns Hopkins University, or Johns Hopkins, with respect to a number of technologies owned by Johns Hopkins. Under one of those agreements, which we entered into in 1998, we licensed a number of technologies relating to devices, systems and methods for performing MRI-guided interventions, particularly MRI-guided cardiac ablation procedures. Therefore, that license is important to the development of the ClearTrace system. Without that license, we may not be able to commercialize some of the components of the ClearTrace system when, and if, developed, subject to FDA clearance or approval. Johns Hopkins has the right to terminate the license under specified circumstances, including a breach by us and failure to cure such breach or in the event we file for bankruptcy. We are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed patents and patent applications. This obligation could require us to take actions related to the development of the ClearTrace system that we would otherwise not take.

### **Risks Related to Regulatory Compliance**

*We operate in a highly-regulated industry and any failure to comply with the extensive government regulations may subject us to fines, injunctions and other penalties that could harm our business.*

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. Government regulations and foreign requirements specific to medical devices are wide ranging and govern, among other things:

- design, development and manufacturing;
- testing, labeling and storage;
- product safety;
- marketing, sales and distribution;
- premarket clearance or approval;
- recordkeeping procedures;
- advertising and promotions;
- recalls and field corrective actions;

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- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; and
- product export.

If we receive regulatory clearance or approval to sell our product candidates, we will be subject to ongoing FDA requirements, including: required submissions of safety and other post-market information; manufacturing facility registration and device listing requirements; compliance with FDA's medical device current Good Manufacturing Practice regulations, as codified in the Quality System Regulation, or QSR; requirements regarding field corrections and removals of our products; reporting of adverse events and certain product malfunctions to the FDA; and numerous recordkeeping requirements. If we or any of our collaborators or suppliers fail to comply with applicable regulatory requirements, a regulatory agency may take action against us, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or orders for the repair, replacement or refund of products;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearances or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted; or
- refusal to grant export approval for our products.

The FDA's and foreign regulatory agencies' statutes, regulations or policies may change, and additional government regulation or statutes may be enacted, which could increase post-approval regulatory requirements, or delay, suspend or prevent marketing of any approved products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

***If we or our third-party suppliers fail to comply with the FDA's QSR or any applicable state equivalent, our manufacturing operations could be interrupted and our potential product sales and operating results could suffer.***

We and some of our third-party suppliers are required to comply with the FDA's QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. We and our suppliers will also be subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market our products in these jurisdictions. The FDA enforces the QSR through periodic and unannounced inspections of manufacturing facilities. Our facilities have not been inspected by the FDA for QSR compliance. We anticipate that we and certain of our third-party suppliers will be subject to future inspections. The failure by us or one of our third-party suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations, could result in enforcement actions against us, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. If we fail to comply with the FDA's QSR or any applicable state equivalent, we would be required to incur the costs and take the actions necessary to bring our operations into compliance, which may have a negative impact on our future sales and our ability to generate a profit.

***Our products may in the future be subject to product recalls that could harm our reputation, business operations and financial results.***

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In

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the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. We may initiate certain voluntary recalls involving our products in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If we determine that certain of those recalls do not require notification to the FDA, the FDA may disagree with our determinations and require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement actions against us, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. Regulatory investigations or product recalls could also result in our incurring substantial costs, losing revenues and implementing a change in the design, manufacturing process or the indications for which our products may be used, each of which would harm our business.

***If our marketed products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.***

Under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In the future, we may experience events that may require reporting to the FDA pursuant to the medical device reporting regulations. In addition, all manufacturers placing medical devices in European Union markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. In addition, failure to report such adverse events to appropriate government authorities on a timely basis, or at all, could result in an enforcement action against us.

***We may incur significant liability if it is determined that we are promoting off-label uses of our products in violation of federal and state regulations in the United States or elsewhere.***

We are initially seeking clearance of our ClearPoint system from the FDA for a general neurological intervention claim. We believe that seeking 510(k) clearance for this general indication is the least burdensome path to initial regulatory clearance. The general indication we are seeking is the same indication for use that applies to other devices that have traditionally been used in the performance of stereotactic neurological procedures, under which a physician merges pre-operative images and data with specialized surgical instruments to help guide the procedure. Our business and future growth, however, may depend substantially on the use or enhancement of our ClearPoint system in deep brain stimulation lead placement procedures. Once 510(k) clearance is obtained, we may seek regulatory clearance or approval, as the case may be, for use of our ClearPoint system for a variety of specific neurological indications, including deep brain stimulation lead placement, to allow us to market and promote our ClearPoint system for those specific uses. Unless and until we receive regulatory clearance or approval for use of our ClearPoint system in these specific procedures, uses in procedures other than general neurological intervention procedures, such as biopsies and catheter and electrode insertion, may be considered off-label uses of our ClearPoint system.

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Under the federal Food, Drug, and Cosmetic Act and other similar laws, we are prohibited from labeling or promoting our products, or training physicians, for such off-label uses. The FDA defines labeling to include not only the physical label attached to the product, but also items accompanying the product. This definition also includes items as diverse as materials that appear on a company's website. As a result, we are not permitted to promote uses of our products that are not cleared or approved, whether on our website, in product brochures or in customer communications. This prohibition means that the FDA could deem it unlawful for us to make claims about the use of our ClearPoint system in deep brain stimulation lead placement procedures or proactively discuss or provide information or training on the use of our ClearPoint system for deep brain stimulation lead placement procedures, with very limited exceptions. However, although manufacturers are not permitted to promote for off-label uses, in their practice of medicine, physicians may lawfully choose to use medical devices for off-label uses. Therefore, if the FDA grants 510(k) clearance for our ClearPoint system for use in general neurological interventions, a physician could use our ClearPoint system for uses not covered by the cleared labeling. This would constitute an off-label use. We expect that physicians will use our ClearPoint system for a variety of specific neurological procedures, including deep brain stimulation lead placement.

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance or approval has not been obtained. If the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and market adoption of the products would be impaired. Due to these legal constraints, our sales and marketing efforts will focus only on the general technical attributes and benefits of our ClearPoint system and the FDA cleared indications for use. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

***We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.***

Although we do not provide healthcare services nor receive payments directly from Medicare, Medicaid or other third-party payors for our products or the procedures in which our products may be used, many state and federal healthcare laws and regulations governing financial relationships between medical device companies and healthcare providers apply to our business and we could be subject to enforcement by both the federal government, private whistleblowers and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- The federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or providing any kickback, bribe, or other remuneration, directly or indirectly, in exchange for or to induce the purchase, lease or order, or arranging for or recommending of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs.
- Federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid, or other federally-funded healthcare programs that are false or fraudulent, or are for items or services not provided as claimed, and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices. Changes to the Federal false claims law enacted as part of the Health Care Reform Law will likely increase the number of whistleblower cases brought against providers and suppliers of health care items and services.

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- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, in addition to the privacy and security rules normally associated with it, which are discussed below, established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services.
- State and foreign law equivalents and analogues of each of the above federal laws, such as anti-kickback and false claims laws and the Foreign Corrupt Practices Act, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, or when physicians are employees of a foreign government entity.
- The Health Care Reform Law, which imposes certain reporting obligations on manufacturers of drugs, devices and biologicals. On March 31, 2013, and on the 90th day of each calendar year thereafter, these manufacturers must report all payments or other transfers of value to or on behalf of a physician or teaching hospital by such manufacturers as well as any ownership or investment interest held by physicians in such manufacturers. The Health Care Reform Law also grants the Office of Inspector General additional authority to obtain information from any individual or entity to validate claims for payment or to evaluate the economy, efficiency or effectiveness of the Medicare and Medicaid programs, expands the permissible exclusion authority to include any false statements or misrepresentations of material facts, enhances the civil monetary penalties for false statements or misrepresentation of material facts, and enhances the Federal Sentencing Guidelines for those convicted of Federal healthcare offenses.

Recently, the medical device industry has been under heightened scrutiny as the subject of government investigations and government enforcement or private whistleblower actions under the Anti-Kickback Statute and the False Claims Act involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including specifically arrangements with physician consultants. For example, four of the five major orthopedic implant manufacturers were required to pay a total of \$311 million and operate for 18 months under federal court supervision in settlement of kickback allegations concerning their physician consulting contracts. We have or expect that we will have arrangements with physicians which may be subject to scrutiny, particularly in light of the new reporting obligations, including consulting contracts for product development and agreements for teaching and training on the safe and effective use of our products. In addition, we may provide customers with information on products that could be deemed to influence their coding or billing practices, and may have sales, marketing or other arrangements with hospitals and other providers that could also be the subject of scrutiny under these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If the surgeons or other providers or entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

***We may be subject to privacy and data protection laws governing the transmission, security and privacy of health information which may impose restrictions on technologies and subject us to penalties if we are unable to fully comply with such laws.***

Numerous federal, state and international laws and regulations govern the collection, use, disclosure, storage and transmission of patient-identifiable health information. These laws include:

- HIPAA and its implementing regulations, the HIPAA Privacy and Security Rules, apply to covered entities, which include most healthcare facilities that purchase and use our products. The HIPAA



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Privacy and Security Rules set forth minimum standards for safeguarding individually identifiable health information, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information and provides certain rights to individuals with respect to that information. HIPAA also requires covered entities to contractually bind third parties, known as business associates, in the event that they perform an activity or service for or on behalf of the covered entity that involves access to patient identifiable health information, including imposing liability on business associates of HIPAA “covered entities”.

- The federal Health Information Technology for Economic and Clinical Health Act, or HITECH, which was enacted in February 2009, strengthens and expands the HIPAA Privacy and Security Rules and its restrictions on use and disclosure of patient identifiable health information.
- Other federal and state laws restricting the use and protecting the privacy and security of patient information may apply, many of which are not preempted by HIPAA.
- Federal and state consumer protection laws are being applied increasingly by the United States Federal Trade Commission, or FTC, and state attorney’s general to regulate the collection, use, storage and disclosure of personal or patient information, through websites or otherwise, and to regulate the presentation of website content.
- Other countries also have, or are developing, laws governing the collection, use and transmission of personal or patient information.
- Federal and state laws regulating the conduct of research with human subjects.

We are required to comply with federal and state laws governing the transmission, security and privacy of patient identifiable health information that we may obtain or have access to in connection with manufacture and sale of our products. We do not believe that we are a HIPAA covered entity because we do not submit electronic claims to third-party payors, but there may be limited circumstances in which we may operate as a business associate to covered entities if we receive patient identifiable data through activities such as training providers on the use of our products or investigating product performance or if our products store patient identifiable health information on behalf of a healthcare provider. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements that will be imposed on us contractually through business associate agreements by covered entities and directly under HITECH provisions that became effective in February 2010. Due to the recent enactment of HITECH, we are not able to predict what the extent of the impact on our business may be. Our failure to comply may result in criminal and civil liability because the potential for enforcement action against business associates is now greater. Enforcement actions can be costly and interrupt regular operations which may adversely affect our business.

In addition, numerous other federal and state laws protect the confidentiality of patient information as well as employee personal information, including state medical privacy laws, state social security number protection laws and federal and state consumer protection laws. These various laws in many cases are not preempted by the HIPAA rules and may be subject to varying interpretations by the courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity and liability.

In connection with any clinical trials we conduct, we will be subject to state and federal privacy and human subject protection regulations. The HIPAA requirement and other human subjects research laws could create liability for us or increase our cost of doing business because we must depend on our research collaborators to comply with the applicable laws. We may adopt policies and procedures that facilitate our collaborators’ compliance, but we cannot ensure that non-employee collaborators or investigators will comply with applicable laws. As a result, unauthorized uses and disclosures of research subject information in violation of the law may occur. These violations may lead to sanctions that will adversely affect our business.

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### **Risks Related to Facilities, Employees and Growth**

*We are dependent on our senior management team, engineering team, sales and marketing team and key research and physician advisors, and the loss of any of them could harm our business.*

We are highly dependent on members of our senior management, in particular Kimble L. Jenkins, our President, Chief Executive Officer and Chairman of the Board of Directors, and Peter G. Piferi, our Chief Operating Officer. We do not have employment agreements with either Mr. Jenkins or Mr. Piferi and, therefore, there are no assurances that the services of these individuals will be available to us for any specified period of time. The loss of members of our senior management team, engineering team, sales and marketing team and key research and physician advisors, or our inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on our business, financial condition and results of operations. We do not maintain, and do not currently intend to obtain, key employee life insurance on any of our personnel other than for Mr. Jenkins and Mr. Piferi. Although we have obtained key employee insurance covering Mr. Jenkins and Mr. Piferi in the amount of \$2,000,000, this would not fully compensate us for the loss of Mr. Jenkins' or Mr. Piferi's services.

*We need to hire and retain additional qualified personnel to grow and manage our business. If we are unable to attract and retain qualified personnel, our business and growth could be seriously harmed.*

Our performance depends on the talents and efforts of our employees. Our future success will depend on our ability to attract, retain and motivate highly skilled personnel in all areas of our organization. We plan to continue to grow our business and will need to hire additional personnel to support this growth. We believe that there are only a limited number of individuals with the requisite skills to serve in many of our key positions, and we compete for key personnel with other medical device companies, as well as universities and research institutions. It is often difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or fill new positions requiring key persons with appropriate experience. If we experience difficulties locating and hiring suitable personnel in the future, our growth may be hindered. Qualified individuals are in high demand, particularly in the medical device industry, and we may incur significant costs to attract and retain them. Employees that hold shares of our common stock or options to purchase our common stock may be more likely to leave us following our initial public offering as a result of the establishment of a public market for our common stock. If we are unable to attract and retain the personnel we need to succeed, our business and growth could be harmed.

*If we do not effectively manage our growth, we may be unable to successfully develop, market and sell our products.*

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. In order to achieve our business objectives, we must continue to grow. However, continued growth presents numerous challenges, including:

- implementing appropriate operational and financial systems and controls;
- expanding our assembly capacity and increasing production through third parties;
- expanding our sales and marketing infrastructure and capabilities;
- improving our information systems;
- identifying, attracting and retaining qualified personnel in our areas of activity; and
- hiring, training, managing and supervising our personnel.

We cannot be certain that our systems, controls, infrastructure and personnel will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop, market and sell our products and our business will be harmed.

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***Our operations are vulnerable to interruption or loss due to natural disasters, power loss and other events beyond our control, which would adversely affect our business.***

We will conduct a significant portion of our activities, including component processing, final assembly, packaging and distribution activities for our ClearPoint system, at a facility located in Irvine, California, which is a seismically active area that has experienced major earthquakes in the past, as well as other natural disasters, including wildfires. We have taken precautions to safeguard our facility, including obtaining business interruption insurance. However, any future natural disaster, such as an earthquake or a wildfire, could significantly disrupt our operations, and delay or prevent product assembly and shipment during the time required to repair, rebuild or replace our facility, which could be lengthy and result in significant expenses. Furthermore, the insurance coverage we maintain may not be adequate to cover our losses in any particular case or continue to be available at commercially reasonable rates and terms. In addition, our facility may be subject to shortages of electrical power, natural gas, water and other energy supplies. Any future shortage or conservation measure could disrupt our operations and cause expense, thus adversely affecting our business and financial results.

### **Risks Related to this Offering**

***An active trading market for our common stock may not develop.***

Prior to this offering, there has been no public market for our common stock. We intend to apply for listing on the Nasdaq Capital Market; however, we may not become listed and an active trading market for our shares may never develop or be sustained following this offering. Accordingly, you may not be able to sell your shares quickly or at the market price if trading in our stock is not active.

***Market volatility may cause our stock price and the value of your investment to decline.***

The initial public offering price for our common stock was determined through negotiations between the underwriters and us. The initial public offering price may vary from the market price of our common stock after the closing of this offering. Investors may not be able to sell their common stock at or above the initial public offering price.

We expect that the price of our common stock will fluctuate substantially, as the market price for the common stock after this offering will be affected by a number of factors, including:

- the receipt, denial or timing of regulatory clearances or approvals of our products or competing products;
- changes in policies affecting third-party coverage and reimbursement in the United States and other countries;
- ability of our products, if they receive regulatory clearance or approval, to achieve market success;
- the performance of third-party contract manufacturers and component suppliers;
- our ability to enhance our sales and marketing capabilities;
- our ability to manufacture our products to commercial standards;
- the success of any collaborations we have or may undertake with other companies;
- our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;
- actual or anticipated variations in our results of operations or those of our competitors;
- announcements of new products, technological innovations or product advancements by us or our competitors;

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- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- trading volume of our common stock;
- changes in earnings estimates or recommendations by securities analysts, failure to obtain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;
- developments in our industry; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

In addition, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. We expect our stock price to be similarly volatile. These broad market fluctuations may continue and could harm our stock price. Following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Class action securities litigation, if instituted against us, could result in substantial costs and a diversion of our management resources, which could significantly harm our business.

***Securities analysts may not initiate coverage for our common stock or may issue negative reports, and this may have a negative impact on the market price of our common stock.***

Securities analysts may elect not to provide research coverage of our common stock after the completion of this offering. The lack of research coverage may adversely affect the market price of our common stock. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us or our business. It may be difficult for companies such as ours, with smaller market capitalizations, to attract securities analysts that will cover our common stock. If one or more of the analysts who elects to cover us downgrades our stock, our stock price would likely decline rapidly. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. This could have a negative effect on the market price of our stock.

***Our directors, executive officers and principal stockholders and their respective affiliates will continue to have substantial control over us after this offering and could delay or prevent a change in corporate control.***

After this offering, our directors, executive officers and holders of more than 5% of our common stock, together with their affiliates, will beneficially own, in the aggregate, approximately % of our outstanding common stock. As a result, these stockholders, acting together, will continue to have substantial control over the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, will continue to have significant influence over the management and affairs of our company. Accordingly, this concentration of ownership may have the effect of:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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***We have not paid dividends in the past and do not expect to pay dividends in the future.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our Board of Directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payments of dividends present in any of our future debt agreements, and other factors our Board of Directors may deem relevant. If we do not pay dividends, a return on your investment will only occur if our stock price appreciates.

***Anti-takeover provisions in our certificate of incorporation, bylaws and Delaware law could prevent or delay a change in control of our company.***

Provisions in our certificate of incorporation and bylaws, which will be effective upon the closing of this initial public offering, as well as provisions of Delaware law, may discourage, delay or prevent a merger, acquisition or change of control. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions:

- provide for a staggered Board of Directors;
- permit our Board of Directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the Board of Directors, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that stockholders will be permitted to amend our amended and restated bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any broad range of business combinations with any stockholder who owns, or at any time in the last three years owned, 15% or more of our outstanding voting stock for a period of three years following the date on which the stockholder became an interested stockholder. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

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***Sales of a substantial number of shares of our common stock in the public market after this offering, or the perception that they may occur, may depress the market price of our common stock.***

Sales of substantial amounts of our common stock in the public market following this offering, or the perception that substantial sales may be made, could cause the market price of our common stock to decline. The lock-up agreements to be delivered by our executive officers, directors and certain of our stockholders provide that the underwriters, in their sole discretion, may release those parties, at any time, or from time to time, and without notice, from their obligation not to dispose of shares of common stock for a period of 180 days after the date of this prospectus, which period may be extended in certain limited circumstances. The underwriters do not have any pre-established conditions to waiving the terms of the lock-up agreements, and any decision by them to waive those conditions would depend on a number of factors, which may include market conditions, the performance of the common stock in the market and our financial condition at that time.

Based on the number of shares of common stock outstanding as of March 31, 2010, upon completion of this offering, \_\_\_\_\_ shares of our common stock will be outstanding. All of the shares sold in this offering will be freely transferable unless held by an affiliate of ours. Of the remaining shares, during the 90 days following the date of this prospectus, \_\_\_\_\_ shares held by non-affiliates, or approximately \_\_\_\_\_ % of our common stock outstanding after this offering, will be freely transferable subject to compliance with Rule 144. Beginning on the 91st day following the date of this prospectus, \_\_\_\_\_ shares of our common stock, or approximately \_\_\_\_\_ % of our common stock outstanding after this offering, will be freely transferable subject to compliance with Rule 144 under the Securities Act. The lockup agreements between the underwriters and our directors, executive officers and certain of our stockholders will expire 180 days after the date of this prospectus, at which time all of our shares of our common stock will be freely transferable subject to compliance with the provisions of Rule 144 under the Securities Act. See “Shares Eligible for Future Sale—Lock-up Agreements.” Our affiliates must comply with the volume, manner of sale, holding period and other limitations of Rule 144. As restrictions on resale end, the market price could drop significantly if the holders of these restricted shares sell them or are perceived by the market as intending to sell them. Any substantial sale of common stock pursuant to any resale registration statements or Rule 144 may have an adverse effect on the market price of our common stock by creating an excessive supply.

We intend to file a registration statement on Form S-8 to register the \_\_\_\_\_ shares subject to outstanding options or reserved for issuance under our stock option plans. The registration statement will become effective when filed, and, subject to applicable lock-up agreements, if any, these shares may be resold without restriction in the public marketplace. For a more detailed description, please see the section of this prospectus entitled “Shares Eligible for Future Sale.”

***New investors in our common stock will experience immediate and substantial dilution after this offering.***

If you purchase shares of our common stock in this offering, you will experience immediate dilution of \$ per share based on the mid-point of the range on the cover page of this prospectus because the price that you pay will be substantially greater than the adjusted pro forma net tangible book value per share of common stock that you acquire. This dilution is due in large part to the fact that many of our earlier investors paid substantially less than the price of the shares being sold in this offering when they purchased their shares of our capital stock. If outstanding options and warrants to purchase our common stock are exercised, you will experience additional dilution. See the section entitled “Dilution” in this prospectus for a more detailed description of this dilution.

***We will incur significant increased costs as a result of operating as a public company, and our management will be required to divert attention from product development and commercialization and to devote substantial resources and time to new compliance initiatives.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We are working with our independent legal and accounting advisors to identify those areas in

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which changes should be made to our financial and management control systems to manage our growth and our obligations as a public company. These areas include corporate control, disclosure controls and procedures and financial reporting and accounting systems, including requirements under the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act. We will incur costs associated with our public company reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the securities exchange on which our stock trades. We will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, for the fiscal year ending December 31, 2010, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial expense and expend significant management time on compliance-related issues.

***We have discretion in the use of the net proceeds from this offering, and we may not use these proceeds effectively.***

The net proceeds from this offering will be used for continuation of research and development activities, for sales and marketing activities and for working capital and other general corporate purposes. Our management will have discretion in the application of the net proceeds from this offering within these categories and could spend the proceeds in ways that do not necessarily improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses, cause the price of our common stock to decline or delay product development.

### **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Use of Proceeds,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the anticipated progress of our research, development and clinical trials;
- the ability to obtain regulatory clearance or approval for product candidates;
- the ability to market, commercialize and achieve market acceptance for current product candidates or any future product candidates or products;
- the ability to generate additional product candidates;
- the ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- the estimates regarding the sufficiency of our cash resources.

In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these words. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

You should refer to the section of this prospectus entitled “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake to update any of the forward-looking statements after the date of this prospectus, except to the extent required by applicable securities laws.



### USE OF PROCEEDS

We estimate that our net proceeds from the sale of \_\_\_\_\_ shares of common stock in this offering will be approximately \$ \_\_\_\_\_ and an additional \$ \_\_\_\_\_ if the underwriters exercise their over-allotment option in full, based upon an assumed initial public offering price of \$ \_\_\_\_\_ per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The principal purposes of this offering are to obtain additional capital and to create a public market for our common stock.

We expect to use approximately \$ \_\_\_\_\_ of the net proceeds from this offering to fund our research and development activities, approximately \$ \_\_\_\_\_ to fund our sales and marketing activities and approximately \$ \_\_\_\_\_ for working capital and general corporate purposes. In addition, we may use a portion of the net proceeds from this offering to acquire equipment, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions. We believe that the net proceeds from this offering, our existing cash resources and interest on these funds will be sufficient to meet our projected operating requirements through the end of 2011.

Pending these uses, we plan to invest the net proceeds in a variety of capital preservation instruments, including short-term, interest bearing obligations, investment grade instruments, certificates of deposit or direct or guaranteed obligations of the United States. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that such funds are readily available to fund our research and development operations.

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### **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors.

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**CAPITALIZATION**

The following table sets forth our capitalization as of December 31, 2009:

- on an actual basis;
- on a pro forma basis to reflect a 1-for- reverse stock split and the conversion into common stock of all outstanding shares of our preferred stock and the bridge notes; and
- on a pro forma as adjusted basis to reflect the pro forma adjustments reflected above and the sale in this offering of shares of common stock at an assumed initial offering price of \$ per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The information in the following table is based on shares outstanding as of December 31, 2009 and excludes:

- 2,412,500 shares of common stock issuable upon exercise of options issued under our stock option plans, at a weighted average exercise price of \$0.92 per share;
- 266,608 shares of common stock issuable upon exercise of options not issued under our stock option plans, at an exercise price of \$2.41 per share;
- 1,642,167 shares of common stock issuable upon exercise of warrants, at a weighted average exercise price of \$0.75 per share;
- 1,776,986 shares of common stock issuable upon the conversion of \$3,553,973 in principal amount of, and interest on, convertible promissory notes, at a conversion price of \$2.00 per share;
- shares of our common stock that may be issued to the underwriters upon exercise of warrants, at an exercise price of \$ per share;
- 101,775 shares of common stock that may be issued pursuant to the placement agent warrant, at an exercise price of \$ per share; and
- 5,000,000 shares of common stock reserved for future issuance under our 2010 Incentive Compensation Plan, which we plan to adopt before the completion of this offering.

You should read the information below in conjunction with the financial statements and the related notes thereto and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus.

	As of December 31, 2009		
	Actual	Pro Forma	Pro Forma As Adjusted
Related party convertible note payable, net of \$1,129,000 unamortized discount	\$ 2,371,000		
Series A convertible preferred stock, \$0.01 par value: 8,000,000 shares authorized and 7,965,000 shares issued and outstanding, actual; and no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	7,965,000	—	
Common stock, \$0.01 par value: 70,000,000 shares authorized and 21,820,440 shares issued and 20,517,120 shares outstanding, actual; 70,000,000 shares authorized and shares issued and outstanding, pro forma; and shares authorized and shares issued and outstanding, pro forma as adjusted	218,205		
Additional paid-in capital	25,631,208		
Treasury stock	(1,679,234)		
Accumulated deficit	(42,022,964)		
Total stockholders’ equity (deficit)	(9,887,785)		
Total capitalization	\$ (7,516,785)	\$	

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**DILUTION**

The historical net tangible book value of our common stock as of December 31, 2009 was approximately \$(10,317,000), or \$(0.50) per share, based on the number of shares of common stock outstanding as of December 31, 2009. Historical net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the actual number of outstanding shares of our common stock. The pro forma net tangible book value of our common stock as of December 31, 2009 was \$ , or \$ per share. Pro forma net tangible book value per share is determined by dividing (x) our total tangible assets less total liabilities by (y) the actual number of outstanding shares of our common stock plus the number of shares issuable upon conversion of all of our outstanding shares of preferred stock and bridge notes into common stock as if such conversion had occurred on December 31, 2009 after giving effect to a 1-for- reverse stock split as if it had occurred on December 31, 2009.

After giving effect to the sale of common stock offered in this offering at the assumed public offering price of \$ per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2009 would have been approximately \$ , or \$ per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to existing stockholders and an immediate dilution of \$ per share to new investors purchasing our common stock in this offering. The following table illustrates this per share dilution to the new investors:

Historical net tangible book value per share as of December 31, 2009	\$ (0.50)
Assumed initial public offering price	
Pro forma net tangible book value per share as of December 31, 2009	
Increase in pro forma net tangible book value per share attributable to this offering	
Pro forma as adjusted net tangible book value per share after offering	
Dilution per share to new investors in this offering	\$

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2009, the differences between the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders and by the investors participating in this offering, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, at an assumed initial public offering price of \$ per share:

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders		%	\$	%	\$
New investors					
Total		100.0%	\$	100.0%	\$

The number of shares of common stock outstanding in the table above is based on the pro forma number of shares outstanding as of December 31, 2009 and assumes no exercise of the underwriters' over-allotment option. If the underwriters' over-allotment option is exercised in full, the number of shares of common stock held by existing stockholders will be reduced to % of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be increased to shares or % of the total number of shares of common stock to be outstanding after this offering.

The above discussion and tables also assume no exercise of any outstanding stock options or warrants. As of December 31, 2009, there were:

- 2,412,500 shares of common stock issuable upon exercise of options issued under our stock option plans, at a weighted average exercise price of \$0.92 per share;

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- 266,608 shares of common stock issuable upon exercise of options not issued under our stock option plans, at an exercise price of \$2.41 per share;
- 1,642,167 shares of common stock issuable upon exercise of warrants, at a weighted average exercise price of \$0.75 per share;
- 1,776,986 shares of common stock issuable upon the conversion of \$3,553,973 in principal amount of, and interest on, convertible promissory notes, at a conversion price of \$2.00 per share;
- 101,755 shares of common stock that may be issued pursuant to the placement agent warrant, at an exercise price of \$            per share; and
- shares of our common stock that may be issued to the underwriters upon exercise of warrants, at an exercise price of \$            per share.

The following table summarizes, on a pro forma basis as of December 31, 2009, after giving effect to the exercise of all stock options and warrants outstanding as of December 31, 2009, the differences between the number of shares of common stock purchased from us, the total consideration and the weighted average price per share paid by existing stockholders and by investors participating in this offering at an assumed initial public offering price of \$            per share, before deducting underwriting discounts and commissions and estimated offering expenses:

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Average Price</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	<u>Per Share</u>
Existing stockholders		%	\$	%	\$
New investors					
<b>Total</b>		<u>100.0%</u>	<u>\$</u>	<u>100.0%</u>	<u>\$</u>

Effective upon the closing of this offering, an aggregate of 5,000,000 shares of our common stock will be reserved for future issuance under our benefit plans. To the extent that any of the outstanding options or warrants are exercised, new options are issued under our benefit plans and those options are exercised or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

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**SELECTED FINANCIAL DATA**

We have derived the following consolidated statement of operations data for the years ended December 31, 2009, 2008 and 2007 and consolidated balance sheet data as of December 31, 2009 and 2008 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the following consolidated statement of operations data for the year ended December 31, 2006 and consolidated balance sheet data as of December 31, 2007 and 2006 from our audited consolidated financial statements not included in this prospectus. We have derived the following consolidated statement of operations data for the year ended December 31, 2005 and the consolidated balance sheet data as of December 31, 2005 from our unaudited consolidated financial statements not included in this prospectus. You should read the consolidated financial data set forth below in conjunction with our consolidated financial statements and related notes and the information under “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results are not necessarily indicative of our results to be expected in any future period.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
<b>Statement of Operations Data:</b>					
Related party license revenue	\$ 2,600,000	\$ 1,950,000	\$ —	\$ —	\$ —
Operating costs and expenses:					
Research and development costs	6,067,617	4,258,492	2,098,672	620,297	288,784
General and administrative expenses	3,595,917	2,920,311	1,413,369	525,323	934,395
Gain on settlement of accounts payable	—	—	—	(483,917)	—
Total operating expenses	<u>9,663,534</u>	<u>7,178,803</u>	<u>3,512,041</u>	<u>661,703</u>	<u>1,223,179</u>
Other income (expense):					
Interest expense, net	(46,276)	(200,982)	(185,096)	(132,847)	(29,659)
Gain on debt extinguishment	—	—	—	—	301,309
Total other income	<u>(46,276)</u>	<u>(200,982)</u>	<u>(185,096)</u>	<u>(132,847)</u>	<u>271,650</u>
Net loss	<u>\$ (7,159,060)</u>	<u>\$ (5,429,785)</u>	<u>\$ (3,697,137)</u>	<u>\$ (794,550)</u>	<u>\$ (951,529)</u>
Net loss per share attributable to common stockholders:					
Basic and Diluted	<u>\$ (0.34)</u>	<u>\$ (0.26)</u>	<u>\$ (0.18)</u>	<u>\$ (0.04)</u>	<u>\$ (0.05)</u>
Weighted average shares outstanding:					
Basic	<u>21,346,533</u>	<u>20,980,324</u>	<u>20,098,058</u>	<u>19,566,981</u>	<u>19,458,938</u>

	As of December 31,				
	2009	2008	2007	2006	2005
<b>Balance Sheet Data (at period end):</b>					
Cash and cash equivalents	\$ 2,569,129	\$ 9,920,801	\$ 3,611,814	\$ 6,068,413	\$ 57,026
Total assets	4,673,688	10,955,360	3,730,092	6,109,753	130,393
Related party convertible notes payable, net of \$1,129,000 unamortized discount					
Convertible preferred stock	2,371,000	—	—	—	—
Common stock, \$0.01 par value	7,965,000	7,965,000	7,965,000	7,965,000	—
Additional paid-in capital	218,205	218,071	201,353	198,780	193,226
Treasury stock	25,631,208	25,490,092	23,888,910	23,023,823	23,365,568
Notes receivable, stockholder	(1,679,234)	—	—	—	—
Accumulated deficit	—	(573,620)	(551,961)	(530,361)	(508,761)
Total stockholders’ equity (deficit)	<u>(42,022,964)</u>	<u>(34,863,904)</u>	<u>(29,434,119)</u>	<u>(25,736,982)</u>	<u>(24,942,432)</u>

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes included elsewhere in this prospectus. This discussion and analysis contains forward-looking statements that are based upon current expectations and involve risks, assumptions and uncertainties. You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis.*

**Overview**

We are a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain and heart using direct, intra-procedural MRI guidance while performing minimally invasive surgical procedures. None of our current product candidates is cleared or approved for sale. As compared to the manner in which the existing procedures are performed, we believe that our product candidates will deliver better patient outcomes in shorter procedure times, enhance revenue potential for both physicians and hospitals, and reduce costs to the healthcare system. Our first product candidate is our ClearPoint system, which is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. Our second product candidate is the ClearTrace system, which is designed to allow catheter-based minimally invasive procedures in the heart to be performed in an MRI suite. Finally, under our SafeLead Development Program we are working with Boston Scientific to incorporate our MRI-safety technologies into Boston Scientific's implantable leads for cardiac and neurological applications.

We have not generated revenues from the sale of our ClearPoint system or the ClearTrace system. In 2008, we received licensing fees totaling \$13,000,000 from Boston Scientific for our MRI-safety technologies, which we used to finance our operations and internal growth. We have also financed our operations and internal growth through private placements of securities, borrowings, and interest earned on the net proceeds from our private placements and the Boston Scientific licensing fees. Prior to 2008, we were a development stage enterprise. We have incurred significant losses since our inception in 1998 as we have devoted substantially all of our efforts to research and development. As of December 31, 2009, we had an accumulated deficit of approximately \$42,023,000. We expect to continue to incur significant operating losses as we develop and commercialize our product candidates, increase our sales and marketing activities, and expand our business generally. We also expect that our general and administrative expenses will increase due to additional operational and regulatory costs and burdens associated with operating as a public company.

**Factors Which May Influence Future Results of Operations**

The following is a description of factors which may influence our future results of operations, including significant trends and challenges that we believe are important to an understanding of our business and results of operations.

**Revenues**

Since inception, we have generated revenues primarily from our collaborative agreements with Boston Scientific, principally from recognition of portions of the \$13,000,000 of licensing fees, which we received in 2008. Revenue associated with these licensing fees is recognized on a straight-line basis over a five year period, which is our estimated period of continuing involvement in the development activities. Additional payments related to substantive, performance-based milestones and incentive payments which may be received under the agreement regarding implantable cardiac leads will be deferred upon receipt and achievement of the specified milestones and recognized over our estimated period of continuing involvement. These revenue recognition

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policies are more fully described in the “Critical Accounting Policies and Significant Judgments and Estimates” section below. We did not report any revenues in 2007, 2006 or 2005.

We can not sell any of our product candidates until we receive regulatory clearance or approval. Future revenues from sales of our products are difficult to predict and may not be sufficient to offset our continuing and increasing research and development expenses and selling, general and administrative expenses for the next several years.

The generation of recurring revenues through sales of our disposable components is an important part of our business model for our ClearPoint system. We anticipate that recurring revenues will constitute an increasing percentage of our total revenues as we leverage each new installation of our ClearPoint system to generate recurring sales of these disposable components. With respect to a single hospital, we do not anticipate that sales of the reusable components of our ClearPoint system will generate recurring revenues.

### ***Research and Development Expenses***

Our research and development expenses consist primarily of costs associated with the conceptualization, design, testing and prototyping of our product candidates. This includes the salaries, travel and benefits of research and development personnel; materials and laboratory supplies used by our research personnel; consultant costs; sponsored contract research and product development with third parties; and licensing costs. From our inception through December 31, 2009, we have incurred approximately \$21,711,000 in research and development expenses. We anticipate that research and development expenses will increase as we: (i) continue to develop enhancements to our ClearPoint system; (ii) continue our early-stage product development efforts for the ClearTrace system; (iii) commence clinical trials for the ablation catheter component of the ClearTrace system; and (iv) expand our research to apply our technologies to additional product applications.

Product development timelines, likelihood of success and total costs vary widely. Currently, we are focused primarily on advancing our ClearPoint system through the 510(k) clearance process. Our ClearPoint system’s initial application will be for general neurological interventions, such as biopsies and catheter and electrode insertion. If 510(k) clearance is obtained, we may seek additional regulatory clearance or approval for use of our ClearPoint system for more specific indications to allow us to market and promote our ClearPoint system for those specific uses. Such additional regulatory clearances or approvals may require us to perform clinical studies. At this time, due to the risks inherent in the product clearance and approval process and given the early stage of development of our product candidates other than our ClearPoint system, we are unable to estimate with any certainty the costs that we will incur in the continued development of our product candidates for commercialization.

### ***General and Administrative Expenses***

Our general and administrative expenses consist primarily of: salaries, travel and benefits for administrative personnel; share-based compensation; professional fees, including fees for attorneys and outside accountants; selling costs; occupancy costs; business insurance; and other general and administrative expenses, which include corporate licenses and taxes, postage, office supplies and meeting costs. Our general and administrative expenses are expected to increase due to the cost associated with the anticipated commercial launch of our ClearPoint system, increased headcount necessary to support our continued growth in operations, and the additional operational and regulatory burdens and costs associated with operating as a publicly traded company. In addition, we expect to incur additional costs associated with protecting our intellectual property rights as necessary to support our product offerings.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management’s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted



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in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements as well as the reported expenses during the reporting periods. The accounting estimates that require our most significant, difficult and subjective judgments include revenue recognition, valuation allowance for deferred tax assets and liabilities, impairment of long-lived assets and the determination of stock-based compensation. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in note 2 to our financial statements included elsewhere in this prospectus, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

*Revenue Recognition.* We evaluate revenue recognition on an agreement by agreement basis which, as of December 31, 2009, principally involved two license agreements with Boston Scientific. Both agreements provide various revenue streams for us, including an up-front licensing fee for one of the licenses, various milestone payments, payments for research and development and consulting services, and royalties.

We evaluate the various elements of these agreements based upon generally accepted accounting principles, or GAAP, for multiple element arrangements to determine whether the various elements represent separate units of accounting. This evaluation requires subjective determinations about the fair value of each element and whether delivered elements have stand alone value and, therefore, are separable from the undelivered contract elements for revenue recognition purposes. In addition, we evaluated repayment provisions associated with one of the license agreements which, under certain conditions, would require us to return payments received under the agreement. In both license agreements, we concluded that all of the contract elements should be treated as a single unit of accounting. As such, all amounts received were initially recorded as deferred revenue and thereafter recognized as revenue over our estimated period of performance on a straight-line basis. In the case of the license with possible repayment obligation provisions, revenue recognition will not occur until the repayment obligation period expires.

Note 2 to our financial statements, “—Revenue Recognition”, more fully describes the deliverables under these license agreements including our rights, obligations and cash flows.

*Valuation Allowance for Deferred Tax Assets and Liabilities.* Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that included the enactment date.

Valuation allowances are recorded for deferred tax assets when the recoverability of such assets is not deemed more likely than not.

We have evaluated the effect of the guidance provided by GAAP regarding accounting for uncertainty in income taxes that became effective in 2009. In that regard, we have evaluated all tax positions that could have a significant effect on the financial statements and determined we have no uncertain tax positions at December 31, 2009 that could have a significant effect on our financial statements. Our tax returns after 2005 remain open for examination.

*Impairment of long-lived assets.* We evaluate the recoverability of our long-lived assets (finite lived intangible assets and property and equipment) whenever adverse events or changes in business climate indicate that the expected undiscounted future cash flows from the related assets may be less than previously anticipated. If the net book value of the related assets exceeds the expected undiscounted future cash flows of the assets, the carrying amount will be reduced to the present value of their expected future cash flows and an impairment loss would be recognized.

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*Share-based compensation.* We account for compensation for all arrangements under which employees and others receive shares of stock or equity instruments (including options and warrants) in accordance with FASB ASC Topic 718 “*Compensation – Stock Compensation*”, or ASC Topic 718. Under ASC Topic 718, the fair value of each award is separately estimated and amortized into compensation expense over the service period. The fair value of our share-based awards is estimated on the grant date using the Black-Scholes valuation model. Our determination of the fair value of our share-based awards on the grant date using valuation models requires the input of highly subjective assumptions, including the expected price volatility and option life. As we have been operating as a private company, we are unable to use actual price volatility and option life data as input assumptions within our Black-Scholes valuation model. Prior to October 2009, we used the expected volatilities based on the historical volatility of the industry sector in which we operate, in accordance with the guidance set forth in ASC Topic 718.

Beginning October 2009, for the calculation of expected volatility, because we lack company-specific historical and implied volatility information, we based our estimate of expected volatility on the average of volatilities of publicly traded companies we deemed similar to us. We intend to consistently apply this process using this same methodology until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

To estimate the expected term, we chose to utilize the “simplified” method for “plain vanilla” options as discussed within the Securities and Exchange Commission’s Staff Accounting Bulletin 107, or SAB 107. We believe that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method are true for us and for our share-based payment arrangements. We intend to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior becomes available.

Our risk-free interest rates are based on a zero-coupon U.S. treasury instrument, the term of which is consistent with the expected term of the stock options. We have not paid and do not anticipate paying cash dividends on our shares of common stock; therefore, the expected dividend yield is assumed to be zero. The fair value of share-based payments are generally amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods.

We believe there is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation under ASC Topic 718. Currently, there is not a market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of stock option awards is determined in accordance with ASC Topic 718 using an option pricing model, that value may not be indicative of the fair value observed in a market transaction between a willing buyer and a willing seller. If factors change and we employ different assumptions in the application of ASC Topic 718 in future periods than those currently applied under ASC Topic 718, the compensation expense we record in future periods under ASC Topic 718 may differ significantly from what we have historically reported.

Total share-based compensation cost for the years ended December 31, 2009 and 2008 was approximately \$131,000 and \$118,000, respectively. On December 31, 2009, the total compensation cost related to non-vested awards not yet recognized was approximately \$397,000 with a weighted average expense recognition period of three years.

*Research and development costs.* Research and development costs consist of direct and indirect costs associated with the development of our technologies. These costs are expensed as incurred.

*Derivative Financial Instruments.* We account for derivative instruments in accordance with FASB ASC Topic 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period as a gain or loss in the statement of operations unless the derivative qualifies for hedge accounting. At December 31, 2009 and 2008, we did not have any derivative instruments that were designated as hedges.

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[Table of Contents](#)[Index to Financial Statements](#)**Results of Operations***Comparison of the Year Ended December 31, 2009 to the Year Ended December 31, 2008*

	December 31,		Percentage Change
	2009	2008	
<b>Revenues</b>	\$2,600,000	\$1,950,000	33%
<b>Research and development costs</b>	6,068,000	4,258,000	43
<b>General and administrative expenses</b>	3,596,000	2,920,000	23
<b>Interest expense, net</b>	\$ (46,000)	\$ (201,000)	(77)

*Revenues.* Revenues were approximately \$2,600,000 for the year ended December 31, 2009 compared to approximately \$1,950,000 for the year ended December 31, 2008, an increase of approximately 33%. Revenues for both periods relate solely to our licensing and development agreements with Boston Scientific. The increase in revenues resulted from the recognition of a full twelve months of licensing fee revenues during the year ended December 31, 2009 compared to the recognition of only nine months of licensing fee revenues for the year ended December 31, 2008.

*Research and development costs.* Research and development expense was approximately \$6,068,000 for the year ended December 31, 2009, compared to approximately \$4,258,000 for the year ended December 31, 2008, an increase of approximately 43%. This increase was due primarily to: (i) an increase of approximately \$1,177,000 related to the employment of additional research and development personnel; (ii) an increase of approximately \$746,000 related to the use of third-parties for research and development services; and (iii) an increase of approximately \$441,000 for materials and supplies necessary for product candidate testing and prototyping, depreciation and miscellaneous research and development expenses. The increase in research and development expenses was offset by decreases in engineering design costs and software development costs of approximately \$356,000 and \$301,000, respectively.

*General and administrative expenses.* General and administrative expense was approximately \$3,596,000 for the year ended December 31, 2009 compared to approximately \$2,920,000 for the year ended December 31, 2008, an increase of approximately 23%. The increase was due primarily to: (i) an increase of approximately \$527,000 in corporate and operations personnel costs; (ii) an increase of approximately \$263,000 in sales and marketing costs incurred in preparation of the anticipated commercial launch of our ClearPoint system; and (iii) an increase of approximately \$129,000 in occupancy costs. Increases in corporate and operating personnel costs were caused mostly by additional hires. The increase in occupancy costs was associated with a full year of lease expense for the year ended December 31, 2009 for both our Irvine, California and Memphis, Tennessee offices as compared to only occupying these offices a portion of the year during 2008. Increases in general and administrative expenses were partially offset by an approximate \$360,000 reduction in professional fees during the year ended December 31, 2009 related to the timing of patent filings.

*Interest expense, net.* Net interest expense was approximately \$46,000 for the year ended December 31, 2009 compared to net interest expense of approximately \$201,000 for the year ended December 31, 2008, a decrease of approximately 77%. Interest expense decreased for the year ended December 31, 2009 as compared to the year ended December 31, 2008 as a result of the amortization of a debt discount related to a convertible note converted in June 2008 of approximately \$395,000 as compared to amortization of debt discount of approximately \$98,000 since inception of the related party convertible note payable in October 2009 through December 31, 2009. Interest income in 2009 decreased from 2008 by approximately \$50,000 due to lower average cash balances.

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*Comparison of the Year Ended December 31, 2008 to the Year Ended December 31, 2007*

	December 31,		Percentage Change
	2008	2007	
<b>Revenues</b>	\$1,950,000	\$ —	—
<b>Research and development costs</b>	4,258,000	2,099,000	103%
<b>General and administrative expenses</b>	2,920,000	1,413,000	107
<b>Interest expense, net</b>	\$ (201,000)	\$ (185,000)	9

*Revenues.* Revenues for the year ended December 31, 2008 were approximately \$1,950,000, compared to zero for the year ended December 31, 2007. The increase in revenues resulted primarily from the recognition of revenues from the licensing fees received under one of our agreements with Boston Scientific.

*Research and development costs.* Research and development expense for the year ended December 31, 2008 was approximately \$4,258,000, compared to \$2,099,000 for the year ended December 31, 2007, an increase of approximately 103%. This increase was due primarily to: (i) an increase of approximately \$474,000 related to the employment of additional research and development personnel; (ii) an increase of approximately \$959,000 related to engineering, design and documentation, materials, third party contract research associated with the development of our ClearPoint system; (iii) an increase of approximately \$263,000 related to sponsored research programs; (iv) an increase of \$313,000 in payments related to the acquisition of licenses; and (v) an increase of approximately \$119,000 related to the use of consultants.

*General and administrative expenses.* General and administrative expense for the year ended December 31, 2008 was approximately \$2,920,000 compared to \$1,413,000 for the year ended December 31, 2007, an increase of 107%. This increase was due primarily to: (i) an increase of approximately \$540,000 in corporate personnel expense relating to the employment of additional administrative personnel; (ii) an increase of approximately \$110,000 in occupancy expense primarily related to rent expense and leasehold improvements at our facility in Irvine, California; (iii) an increase of approximately \$690,000 in professional fees, primarily legal fees, incurred for patent costs; (iv) an increase of approximately \$94,000 in travel related costs; and (v) an increase of approximately \$58,000 related to depreciation expense on property additions.

*Interest expense, net.* Net interest expense for the year ended December 31, 2008 was approximately \$201,000 compared to \$185,000 for the year ended December 31, 2007, an increase of approximately 9%. The difference in net interest expense is a result of the change in the amount of interest income we earned. Although our average cash balances in 2008 were higher than that of 2007, the decline in rate of interest that we earned on our cash balances decreased significantly as we focused on preservation and safeguarding of cash rather than maximizing interest income, resulting in approximately \$16,000 less in interest income in 2008 as compared to 2007. The interest expense for both 2007 and 2008 were the same amount, approximately \$395,000, representing the charge to interest expense for the amortization of the value of warrants granted in connection with a note to Boston Scientific. The value assigned to the warrants was recorded as a discount to the note at the time of issuance and was amortized over the period of time that the note was outstanding.

**Determination of Fair Market Value of Our Common Stock**

The exercise prices of options granted were set by our board of directors. Our board of directors sets the exercise prices of options based on its determination of the fair market value of our common stock at the time of the grants, which determination is made in accordance with federal tax rules, which require reasonable application of a reasonable valuation method.

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We performed valuations of our common stock contemporaneously with the granting of stock options. We believe that all of our stock options have been granted with exercise prices that are equal to or greater than the fair market value of our common stock on the date of grant. From January 1, 2009 through the date of this prospectus, we have granted the following compensatory stock options:

Grant date	Number of Options	Exercise Price	Fair Value of Common Stock <sup>(1)</sup>	Fair Value of Option Grant <sup>(2)</sup>	Intrinsic Value <sup>(3)</sup>
March 17, 2009	10,000	\$ 2.41	\$ 2.41	\$ 0.67	\$
August 20, 2009	37,000	2.41	2.41	0.67	
December 10, 2009	60,000	2.41	2.41	0.81	
December 22, 2009	266,608	2.41	2.41	0.69	

(1) All fair market valuations were determined by our board of directors in consultation with management at the date of each stock option grant.

(2) As determined using the Black-Scholes valuation model at the date of each stock option grant.

(3) Intrinsic value reflects the amount by which \$ (the midpoint of the offering range) exceeds the exercise price of the outstanding stock options.

At December 31, 2009, we had 2,679,108 compensatory stock options outstanding with an intrinsic value of \$ . Intrinsic value reflects the amount by which \$ (the midpoint of the offering range) exceeds the exercise price of the outstanding stock options.

### ***Significant factors, assumptions and methodologies used in determining fair value of our common stock on the grant dates of stock option awards made subsequent to January 1, 2009***

We granted compensatory stock options on four dates subsequent to January 1, 2009. In the absence of a public trading market for our common stock, we determined a reasonable estimate of the then current fair value of our common stock based upon multiple valuation criteria and contemporaneous analyses. Our board of directors exercised judgment in evaluating and assessing the fair value of our common stock on each grant date. Set forth below are significant factors considered, assumptions made and methodologies used in determining fair value on each grant date.

#### ***Valuation Methodologies for March 17, 2009 and August 20, 2009 Grants***

**General.** The fair values for the March 17, 2009 and August 20, 2009 grants each utilized, in part, two alternative valuation approaches. The first approach, referred to as the income approach, is a valuation technique that provides an estimation of the fair value of a business based upon the cash flows that it can be expected to generate over time. The second approach, referred to as the market approach, is a valuation technique that provides an estimation of fair value based on recent transactions that have occurred in our stock, our industry or in related industries.

**Income Approach.** The income approach we utilized begins with an estimation of the annual cash flows that a business is expected to generate over a discrete projection period. The estimated cash flows for each of the years in the period are then converted to their present value equivalent using a discount rate considered appropriate given the risk of achieving the projected cash flows. We selected a discount rate of 35%. In selecting the discount rate, we looked at what we believe are current rates of return expected by investors in various investments with different risk characteristics and we established the discount rate based on what we believed to be the most comparable rate of return range. The present value of the estimated cash flows are then added to the present value equivalent of the residual value of the business at the end of the projection period to arrive at an estimate of fair value. Such an approach necessarily relies on estimations of future cash flows that are inherently uncertain, as well as a

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determination of an appropriate discount rate in order to derive present value equivalents of both the projected cash flows and the residual value of the business at the end of the period. The use of different estimations of future cash flows or a different rate of return could result in a different indication of fair value.

*Market Approach.* The market approach utilized recent sales of our common stock in privately negotiated transactions between our stockholders.

*Determination of Value.* In determining a value, we considered the indications of value from both the income approach and the market approach.

- *Weighting.* Application of the market approach resulted in a higher indication of value than the income approach. We applied a 20% weighting to the income approach and an 80% weighting to the market approach in deriving a final indication of value. We chose to apply only a 20% weighting to the income approach because the assumptions underlying the income approach are subject to significant volatility. We chose to apply an 80% weighting to the market approach because of the isolated and limited nature of the private transactions in our stock.
- *Discount for Lack of Control.* The discount for lack of control, otherwise known as a discount for minority interest, reflects a reduction in value due to the absence of elements of control that do not accrue to a minority stockholder. We selected a lack of control discount of 30%, based on a review of premiums paid in transactions to acquire control of public companies that ranged from 20% to 50%. The lack of control discount took into account the rights, privileges and preferences held by our preferred stockholders.
- *Discount for Lack of Marketability.* A discount for lack of marketability is applied to a minority interest in the equity of a privately-held company due to the fact that a stockholder in a privately-held company has no ready market for his or her interest other than by a private sale to another stockholder or willing buyer. We selected a lack of marketability discount of 35% based on restricted stock studies, studies of private placements of stock in public companies and studies of initial public offerings that primarily observed discounts ranging from 30% to 40%. We chose the mid-point of that range in valuing our common stock due to the historical lack of dividends being paid, restrictions on transferability, and the high volatility of our peer group.

*Fair Value at March 17, 2009.* To determine the fair value of our common stock on March 17, 2009 of \$2.41 per share, our primary considerations included:

- an August 21, 2008 valuation prepared by an unrelated valuation specialist utilizing the valuation methods described above;
- our historical operating and financial results, current cash position and estimated time that our current cash position would fund our operations;
- the liquidation preference and other rights, privileges and preferences associated with our preferred stock;
- our stage of development and business strategy, including the status and estimated timing of clearance of our 510(k) submissions with the FDA for the ClearPoint system and the likelihood and timing of product launch; and
- prevailing economic conditions and outlook at the time.

*Fair Value at August 20, 2009.* To determine the fair value of our common stock on August 20, 2009 of \$2.41 per share, our primary considerations included:

- the August 21, 2008 valuation and the other factors considered in the March 17, 2009 fair value determination noted above;

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- the declining cash balances of the company;
- continued uncertainty regarding FDA clearance of the pending 510(k) submissions for our ClearPoint system;
- the determination by our Board of Directors that no event had occurred which, in their judgment, resulted in neither a higher nor lower value of our common stock than the March 17, 2009 grants; and
- the lack of free accessibility as of such date to the equity capital markets, creating difficulties in marketability and liquidity.

#### ***Valuation Methodology for December 10, 2009 and December 22, 2009 Grants***

*General.* Because we began the process of preparing for our initial public offering in the fourth quarter of 2009, we amended our process to estimate the value of our common stock to utilize a probability-weighted expected return method, or “PWER method”, as detailed in a practice aid issued by the American Institute of Certified Public Accountants entitled “Valuation of Privately Held Company Equity Securities Issued as Compensation”. A PWER method analysis consists of the following five steps:

- Identifying the most likely liquidity events for the company, including when they are expected to occur, the probability of each occurring, and the equity values of the company for each. Scenarios considered can be broken down into four general categories: a strategic sale or merger; an initial public offering; the dissolution of the company; and the company’s private enterprise value (with no liquidity event);
- Determining the value of the common stock for, and as of, each of the liquidity events considered;
- Determining the present value of the common stock for each liquidity scenario;
- Applying the probabilities assigned to each scenario to the present value of the common stock for each scenario to determine the probability-weighted value as of the valuation date; and
- Performing a check-to-value analysis to determine the reasonableness of the value of the common stock and the assumptions relied on.

Using this valuation methodology, we estimated the value of our common stock based upon an analysis of future values of the company assuming various liquidity events as described below.

*Identifying Most Likely Liquidity Events.* We determined that there were four likely liquidity events:

- a sale of our intellectual property in a liquidation scenario;
- completing an initial public offering of our common stock with FDA clearance for our ClearPoint system;
- completing an initial public offering of our common stock without FDA clearance for our ClearPoint system; and
- a sale of the company as a going concern.

*Determining the Value of Common Stock Under Each Liquidity Scenario.* The value resulting from a sale of our intellectual property was based upon management’s expectations as of the valuation date. The value resulting from both initial public offering liquidity events was based upon preliminary discussions of value with the underwriter. The value resulting from a sale of the company was based on conversations with investment bankers, potential buyers and management’s expectations as of the valuation date.

*Determining Present Value.* We selected a discount rate of 35%. In selecting the discount rate, we looked at what we believe are current rates of return expected by investors in various investments with different risk characteristics and we established the discount rate based on what we believe to be the most comparable rate of return range.

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*Weighting of Each Scenario.* The significant drivers and weightings for our December 10, 2009 and December 22, 2009 valuations were:

- sale of intellectual property in a liquidation scenario, 5%;
- initial public offering with FDA clearance for our ClearPoint system, 75%;
- initial public offering without FDA clearance for our ClearPoint system, 0%; and
- sale of the company as a going concern, 20%.

We assigned only a 5% weighting to a sale of intellectual property in a liquidation scenario because we viewed a liquidation sale as unlikely to occur. We assigned a 75% weighting to the initial public offering with FDA clearance for our ClearPoint system because we deemed that scenario to be the most likely liquidity event. We assigned a 0% weighting to an initial public offering without FDA clearance for our ClearPoint system because we believed we would have FDA clearance of our ClearPoint system prior to completing the initial public offering. We assigned a 20% weighting to a sale of the company, as we believed it was the second most likely liquidity event.

*Discount for Lack of Control.* The discount for lack of control, otherwise known as a discount for minority interest, reflects a reduction in value due to the absence of elements of control that do not accrue to minority stockholder. We selected a lack of control discount of 20%, based on a review of premiums paid in transactions to acquire control of public companies that ranged from 20% to 50%.

*Discount for Lack of Marketability.* A discount for lack of marketability is applied to a minority interest in the equity of a privately-held company due to the fact that a stockholder in a privately-held company has no ready market for his or her interest other than by a private sale to another stockholder or willing buyer. Restricted stock studies, studies of private placements of stock in public companies and studies of initial public offerings primarily observed discounts ranging from 30% to 40%. However, we selected a lack of marketability discount of 20% because we had commenced the initial public offering process.

*Fair Value at December 10, 2009.* To determine the fair value of our common stock on December 10, 2009 of \$2.41 per share, our primary considerations included:

- a November 17, 2009 valuation prepared by an unrelated valuation specialist utilizing the PWER method described above;
- the determination by our Board of Directors that no event had occurred which, in their judgment, resulted in either a higher or lower value of our common stock than the March 17, 2009 grants in 2009;
- our historical operating and financial results, current cash position and estimated time that our current cash position would fund our operations; and
- uncertainty regarding FDA clearance of the final 510(k) submission for our ClearPoint system.

*Fair Value at December 22, 2009.* To determine the fair value of our common stock on December 22, 2009 of \$2.41 per share, our primary considerations included:

- a December 21, 2009 valuation prepared by an unrelated valuation specialist utilizing the PWER method described above;
- the determination by our Board of Directors that no event had occurred which, in their judgment, resulted in either a higher or lower value of our common stock than the March 17, 2009 grants in 2009;



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- our historical operating and financial results, current cash position and estimated time that our current cash position would fund our operations; and
- uncertainty regarding FDA clearance of the final 510(k) submission for our ClearPoint system.

### **Liquidity and Capital Resources**

We received \$13,000,000 in licensing fees under one of our agreements with Boston Scientific in 2008. We recognize revenue from these licensing fees over the estimated time period to complete our development work under the agreement. In addition, we are entitled to receive up to \$21,600,000 in future milestone-based payments, subject to our achievement of the milestones stipulated in the agreements and the issuance of certain patents licensed to Boston Scientific, of which there can be no assurance. In addition to payments received from Boston Scientific, we have financed our operations and internal growth almost exclusively through private placements of preferred stock and borrowings. We have incurred significant losses since our inception in 1998. As of December 31, 2009, we had an accumulated deficit of approximately \$42,023,000. Our accumulated deficit resulted principally from research and development activities and the costs to support such efforts as recorded in general and administrative costs.

During 2009, Boston Scientific loaned us \$3,500,000 pursuant to the terms of three convertible promissory notes. Interest on the loans accrues at 10% per annum and compounds annually. The Boston Scientific loans are secured by a first priority security interest in all of our assets. Each loan matures on the second anniversary of the date on which the funds were advanced; however, we can prepay each loan at anytime prior to its respective maturity date. At the option of Boston Scientific, these loans are convertible into one share of our preferred stock for every \$2.00 of principal and interest outstanding at the time of conversion. To the extent that Boston Scientific has not exercised its conversion right prior to the completion of this offering, Boston Scientific will no longer have the right to convert the notes into shares of stock.

In March 2010, we issued 10% senior unsecured convertible notes, or the bridge notes, in the aggregate principal amount of approximately \$4.1 million in a private placement, or the bridge financing. Upon consummation of this offering, the bridge notes will automatically convert into shares of our common stock at the lesser of \$2.00 per share or 80% of the public offering price. The bridge notes mature two years from the date of issuance, unless earlier converted, and accrue interest at the rate of 10% per annum. All accrued interest will be paid in cash and will not be converted into shares of our common stock. We incurred approximately \$300,000 of expenses related to the bridge financing, including legal fees and placement agent fees. We intend to use the proceeds of the bridge financing for working capital and general corporate purposes.

*Net Cash Flows from Operating Activities.* Net cash flows from operating activities for the years ended December 31, 2009, 2008, and 2007 was approximately \$(9,166,000), \$7,256,000, and \$(2,994,000), respectively. The use of cash in the years ended December 31, 2009 and 2007 resulted primarily from funding our net losses. The positive net cash for the year ended December 31, 2008 resulted from the \$13 million in licensing fees under one of our agreements with Boston Scientific.

*Net Cash Flows from Investing Activities.* Net cash flows from investing activities for the years ended December 31, 2009, 2008, and 2007 was approximately \$(282,000), \$(947,000), and \$(62,000) respectively. Net cash used in investing activities for the years ended December 31, 2009, 2008, and 2007 was primarily related to the purchase of property and equipment and the acquisition of intellectual property licenses.

*Net Cash Flows from Financing Activities.* Net cash flows from financing activities for the years ended December 31, 2009, 2008, and 2007 was approximately \$2,096,000, zero and \$600,000, respectively. Net cash flows from financing activities for the year ended December 2007 was primarily attributable to the issuance of preferred stock and borrowings during the years less repayments made on previous amounts borrowed by us.

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*Operating Capital and Capital Expenditure Requirements.* To date, we have not commercialized any of our current product candidates and we have not achieved profitability. We anticipate that we will continue to incur substantial net losses for the next several years as we develop our product candidates, prepare for the potential commercial launch of our ClearPoint system, expand our corporate infrastructure to market and sell our ClearPoint system and operate as a publicly traded company, develop the ClearTrace system and pursue additional applications for our technology platforms.

As of December 31, 2009, we had approximately \$2,569,000 in cash, cash equivalents and short-term investments. Our cash and investment balances are held in a variety of interest bearing instruments, including interest bearing demand accounts and certificates of deposit. Cash in excess of immediate requirements is invested primarily with a view to liquidity and capital preservation. Even if we receive regulatory clearance for our ClearPoint system for a general neurological intervention claim, we do not expect to generate product revenue until the second half of 2010. We do not anticipate generating any product revenue in the United States unless and until we successfully obtain FDA clearance for our ClearPoint system. We believe the net proceeds from this offering, together with our cash, cash equivalents and investment balances and interest income we earn on these balances will be sufficient to meet our anticipated cash requirements through the end of 2011. If our available cash, cash equivalents and investment balances and net proceeds from this offering are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or enter into a credit facility. The sale of additional equity and debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities, which could materially harm our business.

Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to complete development of our product candidates and the cost to commercialize our products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the "Risk Factors" section of this prospectus. We have based these estimates on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our ClearPoint system and the ClearTrace system, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete the development of our product candidates and successfully deliver commercial products to the market. Our future capital requirements will depend on many factors, including but not limited to the following:

- the scope, rate of progress and cost of our research and development activities;
- the achievement of milestone events under, and other matters related to, our agreements with Boston Scientific and Siemens;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the cost and timing of clinical trials;
- the cost and timing of regulatory filings, clearances and approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities and other corporate infrastructure;
- the cost of establishing product inventories;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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The following table summarizes our outstanding future contractual obligations as of December 31, 2009 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Operating Lease Obligations	\$ 579,000	\$ 168,000	\$ 353,000	\$ 58,000	\$ —
Long-Term Debt Obligations	3,500,000	—	3,500,000	—	—
Shared Research Obligations	1,094,000	907,000	187,000	—	—
Co-Development Obligations	2,326,000	1,257,000	1,069,000	—	—
Software License Obligations	1,575,000	525,000	1,050,000	—	—
Minimum Royalty Payment Obligations	1,387,500	37,500	187,500	150,000	1,012,500
Total	<u>\$10,461,500</u>	<u>\$2,894,500</u>	<u>\$6,346,500</u>	<u>\$208,000</u>	<u>\$1,012,500</u>

Our long term commitments under operating leases shown above consist of payments relating to our facilities under leases that as of December 31, 2009 expire in 2010, 2012 and 2014. Our long-term debt obligations consist of the principal amounts owed under our convertible promissory notes issued to Boston Scientific. Shared research obligations consist of amounts payable under research agreements with certain universities. Co-development obligations consist of the payment obligations to Siemens in connection with the ClearTrace system software development. Software license obligations represent minimum purchase commitments under a master service and license agreement for the license of software code that is used in our ClearPoint system. Minimum royalty payment obligations consist of the minimum royalty payments due to a licensor.

### Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in demand deposit accounts and certificates of deposit. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We do not currently use derivative financial instruments. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. We have operated solely in the United States. Accordingly, we do not have any material exposure to foreign currency rate fluctuations.

### Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

### Recent Accounting Pronouncements

In August 2009, the Financial Accounting Standard Board, or FASB, issued Accounting Standard Update, or ASU, No. 2009-03, *SEC Update—Amendments to Various Topics Containing SEC Staff Accounting Bulletins*, or ASU No. 2009-03. This ASU updated cross-references to Codification text. The adoption of ASU 2009-03 will not have a material impact on our financial statements.

In August 2009, the FASB issued ASU No. 2009-04, *Accounting for Redeemable Equity Instruments—Amendment to Section 480-10-S99*, or ASU No. 2009-04. This ASU represents an update to Section 480-10-S99, *Distinguishing Liabilities from Equity*, per Emerging Issues Task Force Topic D-98, “Classification and Measurement of Redeemable Securities.” The adoption of ASU 2009-04 will not have a material impact on our condensed financial statements.

In August 2009, the FASB issued ASU No. 2009-05, *Fair Value Measurements and Disclosures (Topic 820)—Measuring Liabilities at Fair Value*, or ASU No. 2009-05. This ASU amends Subtopic 820-10, Fair Value

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Measurements and Disclosures—Overall, to provide guidance on the fair value measurement of liabilities. The adoption of ASU 2009-05 is not expected to have a material impact on our financial statements.

In September 2009, the FASB issued ASU No. 2009-07, *Technical Corrections to SEC Paragraphs*, or ASU No. 2009-07. This ASU corrected SEC paragraphs in response to comment letters. The adoption of ASU 2009-07 will not have material impact on our financial statements.

In September 2009, the FASB issued ASU No. 2009-08, *Earnings Per Share Amendments to Section 260-10-S99*, or ASU No. 2009-08. This ASU represents technical corrections to Topic 260-10-S99, Earnings per Share, based on EITF Topic D-53, Computation of Earnings Per Share for a Period that Includes a Redemption or an Induced Conversion of a Portion of a Class of Preferred Stock and EITF Topic D-42, The Effect of the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock. The adoption of ASU 2009-08 will not have material impact on our financial statements.

In September 2009, the FASB issued ASU No. 2009-09, *Accounting for Investments-Equity Method and Joint Ventures and Accounting for Equity-Based Payments to Non-Employees*, or ASU No. 2009-09. This ASU represents a correction to Section 323-10-S99-4, *Accounting by an Investor for Stock-Based Compensation Granted to Employees of an Equity Method Investee*. Section 323-10-S99-4 was originally entered into the Codification incorrectly. The adoption of ASU 2009-09 will not have material impact on our financial statements.

In September 2009, the FASB issued ASU No. 2009-12, *Fair Value Measurements and Disclosures (Topic 820), Investments in Certain Entities that Calculate Net Asset Value per Share (or Its Equivalent)*, or ASU No. 2009-12. This ASU amends Subtopic 820-10, *Fair Value Measurements and Disclosures Overall*, to provide guidance on the fair value measurement of investments in certain entities that calculate net asset value per share (or its equivalent). The adoption of ASU 2009-12 will not have material impact on our financial statements.

In October 2009, the FASB issued Accounting Standards Update No. 2009-13 (“ASU 2009-13”), which addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified beginning in fiscal years on or after June 15, 2010. Early adoption is permitted. We are currently evaluating the impact that the adoption of this standard will have on our consolidated financial statements, if any.

## BUSINESS

### Overview

We are a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain and heart using direct, intra-procedural MRI guidance while performing minimally invasive surgical procedures. For the last five years, our business has consisted solely of research and development activities for our ClearPoint system, the ClearTrace system and the SafeLead Development Program and their underlying technologies.

We believe that our product candidates will deliver better patient outcomes, enhance revenue potential for both physicians and hospitals, and reduce costs to the healthcare system as described in more detail below:

- *Better Patient Outcomes.* We believe that if a physician can see the surgical field, the surgical instruments and the patient's anatomy at the same time and in the same "imaging space," the physician can more efficiently perform a surgical intervention in the brain or heart. Subject to appropriate regulatory clearance or approval, our product candidates are being designed to enable physicians to identify the target site, guide the surgical instrument to the site, deliver the therapy, monitor for adverse events and complications and confirm the desired results of the procedure, all under continuous, intra-procedural, high resolution MR imaging. We believe that these capabilities will translate directly into better clinical outcomes for the patients undergoing the procedures due to improved efficiency, the potential for the reduction of adverse events and side effects as well as the potential for faster recovery times.
- *Enhance Revenue Potential.* We believe that use of our product candidates will reduce the amount of time needed to perform the procedures for which they are designed. As a result, we believe that our product candidates will improve the overall economics of the procedures for both the performing physician and the hospital. With respect to the physician, we anticipate that the physician will receive the same fee payment for performing a procedure using our product candidates as for performing the procedure using conventional means. However, as we believe the procedure will take less time to perform with the use of our product candidates, the physician's fee should be higher, when measured on a per hour basis. Likewise, if procedure times are shorter, the physician could perform more procedures. With respect to the hospital, we believe that shorter procedure times could lead to more efficient use of hospital resources and could increase the hospital's capacity for more procedures. Our ClearPoint system is designed to enable certain procedures to be performed in the MRI suite, which we believe would make the operating room available for other procedures to be performed. The additional procedures would result in additional revenue for the hospital.
- *Reduce Costs to the Healthcare System.* As discussed above, we believe that use of our product candidates could result in better patient outcomes along with more efficient utilization of physician and hospital time and resources. If patient outcomes and procedure efficiencies are improved by use of our product candidates, we believe that the result will be a reduction in overall healthcare costs. In addition, if higher success rates are achieved by use of our product candidates, we believe this would mitigate the need for follow-up procedures to be performed on the same patient simply to achieve the original desired clinical result. As a result, the costs associated with follow-up procedures, such as in-patient hospital stays and physician fees, would not be incurred. Similarly, if the risk for complications during the procedure is reduced, the expected costs associated with the procedure also should be reduced.

Millions of people suffer from brain and heart diseases and disorders. While some patients can be treated with medication, others require surgery. Current surgical interventions include both open and minimally invasive procedures. Given the option, patients, physicians and hospitals alike prefer minimally invasive procedures over open procedures. Despite the many benefits of minimally invasive procedures, they can still present significant limitations, most notably restricted vision of the patient's anatomy, surgical field and instruments. Because of this restricted visibility, some minimally invasive procedures in the brain and heart are lengthy, difficult on patients, and require substantial physician and hospital resources. As a result, there is a need for a new and improved platform for those procedures in the brain and heart.

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Utilizing the superior imaging capabilities of MRI, subject to appropriate FDA clearance or approval, our product candidates are designed to enable physicians to:

- *Guide* a surgical instrument within the patient as it is advanced towards the therapeutic target;
- *Deliver* a planned therapy with precise visualization of a patient's anatomy, the surgical field and instruments;
- *Monitor* for adverse events during and immediately after the administration of the therapy; and
- *Confirm* the desired results of a procedure.

Our first product candidate is our ClearPoint system, which is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The initial application for our ClearPoint system will be general neurological interventional procedures, such as biopsies and catheter and electrode insertion. Our ClearPoint system is currently pending FDA pre-market notification, or 510(k) clearance. If 510(k) clearance is obtained, we may seek additional regulatory clearance or approval for the use of our ClearPoint system for more specific indications, which will allow us to market and promote our ClearPoint system for those specific uses. Such additional regulatory clearances or approvals may require us to perform clinical studies.

We believe that one of the more valuable future applications for our ClearPoint system, subject to appropriate FDA clearance or approval, will be use in MRI-guided deep brain stimulation lead placement. A deep brain stimulation lead is a thin, insulated wire with exposed electrodes that is implanted in a specific area of the brain and connected to an electronic device that is implanted in the chest. Deep brain stimulation is an approved therapy for treating the symptoms of movement disorders like Parkinson's disease and psychological disorders like treatment resistant obsessive compulsive disorder. Clinical results for patients implanted with deep brain stimulation leads have been positive. However, despite that positive clinical outcome data, we believe that patient and physician adoption of deep brain stimulation therapy has been slowed significantly due to the arduous and time-consuming nature of the standard procedure by which deep brain stimulation leads are implanted in the patient's brain. Using our ClearPoint system, a physician sees and selects a neurological target, aims our targeting device and watches as the surgical instrument is advanced to the target, significantly reducing the time and complexity of the implantation procedure.

Our second product candidate is the ClearTrace system, which is designed to allow catheter-based minimally invasive procedures in the heart to be performed using continuous, intra-procedural MRI guidance. Some catheter-based cardiac interventions, such as stent placement, do not require detailed visualization of the cardiac tissue. However, we believe that other procedures, such as cardiac ablation to treat arrhythmias, would significantly benefit from continuous high resolution imaging of cardiac tissue and the surgical instruments. During cardiac ablation, a physician attempts to restore a normal heart rhythm by destroying small areas of heart tissue to block irregular electrical impulses that cause an irregular heart beat, or arrhythmia. We expect that the ClearTrace system's initial application will be for catheter-based cardiac ablation to treat atrial fibrillation. Atrial fibrillation is the most common cardiac arrhythmia affecting over three million people in the United States alone. In May 2009, we entered into an exclusive co-development agreement with Siemens, the global market leader in MRI scanners, for the development and commercialization of the hardware and MRI software necessary for the ClearTrace system. Because of Siemens' market-leading position, we believe that our exclusive relationship secures a strategic market position for the ClearTrace system. Our development activities on the ClearTrace system are ongoing. We have not made any filings seeking regulatory clearance or approval for the ClearTrace system. We believe most components of the ClearTrace system will be subject to the FDA's 510(k) regulatory process. However, the ablation catheter component will require FDA approval of a PMA. We will be required to conduct a clinical trial to support the PMA for the ablation catheter, which we anticipate commencing in the second half of 2011.

Our third area of activity is referred to as the SafeLead Development Program. Over the last ten years, we have pioneered several technologies that improve the MRI-safety profile of implantable medical leads. These leads are thin, insulated wires that are connected to implantable generators, such as a pacemaker or neurostimulator, and deliver electrical pulses or stimulation to a specific area of the body, such as the heart or the

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brain. During an MRI scan, these leads are susceptible to heating, which could burn and destroy adjacent tissue. Our technologies address this issue by maintaining lead temperatures well within safe levels during an MRI scan. In March 2008, we entered into an exclusive licensing and development agreement with Boston Scientific for the incorporation of our MRI-safety technologies into Boston Scientific's implantable cardiac leads. We previously entered into a similar arrangement with Boston Scientific with respect to its products for neurological applications. Under our agreements with Boston Scientific, we received licensing fees of \$13,000,000 in 2008 and we are entitled to receive up to approximately \$21,600,000 in future milestone-based payments, subject to our achievement of the milestones stipulated in the agreements and the issuance of certain patents licensed to Boston Scientific. Boston Scientific has also agreed to pay us royalties on net sales of products that incorporate our licensed intellectual property. We believe that our MRI-safety technologies, when integrated into Boston Scientific's implantable leads, could represent a meaningful market differentiator over existing implantable lead designs.

Our ClearPoint system and the ClearTrace system are integrated systems of reusable hardware components, disposable components and intuitive, menu-driven software. Our business model for both the ClearPoint and ClearTrace systems is focused on producing high margin revenue from recurring sales of the disposable components. We intend to make our reusable components available to hospitals at lower margins. We do not expect that the cost of the reusable components of our ClearPoint system and the ClearTrace system will negatively impact the adoption rate of our systems among hospitals.

We have a significant intellectual property portfolio in the field of MRI-guided interventions. In addition, we have meaningful collaborations with major industry participants and renowned academic institutions. Our technologies have been the subject of numerous peer-reviewed articles in medical and scientific journals. As a result of our intellectual property and collaborative relationships, we believe that we are well positioned to remain on the forefront of the emerging market of MRI-guided minimally invasive surgical procedures.

### **Industry Background**

#### ***Development of Minimally Invasive Surgical Procedures***

Over the past few decades, one of the most significant medical trends has been the development of minimally invasive surgical methods and techniques. As its name implies, a minimally invasive procedure is a less invasive approach than open surgery. Minimally invasive procedures typically have involved use of laparoscopic devices, catheter-based devices or remote-control manipulation of instruments once inside the body.

Compared to open surgical techniques, minimally invasive techniques offer potentially superior benefits for patients, physicians and hospitals:

- For the patient, these techniques result in reduced procedure-related pain, minimal scarring and reduced pain at the incision site, shorter post-operative hospital stays and faster recovery times;
- For the physician, these techniques reduce procedure-related complications and have the potential to reduce risks associated with more invasive procedures; and
- For the hospital, these procedures result in reduced hospital stays with faster recovery times, lower rates of complications, and reduced costs.

Procedures commonly performed using minimally invasive techniques include knee surgery, gastric surgery, cardiovascular balloon angioplasty, stent placement and tumor biopsy. In the United States alone, approximately 4.9 million minimally invasive surgical procedures are performed annually.

One of the ongoing challenges of minimally invasive procedures is the physician's ability to "see" what the physician is doing inside a patient's body. Technological advances in imaging modalities that permit a physician to see inside a human body have enabled the development and growth of minimally invasive surgical procedures.

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One such imaging modality is endoscopy, which involves examining the inside of a person's body using a long, thin, flexible tube with a light and a video camera that displays images of the inside of the patient's body on a screen. The development of endoscopic visualization techniques reinvented the manner in which knee surgery was performed. Another imaging modality is fluoroscopy, which uses a continuous X-ray beam to create a sequence of images that are projected onto a television-like monitor. Fluoroscopic imaging enabled revolutionary improvements in the treatment of cardiovascular disease by guiding balloon angioplasty procedures and the placement of cardiac stents. The development of endoscopic and fluoroscopic techniques have dramatically increased the number of procedures performed when compared to the number of open procedures previously performed. While endoscopic and fluoroscopic imaging techniques are optimal for some minimally invasive procedures, we believe that many procedures in the brain and heart would benefit from a different imaging method.

#### ***Magnetic Resonance Imaging***

MRI is a widely practiced imaging technique that uses spatially varying magnetic fields to produce images of the human anatomy. Hydrogen nuclei, present in molecules throughout the body, are slightly magnetic. When placed in large external magnetic fields, they can be induced to emit or resonate radio frequency signals. These radio frequency signals are used to construct images of human anatomy, including high resolution images of soft tissue.

MRI has important and advantageous properties that differentiate it from other imaging methods. MRI scans can provide images of any part of the body, in any plane of view, and offer more detailed information than other modalities, including fluoroscopy and computed tomography. Some of the unique advantages of MRI include:

- no harmful ionizing radiation exposure for either the patient or the physician;
- soft tissue imaging that enables superior tissue visualization and enhanced differentiation between healthy and diseased tissues;
- unlimited orientation and positioning of the imaging plane;
- ability to directly acquire volumetric (three dimensional) data sets; and
- ability to evaluate both the structure and certain functions of internal organs.

MRI scanners are available in a number of different configurations and field strengths, which refers to the strength of the magnet used to create the magnetic field. Magnetic field strength is measured in Tesla, or T. The most common field strength for MRI scanners is 1.5T. Most MRI scans are performed using 1.5T MRI scanners. Higher field strength scanners such as 3T MRI scanners, have been introduced in clinical practice and are in the early stages of commercial market adoption. These 3T MRI scanners provide faster scanner speeds and even higher resolution images than 1.5T MRI scanners.

#### **The SurgiVision Solution**

The last 20 years have witnessed significant advances in minimally invasive surgical techniques. However, we believe that some minimally invasive procedures within the brain and heart have been slow to develop and gain wide acceptance largely because of the inherent limitations of traditional imaging methods such as endoscopy or fluoroscopy. Neither of these imaging methods provides the physician with sufficient visualization of the brain or heart tissue to perform the next generation of minimally invasive neurological and cardiac procedures. Utilizing the power of MRI, our product candidates provide that capability. Our product candidates are designed, subject to appropriate FDA clearance or approval, to enable physicians to:

- *Guide* the surgical instrument within the patient as it is advanced towards the therapeutic target. For example, a physician will be able to watch a probe as it moves through the brain towards its target point or visualize and steer a catheter into a chamber of the heart.
- *Deliver* the planned therapy with continuous high resolution visualization of a patient's anatomy, the surgical field and instruments. For example, a physician will be able to visualize ablation lesions in the heart as the physician creates them.



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- *Monitor* for adverse events during and immediately after the administration of the therapy. For example, if a blood vessel in the brain is ruptured, hemorrhage will be visible within seconds and remedial action can be undertaken immediately.
- *Confirm* the desired results of a procedure. For example, a physician will be able to confirm, with specificity, correct anatomical placement of a device or delivery of a therapy in the brain or heart.

We believe the combination of MRI's continuous high resolution imaging capabilities with minimally invasive surgical techniques will create an innovative platform for performing the next generation of procedures in the brain and heart.

### **Our Product Candidates**

The following table summarizes key information about our product candidates:

<b>Product Candidates</b>	<b>Regulatory Status</b>	<b>Target Market</b>	<b>Development Partner</b>
ClearPoint Neuro Intervention System	510(k) Clearance Pending	Initial target market is general neurological interventions, such as biopsies and catheter and electrode insertion. Subsequent target markets may include deep brain stimulation lead placement and precision delivery of drugs and biologics.	Developed Internally
ClearTrace Cardiac Intervention System	Development Stage	Initial target market is catheter-based cardiac ablation to treat atrial fibrillation. Subsequent target markets may include precision delivery of drugs and biologics.	Siemens
SafeLead Development Program <sup>(1)</sup>	Development Stage <sup>(2)</sup>	Target market is implantable leads for cardiac and neurological applications.	Boston Scientific

(1) The SafeLead Development Program is a collaborative effort with Boston Scientific to incorporate our MRI-safety technologies into Boston Scientific's implantable lead designs.

(2) Boston Scientific is responsible for any regulatory filings with respect to its implantable leads.

### ***ClearPoint Neuro Intervention System***

#### *General*

Our first product candidate is our ClearPoint system, which is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. Our research efforts for our Clear Point System began in 2003. Our ClearPoint system's initial application will be for general neurological interventions, such as biopsies and catheter and electrode insertion. Specifically, we are seeking FDA 510(k) clearance of our ClearPoint system to provide guidance for the placement and operation of instruments or devices during the planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. If we obtain 510(k) clearance for the general neurological intervention claim, we may seek additional regulatory clearance or approval for use of our ClearPoint system for more specific indications to allow us to market and promote our ClearPoint system for those specific uses. Such additional regulatory clearances or approvals may require us to perform clinical studies.

We believe that one of the more valuable future applications for our ClearPoint system will be use in MRI-guided deep brain stimulation lead placement, assuming we can obtain any necessary FDA clearance or approval. Deep brain stimulation is an approved therapy for treating the symptoms of movement disorders such

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as Parkinson's disease and psychological disorders like treatment resistant obsessive compulsive disorder. Clinical results for patients implanted with deep brain stimulation leads have been very positive. However, despite the positive clinical outcome data, we believe patient and physician adoption of deep brain stimulation therapy has been slowed significantly due to the arduous and time-consuming nature of the standard procedure by which deep brain stimulation leads are implanted in the patient's brain. Using our ClearPoint system, a physician sees and selects a neurological target, aims our targeting device and watches as the surgical instrument is advanced to the target, significantly reducing the time and complexity of the interventional procedure.

Another future ClearPoint system application for which we may seek specific FDA clearance or approval is the delivery of drugs and biologic agents to precision targets in the brain to treat a variety of neurological diseases and conditions, including brain tumors. We believe that many therapies are currently not available because the drugs and biologic agents cannot be delivered effectively to their neurological targets. Delivery challenges include penetration of the blood-brain barrier, which is a protective barrier between brain tissues and circulating blood preventing some substances from entering the brain, and the risk of serious side effects which can occur if the drugs or biologics are unintentionally delivered to the tissue that surrounds the intended target site. We believe that our ClearPoint system can address these significant issues.

### *Components*

Our ClearPoint system is an integrated system of reusable hardware components, disposable hardware components and intuitive, menu-driven software. Pictures of our ClearPoint system and its components are included on the inside front cover of this prospectus.

*Reusable Hardware Components.* Our reusable hardware components consist primarily of an imaging head coil, head fixation frame, computer workstation and in-room monitor. The architecture of our imaging head coil allows for surgical access to the patients while maintaining high quality imaging capability. The head fixation frame is integrated with the head coil and is designed to optimize the placement of the head coil in proximity to the patient's head. Our ClearPoint system software is installed on a computer workstation networked with an MRI scanner, for which we use a commercially available laptop computer. The in-room monitor allows the physician to view the display of our ClearPoint system workstation from the scanner room while performing the procedure.

*Disposable Hardware Components.* Our disposable hardware components consist primarily of our SmartFrame device, a hand controller and a surgical kit. Our SmartFrame device is an adjustable trajectory frame that attaches to the patient's skull and that holds the targeting cannula. The hand controller attaches to our SmartFrame device, and it is used by the physician to adjust the roll, pitch and X and Y orientation of the targeting cannula. The surgical kit includes all other accessory components necessary for the MRI-guided neurological procedure, such as our SmartGrid patch, which is an MRI-visible marking grid, and customized surgical draping.

*Software.* Our ClearPoint system software guides the physician in surgical planning, device alignment, navigation to the target and procedure monitoring. The software receives standard images from the MRI scanner via a network connection to the scanner. The software leads the physician through a series of predefined steps, including MR image acquisition, establishment of image orientation landmarks, target identification and selection, trajectory planning, entry point planning and marking, targeting cannula orientation and refinement, and confirmation that the desired anatomical target(s) have been reached. The software uses image segmentation algorithms to help locate and identify our SmartFrame device and its targeting cannula, the probe and the anatomical structures of the brain. The software also performs geometric computations to provide the physician with information regarding the positioning of instruments inserted into the patient's brain relative to the target anatomical structures. At the completion of the procedure, the software generates an automated report that includes the key metrics from the procedure. Our ClearPoint system software will be included with the initial installation of our ClearPoint system pursuant to an end-user license agreement at no additional charge.

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### *Current Neurological Interventions*

Performing minimally invasive interventions in the brain presents special challenges, including a need to reach small therapeutic targets often located deep within the brain. To reach these targets, the physician must act with precision to avoid damaging adjacent areas that can be responsible for important neurological functions, such as memory or speech, or penetrating blood vessels which can lead to a life-threatening hemorrhage. To overcome these obstacles, the medical community has developed complicated surgical techniques, commonly referred to as stereotaxy, under which a physician merges pre-operative images and data with specialized surgical instruments to help guide the surgical intervention. Despite years of development and clinical experience, conventional stereotactic procedures remain complicated and time-consuming for many neurological interventions and can be extremely difficult on the patient.

In spite of their shortcomings, current stereotaxy-based approaches are commonly used to perform neurological interventions. These procedures include pre-operative biopsy and the insertion of catheters or electrodes in the brain. In 2007, industry analysts estimated that over 130,000 minimally invasive neurological interventions would be performed in the United States in 2008, including approximately 17,000 biopsies, 75,000 catheter insertions, and 8,000 electrode insertions. We believe our ClearPoint system is an innovative new approach to perform a subset of these neurological procedures.

### *Our ClearPoint System Solution*

The design of our ClearPoint system significantly simplifies how neurological interventions are performed. Our solution, unlike some conventional approaches, begins with the patient in an MRI suite under general anesthesia and without interruption to the patient's prescription drug regimen. Once placed in the MRI, the patient's head is immobilized in our imaging head coil and integrated head fixation frame with the patient's head accessible to the surgeon. The physician then places our MRI-visible SmartGrid patch onto the patient's head where the physician expects to enter the skull.

The patient is then moved to the center of the scanner and images are taken of the patient's brain that include the target area and our SmartGrid patch. Once the imaging is complete, the images are transferred to our ClearPoint system workstation so that the physician can determine the specific target site within the brain and the optimal trajectory path for the placement of the interventional device. With the trajectory path established, our ClearPoint system software will identify the specific location on our SmartGrid patch that corresponds with where the planned trajectory intersects the skull. The physician will then mark the skull using our custom marking tool. At the site of the mark, the physician will create a small 14 millimeter hole, which is called a burr hole, in the patient's skull.

The SmartFrame device is centered and attached over the burr hole. The target and planned trajectory is reconfirmed by the physician using our ClearPoint system workstation. Using the hand controller, the physician positions the MRI-visible SmartFrame device to align the instrument with the planned trajectory. During this process, the software estimates a number of turns and direction of turn on each of the hand controller's color coded thumbwheels to align the instrument to the planned trajectory.

Once our SmartFrame device has been aligned to the proper trajectory, the depth dimension is calculated by the software. Immediately before insertion and partway through insertion, scans are taken to ensure that the stylet is correctly tracking along the planned trajectory. The surgeon continues advancing the stylet towards the target site until it "snaps" into place on the SmartFrame device indicating that the stylet has reached the proper depth. At this time, images are taken at the target site to insure the peel away sheath and stylet are in the proper location relative to the desired target. Once proper location is confirmed, the stylet is removed, leaving behind a channel to the target site created by the peel away sheath. Now the interventional device can be inserted and the peel away sheath is removed.

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### *Potential Future Applications for our ClearPoint System*

#### *Deep Brain Stimulation*

Deep brain stimulation is a therapy that uses mild electrical pulses from an implanted device to stimulate the brain. A deep brain stimulation system looks and operates much like a cardiac pacemaker, except that instead of sending pulses to the heart, it delivers electrical stimulation to a precisely targeted area in the brain. Deep brain stimulation is currently approved by the FDA for the treatment of Parkinson's disease, essential tremor, dystonia and obsessive compulsive disorder. United States regulatory approval is being sought for the use of deep brain stimulation to treat epilepsy, and deep brain stimulation is also being investigated for treatment-resistant major depression along with other neurological and psychiatric disorders. Several types of medications are available as the first line of treatment for these conditions. However, over time, these medications often become less effective at controlling symptoms and may begin to cause side effects. For those patients who fail to respond to, or have developed side effects from, standard drug therapies, deep brain stimulation can be an appropriate therapy.

To date, more than 60,000 people worldwide have undergone a deep brain stimulation procedure. The FDA has approved the use of deep brain stimulation for the treatment of Parkinson's disease and essential tremor. The FDA has also approved the use of deep brain stimulation for the treatment of dystonia and obsessive compulsive disorder pursuant to humanitarian device exemptions. We believe that the market for deep brain stimulation therapy is sizable because of the number of people suffering from these diseases or disorders for whom deep brain stimulation may be an appropriate treatment. FDA approval is currently being sought for the use of deep brain stimulation to treat epilepsy. Deep brain stimulation is also being investigated as a therapy for treatment-resistant major depression. We believe that the market for deep brain stimulation is growing because FDA approval is being sought and investigations are being conducted for these additional uses of deep brain stimulation therapy. The diseases and disorders, patient populations, potential deep brain stimulation candidates and status of FDA approval are described in the following table:

**United States Deep Brain Stimulation Market**

<b>Indication</b>	<b>Patient Population</b>	<b>Potential DBS Candidates<sup>(1)</sup></b>	<b>FDA Approval</b>
Parkinson's Disease	1,500,000	150,000	Approved
Essential Tremor	4,000,000	75,000	Approved
Dystonia	250,000	25,000	Approved <sup>(2)</sup>
Obsessive Compulsive Disorder	3,300,000	100,000	Approved <sup>(2)</sup>
Epilepsy	2,300,000	250,000	Pending
Treatment-Resistant Major Depression	6,000,000	1,200,000	Unknown <sup>(3)</sup>
Subtotal	17,350,000	1,800,000	

(1) The potential deep brain stimulation candidates are based on publicly available industry research reports and third-party corporate presentations. Based on informal discussions with neurosurgeons who perform deep brain stimulation implantation procedures, we elected to present a lower number of potential candidates for obsessive compulsive disorder and epilepsy than that contained in industry research reports or third-party corporate presentations.

(2) Pursuant to a Humanitarian Device Exemption—Efficacy has not been established.

(3) Although this indication is being actively investigated for deep brain stimulation therapy, no submissions have been filed with the FDA seeking approval and there can be no assurance that approval will ever be sought or received.

#### *Conventional Deep Brain Stimulation Lead Placement Procedure*

Despite the large potential market for deep brain stimulation and many years of research experience with deep brain stimulation technology, we believe that the conventional deep brain stimulation lead placement procedure has led to an under-developed market. The current approach for implantation of deep brain stimulation

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leads is a complex and lengthy procedure that is performed in an operating room. We believe that many patients identified by their physicians as candidates for deep brain stimulation therapy elect not to proceed with the treatment because of the arduous aspects of the procedure, namely:

- The patient is awake for his own brain surgery;
- The patient's head is affixed to a large, metal frame by skull pins;
- A Parkinson's patient must stop taking medication prior to the procedure, which can result in uncontrolled body tremors during the procedure; and
- The procedure can last more than six hours.

The standard lead implantation approach is based on a technique called frame-based stereotaxy. In this method, a large, metal stereotactic frame is fixed to the patient's skull, using skull pins, to provide a fixed and common coordinate system. After the frame is attached to the patient's skull, the patient is then imaged pre-operatively in order to obtain images showing both the stereotactic frame axes and the anatomical structures of the patient's brain. These pre-operative images are then loaded into a surgical planning workstation. Surgical planning software is used to identify the neurological target for the deep brain stimulation therapy, as well as to define a trajectory path for the deep brain stimulation lead from the skull through the brain tissue to the target. The planned trajectory and target location is then calculated in relation to the frame axes and then used to guide the surgery.

Successful deep brain stimulation therapy requires a high degree of accuracy in the placement of deep brain stimulation leads within specific deep brain structures. Because frame-based stereotaxy relies on pre-operative images, and not intra-procedural images, errors in the alignment of the pre-operative images with the patient's brain anatomy can, and often do, occur as a consequence of brain shift, variation in patient hydration, registration errors or misalignment of the frame. As a result, the physician often must undertake additional steps to further refine the process of locating the patient's neurological targets. These steps include physiological "mapping" of the brain and require an additional procedural step called microelectrode recording, which is a tedious and time-consuming process during which small probes containing microelectrodes are inserted into the deep brain structures multiple times. As these microelectrode recording probes are passed through brain tissue, they pick up electrical activity. The microelectrode recording system then converts the electrical activity into audible tones. In hearing these various audible tones, a trained neurologist or neurophysiologist can distinguish different regions of the brain. Based on these tones, locations are mapped against the pre-operative images and used to refine and adjust the neurological target as depicted on those pre-operative images. New coordinates are then calculated and a new trajectory is planned. To further confirm locations in the brain, various physiologic responses are induced or monitored with the microelectrodes. These physiological mapping steps require the patient to be awake and off medications.

### *Our ClearPoint System Solution*

We believe that deep brain stimulation therapy would benefit from simplified lead implantation methodologies and that our ClearPoint system represents a dramatic improvement over the current approach. We anticipate that a deep brain stimulation lead implantation procedure utilizing our ClearPoint system will have the following attributes:

- the procedure will be performed in a standard 1.5T MRI scanner;
- the patient can be under general anesthesia and remain on his or her medication;
- intra-procedural MRI-guidance will be used to:
  - see and select the target site;
  - plan the path to the target site;
  - guide an instrument to the target site;

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- monitor for any adverse events or complications that might occur during the procedure; and
- confirm that the target site has been reached; and
- the procedure is designed to be completed in approximately two to three hours.

The process of a deep brain stimulation lead implantation procedure utilizing our ClearPoint system would be substantially similar to the process described above in “—Our ClearPoint System Solution” on page 57.

### *Precision Delivery of Drugs and Biologics*

Another potential ClearPoint system application for which we may seek specific FDA clearance or approval is the delivery of drugs and biologic agents to precision targets in the brain. Recently, drug companies and researchers have identified various compounds that may treat a number of neurological diseases, including movement and psychiatric disorders and brain tumors. Based on peer reviewed articles in medical and scientific journals, we believe that some of these therapies are currently not available because the drugs and biologic agents cannot be delivered effectively to their neurological targets. Delivery challenges include penetration of the blood-brain barrier and the risk of serious side effects which can occur if the drugs and biologics are unintentionally delivered to the tissue that surrounds the intended target site. We believe our ClearPoint system addresses these significant issues.

We are presently conducting animal studies in close collaboration with renowned researchers in the field. These preliminary studies are demonstrating our ClearPoint system’s capability to allow the physician to identify a precise neurological target area, guide an injection catheter into the target area, and watch the dispersion of the material within the target area as it is injected. We believe these capabilities for precision delivery are unique and remove a major barrier that has been preventing promising therapies from reaching the market.

### *Regulatory Status*

We are seeking marketing clearance of our ClearPoint system through the FDA’s 510(k) premarket notification process. We originally filed five 510(k) submissions seeking marketing clearances for the individual devices comprising our ClearPoint system. However, based on discussions with the FDA, we consolidated two of these devices into one 510(k) to obtain clearance of these devices as a system. A description of our 510(k) filings and the current status of those filings are indicated below:

<b>510(k) Submission</b>	<b>Original Submission Date</b>	<b>Current Status</b>
Head coil	February 10, 2009	Received marketing clearance on March 16, 2009
Head fixation frame and base table mount	May 19, 2009	Received marketing clearance on August 25, 2009
ClearPoint surgical draping	May 6, 2009	Received marketing clearance on September 22, 2009
SmartFrame device & ClearPoint workstation (including software)	May 6, 2009 <sup>(1)</sup>	Pending marketing clearance

(1) We filed our original 510(k) submission with the FDA on May 6, 2009. Based on discussions with the FDA, we withdrew the original submission and filed a new 510(k) submission on March 24, 2010.

In the pending 510(k) submission, we are seeking a 510(k) clearance to market our ClearPoint system for use in general neurological interventions, such as biopsies and catheter and electrode insertion. We believe that seeking 510(k) clearance for this indication is the least burdensome path to initial regulatory clearance. The indication we are seeking is the same indication for use that applies to other devices that have traditionally been

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used in the performance of stereotactic neurological procedures. If we obtain clearance for our pending 510(k) submission, we may seek additional regulatory clearance or approval for use of our ClearPoint system for specific neurological indications, such as deep brain stimulation lead placement or precision delivery of drugs or biologics, to allow us to market and promote our ClearPoint system for those specific uses. We believe that all components of our ClearPoint system are Class II medical devices and subject to the 510(k) clearance process.

Unless and until we receive regulatory clearance or approval for use of our ClearPoint system for specific indications, uses in procedures other than general neurological interventions, such as biopsies and catheter and electrode insertion, may be considered off-label uses of our ClearPoint system, in which case we would be prohibited from promoting our system, or training physicians, for those specific uses. However, in their practice of medicine, physicians may lawfully choose to use medical devices for off-label uses. Therefore, if the FDA grants 510(k) clearance for our ClearPoint system for use in general neurological interventions, a physician may use our ClearPoint system for uses not covered by the cleared labeling. We expect that physicians will use our ClearPoint system for a variety of specific neurological procedures, including deep brain stimulation lead placement.

### ***The ClearTrace Cardiac Intervention System***

#### *General*

Our second product candidate is the ClearTrace system, which is designed to allow catheter-based minimally invasive procedures in the heart to be performed using continuous, intra-procedural MRI guidance. Catheter-based cardiac interventions performed in a fluoroscopy suite, generally referred to as a Cath Lab, have been the standard of care for the treatment of many cardiac disorders, such as cardiovascular disease. Some of these procedures, such as stent placement, are well suited for fluoroscopic imaging because they do not require continuous, detailed visualization of the cardiac tissue. However, other procedures are not well suited for fluoroscopy because of the clinical need for continuous high resolution imaging of the cardiac anatomy along with the interventional instruments. One example of such a procedure is cardiac ablation to treat atrial fibrillation, which is typically performed in a specialized suite referred to as an EP Lab. Another example is the precision delivery of biologics, including stem cells and gene therapies, directly into the wall of the heart, which represents a promising therapy being researched for the treatment of heart failure.

The ClearTrace system will be similar to the conventional Cath Lab or EP Lab, but with two critical distinctions. First, unlike the Cath Lab or EP Lab, the ClearTrace system will provide a continuous, four dimensional imaging environment (the fourth dimension being time), that will include detailed visualization of cardiac tissue, along with the cardiac catheters used to deliver the therapy. We believe this capability is required for the next generation of interventional cardiac therapies. Second, the ClearTrace system will eliminate all dangerous radiation exposure for both the patient and physician from the X-ray utilized in current procedures. Under current catheter-based treatments utilizing fluoroscopy, X-ray exposure can exceed 45 minutes. Scientific studies have shown that extended exposure to radiation can result in damage to organs or cause cancer. We believe that the attributes of the ClearTrace system position it to be the therapy of choice for cardiac ablation procedures to treat atrial fibrillation and future biologic therapies for heart failure and other similar cardiac disorders.

Like our ClearPoint system, the ClearTrace system will be an integrated system of hardware components, disposable components and intuitive software. The disposable components will consist of an ablation catheter, a mapping catheter, a coronary sinus catheter and a septal puncture kit, all of which will be MRI-compatible. The reusable components will include a tightly integrated software system and device interfaces to the MRI scanner. The ClearTrace system is designed for procedures that initially will be performed using a 3T MRI scanner.

We began preliminary research for an MRI-guided cardiac ablation procedure shortly following our inception in 1998. As a culmination of our research efforts, in May 2009, we entered into an exclusive co-development agreement with Siemens, the global market leader in MRI scanners, for the development and

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commercialization of the hardware and MRI software necessary for the ClearTrace system. Under the terms of this agreement, we are working together with Siemens on the development of the ClearTrace software and the integration of system components. Once product development is completed, we will work together with Siemens on the commercial launch and field support of the ClearTrace system. Because of Siemens' market-leading position, we believe that our exclusive relationship secures a strategic market position for the ClearTrace system.

### *Components*

The ClearTrace system is an integrated system of reusable hardware components, disposable hardware components and intuitive, menu-driven software.

*Reusable Hardware Components.* Our primary reusable hardware component is our ClearConnect system, which is an MRI-compatible hardware and cable management system to safely enable MRI-guided cardiac ablation procedures in a Siemens 3T MRI scanner.

*Disposable Hardware Components.* Our disposable hardware components consist primarily of a septal puncture kit, mapping catheter, a coronary sinus catheter and ablation catheter. Our septal puncture kit consists of a septal puncture needle, a dilator and sheath and will be used to perform an MRI-guided puncture of the septum of the heart to allow movement between the right atrium and left atrium. Our mapping catheter will be used for MRI-guided collection of intracardiac electrocardiogram signals and will include analog/digital filtering to enable electrocardiogram collection during scanning. Our coronary sinus catheter will be used to collect additional electrocardiogram signals and to provide cardiac pacing and defibrillation, as needed during the procedure. Our ablation catheter will be used to perform MRI-guided delivery of ablative energy to create cardiac lesions. All catheters and components will be MRI-compatible and tightly integrated with the MRI scanner.

*Software.* The ClearTrace system includes intuitive, menu-driven software to assist the physician in: surgical planning; creating three dimensional volumes of cardiac chambers; navigating our ClearTrace catheters within the cardiac chambers; visualizing lesions as they are formed; tracking of prior lesion locations; evaluating ablated cardiac tissue; and monitoring for possible adverse events. Under our co-development agreement, Siemens is responsible for developing the ClearTrace system software to our specifications. The ClearTrace system software will be integrated with our disposable hardware components.

### *Current Atrial Fibrillation Treatments*

Cardiac arrhythmia is an abnormal beating of the heart that can result in insufficient blood flow, which may cause dizziness, inadequate function of important organs in the body, stroke and even death. Atrial fibrillation affects over three million people in the United States alone, making it the most common form of cardiac arrhythmia. Atrial fibrillation is characterized by the irregular fluttering and/or very rapid beating of the atria resulting from the malfunctioning of the electrical conduction system in the walls of the atria. Atrial fibrillation is a leading cause of stroke among persons 65 years or older and it is associated with increased risk of morbidity and mortality as well as a reduced quality of life.

Most atrial fibrillation treatments are palliative and do not cure atrial fibrillation. The most common are anti-arrhythmic and anticoagulant drugs. However, anti-arrhythmic drug therapy often becomes less effective over time, with approximately half of the patients developing resistance to the drugs. In addition, anti-arrhythmic drugs have potentially severe side effects including pulmonary fibrosis, impaired liver function, thyroid problems and the development of worse and even life-threatening ventricular arrhythmias.

One highly effective, curative therapy for atrial fibrillation used today is an open-heart operation, commonly known as the surgical "Cox-Maze" procedure, which has reported success rates as high as 96%. During this open heart procedure, the physician makes a series of cuts in a specific "maze-like" formation along the inside walls of



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the left atrium with a scalpel, and then sutures these cuts back together. The scars create an uninterrupted conduction block containing the chaotic electrical impulses that cause atrial fibrillation, thereby returning the heart to a normal rhythm. The open heart Cox-Maze procedure is usually done in tandem with another open heart procedure, such as a valve replacement or coronary artery bypass, because this operation is traumatic to the patient, very expensive, and typically associated with long hospital stays and a three to six month recovery time.

Because of the effectiveness of the Cox-Maze method, the medical community has been working for years to develop a less invasive approach that generates comparable clinical outcomes. The current minimally invasive approach is performed in the EP Lab with the physician relying upon fluoroscopic imaging to guide a catheter through a blood vessel into the right atrium, puncturing the septum and advancing the catheter into the left atrium of the heart. The physician then delivers energy through the catheter to create lesions and scar the target tissue. During the procedure, the physician is assisted in guiding and positioning the catheter primarily by fluoroscopic imaging. However, fluoroscopic imaging has significant limitations, namely it does not permit the physician to see the cardiac anatomy and tissue, the location of the catheter in relation to the cardiac tissue, or the intra-procedural creation of the lesions necessary to create the conduction block. Furthermore, the use of fluoroscopy exposes both patient and physician to dangerous radiation for an extended period of time.

The open Cox-Maze procedure has been considered the gold standard for surgical treatment of atrial fibrillation with reported success rates as high as 96%. However, because the Cox-Maze procedure is highly invasive, it is infrequently used as a stand alone therapy to treat atrial fibrillation. The current catheter-based approach is promising due to its less invasive nature, but the approach has been hampered by disappointing success rates, some as low as 50% to 75%. We believe that the success rate of the current catheter-based approach is dramatically lower because the physician cannot see the cardiac tissue.

#### *The ClearTrace System Solution*

The ClearTrace system represents a new paradigm in performing cardiac interventions by using MRI to allow the physician to see the cardiac tissue, as if performing an open heart Cox-Maze procedure, but with a minimally invasive approach. The ClearTrace system offers a novel, comprehensive solution for the planning, delivering and intra-procedural assessment of catheter-based cardiac interventions. The following discussion outlines the key steps in performing a ClearTrace system procedure to treat atrial fibrillation.

At the start of a ClearTrace procedure, a MRI scan is performed of the patient's heart and surrounding vasculature. Using the images from the scan, the ClearTrace system software generates a three dimensional volumetric model of the patient's cardiac chambers that the physician will use as a guide while performing the procedure. Additional MRI images and patient data can be mapped onto the surface of the three dimensional model as needed by the physician. Referencing the three dimensional model and surface mapped image data and using real time MRI scans of the patient's heart, the physician plans the cardiac ablation procedure.

The ClearTrace coronary sinus catheter is then advanced through a blood vessel under MRI guidance and placed in the coronary sinus to collect electrocardiogram signals and to provide cardiac pacing and defibrillation, as may be needed during the procedure. The remaining ClearTrace catheters are then advanced through a blood vessel under MRI guidance into the right atrium of the heart. In accordance with the ClearTrace system plan, the physician will advance the catheters through the targeted site on the septum and into the left atrium. Referencing the ablation plan, and with continuous intra-procedural visualization of the catheters and patient anatomy, the physician will advance the catheters to the site of the first planned ablation. With the ClearTrace ablation catheter in the correct location, the physician will begin applying energy to the tip of the catheter to create a lesion.

During ablation, the ClearTrace system will present intra-procedural MR images that will allow the physician to see the changes in the tissue caused by the ablative energy, giving the physician the visualization capabilities similar to what he has in the open heart Cox-Maze procedure. The physician will then repeat the process of creating and visualizing lesions within the left atrium until the ablation plan has been completed. The physician will complete the procedure by taking a final scan to confirm the proper placement of all lesions.

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By allowing the physician to see the lesions during the procedure, we believe the physician can make better decisions about where to ablate, what amount of energy to apply and how long to apply the energy. We believe this improved decision making capability will result in improved outcomes and reduced adverse events. In addition to the ability to visualize the changes in the cardiac tissue, the physician will also be able to use a loop catheter to measure electrical signals from the inside surface of the left atrium to further guide and confirm the effectiveness of the ablation process.

### *Other Potential Applications*

We believe the ClearTrace system's unique ability to provide continuous, high resolution imaging of the cardiac anatomy, including the walls of the heart, during an interventional procedure will be valuable in treating other cardiac disorders. For example, we believe the ClearTrace system could serve as an ideal platform for delivering drugs and biologics directly into the heart wall. The medical community is developing novel compounds that have the potential to address significant cardiac disorders, such as heart failure. However, some of these compounds must be injected directly into the heart wall, with precision placement at the boundary of healthy and diseased tissue. Using the ClearTrace system, a physician will be able to navigate within the heart to the boundary between healthy and diseased tissue, place the catheter tip on the boundary, inject the compound and watch the dispersion of the compound into the heart wall.

### *Regulatory Status*

Development activities for the ClearTrace system are ongoing, and we have made no filings seeking appropriate regulatory approval or clearance for the ClearTrace system. We believe that most components of the ClearTrace system will be Class II medical devices and fall under the FDA's 510(k) regulatory process. However, the ablation catheter component will be a Class III medical device and require FDA approval of a PMA. Therefore, we will be required to conduct a clinical trial to support the PMA for the ablation catheter, which we anticipate commencing in the second half of 2011.

### *SafeLead Development Program*

Our third area of activity is referred to as the SafeLead Development Program. Over the last ten years, we have pioneered several technologies that improve the MRI-safety profile of implantable medical leads. These leads are thin, insulated wires that are connected to implantable generators, such as a pacemaker or neurostimulator, and deliver electrical pulses or stimulation to a specific area of the body, such as the heart or the brain. The current market for active implantable cardiac and neurological devices exceeds \$11 billion in annual revenues with more than 500,000 devices implanted per year.

It is estimated that between 50% and 75% of patients with an implantable device are expected to need an MRI scan during the lifetime of their devices. However, implantable medical leads are susceptible to heating in the MRI environment. An MRI scanner transmits radio frequency energy during the scanning process. Because the implantable lead contains metallic wire, which acts like an antenna, some of the radio frequency energy transmitted by the MRI scanner is absorbed by the lead. This could cause the lead to heat. The extent to which an implantable lead may heat can depend on many factors, such as the lead itself, the position of the patient in the MRI scanner, the clinical scanning sequence used and the location and trajectory of the lead in the patient. Scientific studies have shown that implantable leads may heat during an MRI scan to temperatures that can burn or destroy tissue. If that happens in the heart or brain, the patient could suffer a stroke, paralysis or even death. As a result, people with active implantable devices are prohibited from undergoing an MRI scan.

Our technologies address this issue by maintaining lead temperatures well within safe levels during an MRI scan. Current safety standards for active implantable medical devices require that MRI-related heating may not exceed 1 degree Celsius in the brain and 2 degrees Celsius in the heart. Our testing has shown that our technologies limit lead heating to less than 1 degree Celsius. Therefore, we believe our MRI-safety technologies

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will permit a patient with an implantable medical device to undergo an MRI scan. Manufacturers' studies have shown that cardiologists identify "MRI compatibility" as one of the main features that would drive a change in brand preference.

While we have been developing our MRI-safety technologies underlying the SafeLead Development Program for the last ten years, the SafeLead Development Program commenced in December 2005 when we signed our first agreements with Boston Scientific for the incorporation of our MRI-safety technologies into Boston Scientific's implantable leads for neurological applications. In March 2008, we entered into similar agreements with Boston Scientific for the incorporation of our MRI-safety technologies into Boston Scientific's implantable cardiac leads. In connection with the cardiac agreements, we received licensing fees of \$13,000,000 in 2008. In addition, we are entitled to receive up to \$21,600,000 in future milestone-payments under both the cardiac and neuro agreements, subject to our achievement of the milestones stipulated in the agreements and the issuance of certain patents licensed to Boston Scientific. Boston Scientific has also agreed to pay us royalties on net sales of products that are covered by a licensed patent. We believe our safety technologies, if integrated into Boston Scientific's implantable leads, could represent a meaningful market differentiator over existing implantable lead designs.

The SafeLead Development Program is still in its developmental stages and no regulatory filings have been made with the FDA with respect thereto. Boston Scientific is responsible for making any regulatory filings with the FDA with respect to its products that incorporate our MRI-safety technologies. Boston Scientific will control the timing and manner of any regulatory filing, and will be responsible for the costs associated with any regulatory filing. We do not anticipate that we will be able to influence the process or timing in any meaningful way. We believe that any Boston Scientific product incorporating our MRI-safety technologies will be a Class III medical device and require a PMA submission.

### **Our Strategy**

Our key objective is to develop and commercialize medical systems to enable minimally invasive surgical procedures to be performed under direct, intra-procedural MRI guidance. Key elements of our strategy to achieve this objective are to:

- **Obtain regulatory clearance of our ClearPoint system.** We are seeking marketing clearance of our ClearPoint system through the FDA's 510(k) premarket notification process. We are focused on obtaining regulatory clearance and preparing for the potential commercial launch of our ClearPoint system for a general neurological intervention claim. If our initial 510(k) clearance is obtained, we may seek additional regulatory clearances or approvals for use of our ClearPoint system for a variety of specific neurological indications, including deep brain stimulation lead placement, to allow us to market and promote our ClearPoint system for those specific uses.
- **Maximize installation and adoption of our ClearPoint system.** If regulatory clearance is obtained, we plan to focus our initial marketing efforts on key physicians and hospitals to adopt use of our ClearPoint system for general neurological interventional procedures. Our strategy is to convince those physicians that our ClearPoint system offers a better procedural solution to their patients. With the physicians serving as our internal champions, we will work with the physicians to encourage hospitals to install and adopt our ClearPoint system. In hospitals where our ClearPoint system has been installed, we will focus on selling our disposable components to generate recurring revenue.
- **Continue development of the ClearTrace system with Siemens.** We will continue to co-develop the ClearTrace system with Siemens. Together we will work to generate awareness among leading physicians of the benefits of an MRI-guided approach to cardiac ablation for the treatment of atrial fibrillation. Upon regulatory approval, we will work with Siemens to promote installation of the MRI software and our reusable components for the ClearTrace system within Siemens' MRI customer base. In hospitals where the ClearTrace system has been installed, we will focus on selling our disposable components to generate recurring revenue.

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- ***Pursue SafeLead Development Program with Boston Scientific.*** We will continue collaboration with Boston Scientific with respect to the incorporation of our MRI-safety technologies into Boston Scientific's implantable leads for cardiac and neurological applications.
- ***Build upon our core technologies to continue to develop MRI-based products.*** Our research and development efforts to date have focused on developing novel MRI-related technologies. We have significant intellectual property protection in this particular area. As the field of MRI-guided interventions grows, we intend to develop future enhancements to our ClearPoint system and the ClearTrace system, as well as researching opportunities for new products.

### **Licenses and Collaborative Relationships**

In addition to our internally-developed technologies and devices, we have established and intend to continue to pursue licenses and collaborative relationships with medical device companies and academic institutions to further the development and commercialization of our core technologies and product platforms.

#### **Siemens**

In May 2009, we entered into a cooperation and development agreement with Siemens to develop the hardware and MRI software systems for MRI-guided, catheter-based ablation to treat atrial fibrillation and other cardiac arrhythmias. Under this agreement, Siemens is responsible for developing the software in accordance with our specifications, and we are responsible for developing the catheters and other hardware, other than the MRI scanner and workstation, necessary for the MRI-guided cardiac ablation procedures and for the integration work necessary to combine the software, catheters and other hardware to create the ClearTrace system. We are obligated to pay Siemens up to approximately \$2,500,000 in milestone-based payments associated with Siemens' successful development of the software. These payments started in the second quarter of 2009 and will continue through the third quarter of 2011. Once the software is commercially available, Siemens will pay to us a fixed amount for each software license sold by Siemens until we recoup our investment. The term of the agreement will expire once (i) all software, catheter and other hardware development and integration work has been successfully completed, (ii) requisite regulatory clearances or approvals have been obtained in at least the United States, Canada and Europe, and (iii) the product has been clinically released in at least the United States, Canada and Europe. The agreement provides for exclusivity for a period of five years following the date of regulatory clearance and/or approval, determined on a country-by-country basis. During the exclusivity period, Siemens may not market or offer software that is intended to work with a third party's catheters to conduct an MRI-guided cardiac ablation procedure, and we may not sell or offer any catheters that are intended to be used with an MRI scanner manufactured by a third party to conduct an MRI-guided cardiac ablation procedure. For two years after the exclusivity period ends, neither we nor Siemens may enter into an agreement or relationship with a third party that excludes or prevents the use of our devices with Siemens' MRI systems, and vice versa, in the field of MRI-guided cardiac ablation procedures. Prior to or upon expiration of the term of the cooperation and development agreement, we anticipate entering into a separate sales and marketing agreement with Siemens.

#### **Boston Scientific**

We have entered into development and license agreements with affiliates of Boston Scientific. We are working together with Boston Scientific in the application of our technologies for potential use in Boston Scientific's active implantable devices.

*Neuro.* In December 2005, we entered into a development agreement and license agreement with Boston Scientific in the neurological field:

- ***System and Lead Development and Transfer Agreement.*** We are working jointly with Boston Scientific to design and develop MRI-compatible and MRI-safe implantable leads for neurological applications, such as implantable deep brain stimulation leads. Under the development agreement, we could receive

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up to \$1,600,000 in future milestone-based payments associated with successful development and regulatory approval of the leads. In addition, we could receive over \$500,000 in incentive payments for incremental development work Boston Scientific may request. However, if our development milestones are not completed by December 31, 2012, the development agreement requires us to repay Boston Scientific certain amounts, including any milestone payments previously paid to us by Boston Scientific under this agreement and any patent prosecution costs incurred by Boston Scientific with respect to the intellectual property licensed to Boston Scientific pursuant to the technology license agreement described below. We cannot calculate the possible repayment amount at this time, but it could be significant.

- *Technology License Agreement.* Under the license agreement, we granted Boston Scientific an exclusive worldwide license with respect to certain of our owned or licensed intellectual property in the neurological field to make, use, import, lease and sell neuro-related leads, neuro-related lead extensions, and neuro-related lead-type devices, such as implantable pulse generators. The license included a sublicense of applicable intellectual property that we licensed from Johns Hopkins. Boston Scientific has agreed to pay us royalties on net sales of products that are covered by a licensed patent; however, Boston Scientific has no obligation to include the licensed intellectual property in its products or product candidates. Pursuant to the system and lead development and transfer agreement described above, Boston Scientific is responsible for patent prosecution of the licensed intellectual property and the payment of costs associated with patent prosecution.

*Cardiac.* In March 2008, we entered into a development agreement and license agreement with Boston Scientific in the field of implantable medical leads for cardiac applications.

- *Development Agreement.* Under the development agreement, we are working jointly with Boston Scientific to assess the feasibility of and, upon successful completion of feasibility studies, to design and develop three different MRI-compatible, MRI-safe implantable leads, a lead intended for bradycardia, a lead intended for tachycardia and a lead intended for heart failure. We could receive up to \$20,000,000 in future milestone-based payments associated with the successful development and regulatory approval of those implantable lead types. No earned milestone payments will be made unless and until the applicable lead is covered by an issued patent licensed to Boston Scientific pursuant to the technology license agreement described below. The development agreement is scheduled to expire upon FDA approval of a design for each of the three different lead types. However, Boston Scientific has the one-time option, within 60 days after successful completion of the first lead feasibility study, to cease further development and to terminate the development agreement.
- *Technology License Agreement.* Under the license agreement, we granted Boston Scientific an exclusive worldwide license with respect to certain of our owned or licensed intellectual property in the field of implantable medical leads for cardiac applications to make, have made, use, promote, market, import, distribute, lease, sell, offer for sale and commercialize products in that particular field of use. The license included a sublicense of applicable intellectual property that we licensed from Johns Hopkins. We received licensing fees of \$13,000,000 in 2008. Boston Scientific has also agreed to pay us royalties on net sales of products that are covered by a licensed patent; however, Boston Scientific has no obligation to include our licensed intellectual property in its products or product candidates. Boston Scientific is responsible for patent prosecution of the licensed intellectual property and the payment of costs associated with patent prosecution. If Boston Scientific elects to exercise its termination option under the development agreement described above, the license we granted Boston Scientific will automatically become non-exclusive with respect to some intellectual property, other intellectual property will be removed the scope of the license and revert to us, and Boston Scientific will not be obligated to pay us future royalties or sublicense revenues based on sales of products covered by any issued patent that remains subject to the non-exclusive license.

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### ***University of California, San Francisco***

In August 2007, we entered into a research agreement with the University of California, San Francisco, or UCSF, which has been amended from time to time since that date. Under our agreement, UCSF personnel are conducting research activities to assess the safety and clinical efficacy of interventional MRI guidance for the performance of certain minimally invasive neurological procedures. We agreed to make periodic payments to UCSF to fund its research. In addition, to further support UCSF's research activities, we agreed to make an in-kind contribution to UCSF of some of the reusable components of our ClearPoint system and other MRI-related equipment. In return for supporting UCSF's research, we received the first option to license, exclusively or non-exclusively, any intellectual property conceived or created by UCSF personnel under the research project. Our agreement with UCSF will terminate November 1, 2011, unless UCSF and we agree to extend the term.

### ***The University of Utah***

In July 2007, we entered into a research agreement with The University of Utah, or Utah, which has been amended from time to time since that date. Under the agreement, Utah personnel are conducting research activities and experiments to develop knowledge, techniques, methods and technologies related to MRI-guided cardiac ablation, including a specific focus on MRI-guided cardiac ablation to treat atrial fibrillation. We agreed to make periodic payments to Utah to fund its research activities. In return, Utah granted us a non-exclusive, worldwide license to any intellectual property created or conceived by Utah personnel in the performance of the research. In addition, we also received the first option to license exclusively any such intellectual property. Our agreement with Utah will terminate December 31, 2010, unless Utah and we agree to extend the term.

### ***The Johns Hopkins University***

We have in place five exclusive license agreements with Johns Hopkins. For additional information regarding these licenses, see "Business – Intellectual Property."

## **Sales and Marketing**

Commercializing our ClearPoint system will involve marketing to:

- physicians who care for patients suffering from neurological disorders, including neurosurgeons, who perform the neurological procedures, and neurologists, who interact with patients prior to and following the therapy and who refer patients to therapy;
- hospitals involved in the treatment of neurological disorders and the opinion leaders at these hospitals; and
- patients who suffer from neurological disorders.

There are approximately 3,500 neurosurgeons in the United States. Similar to many fields of medicine, some neurosurgeons elect to focus on a particular specialty within the neurological field. For example, some neurosurgeons focus their practice on spine surgeries, others more on open craniotomy surgeries and others more on minimally invasive approaches, such as functional neurosurgery. We believe our ClearPoint system is most applicable to those functional neurosurgeons, of which there are approximately 300 in the United States. Part of our business objective is to encourage adoption of our ClearPoint system by functional neurosurgeons by securing placement of our system within their hospitals. We believe our ClearPoint system represents an attractive platform for the functional neurosurgery team within a hospital to perform various general neurological interventions.

Once our ClearPoint system is commercially available in the United States, we will add to our existing sales and marketing capabilities to build a small, highly focused sales force to market our ClearPoint system in the United States. Given the number of functional neurosurgeons in the United States, we believe a small, direct sales force will be sufficient and effective for us to reach our target market. If we obtain regulatory clearance, our initial, controlled commercial launch of our ClearPoint system will be coordinated primarily by our Vice

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President, Product Management and our two Clinical Engineering Managers, one of whom is located on the east coast of the United States and the other of whom is located on the west coast of the United States. We have not finalized a sales and marketing plan to commercialize our ClearPoint system outside the United States; however, any such plan could involve the establishment of collaborations with third-parties.

Given the stage of development of the ClearTrace system, we have not developed a sales and marketing plan to commercialize ClearTrace either inside or outside the United States. We will not develop a sales and marketing plan to commercialize any of our SafeLead Development Program technologies as Boston Scientific is in control of the commercialization of those technologies for its implantable medical leads.

### **Research and Development**

Continued innovation through research and development is critical to our future success. As of March 31, 2010, our research and development team, which is based primarily in our Irvine, California facility, consisted of 11 employees. We have assembled an experienced team with recognized expertise in both the development of medical devices and advanced MRI technologies, including interventional MRI microcoils and catheters. We believe that our current research and development team is sufficient for our current needs; however, we may increase the size of our team depending on the progress of our ongoing research and development efforts.

Our principal research and development goals are:

- to complete development of the ClearTrace system in cooperation with Siemens;
- to continue to enhance our ClearPoint system; and
- to provide technical support and expertise in the area of MRI safety to Boston Scientific under our SafeLead Development Program.

We have historically spent a significant portion of our capital resources on research and development. Our research and development expenses were approximately \$2,099,000 for the year ended December 31, 2007, \$4,258,000 for the year ended December 31, 2008 and \$6,068,000 for the year ended December 31, 2009.

### **Manufacturing and Assembly**

Our ClearPoint system includes off-the-shelf components, custom-made components produced to our proprietary specifications by various third-parties, and components that we assemble in our Irvine, California facility. We use third parties to manufacture these components to utilize their individual expertise, minimize our capital investment and help control costs. We purchase most custom-made components of our ClearPoint system from a single source due to quality considerations, lower costs and constraints resulting from regulatory requirements; however, we believe alternative sources are available, if needed. Generally, we purchase our components through purchase orders and do not have long-term contracts with most of our suppliers.

Our Irvine, California facility is structured to complete component processing, final assembly, packaging and distribution activities for our ClearPoint system. The assembly process is performed in a controlled environment as required for medical device assembly by applicable regulation. Our operations are subject to extensive regulation by the FDA under its QSR, which requires that manufacturers have a quality management system for the design and production of medical devices. In addition, in the event we expand our business outside the United States, we will also become subject to international regulatory requirements.

Our Irvine, California facility is FDA-registered, and we believe it is compliant with the FDA's QSR. We have instituted a quality management system, under which we have established policies and procedures that control and direct our operations with respect to design, procurement, manufacture, inspection, testing, installation, data analysis, training and marketing. We review and internally audit our compliance with these policies and procedures, which provides a means for continued evaluation and improvement. As required by our

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quality management system, we undertake an assessment and qualification process for each third party manufacturer or supplier that we use. Typically, our third-party manufacturers and suppliers are certified to ISO standard 9001 and/or 13485. We also periodically perform audit procedures on our third-party manufacturers and suppliers to monitor their activities for compliance with our quality management system. Our facility and the facilities of the third-party manufacturers and suppliers we use are subject to periodic inspections by regulatory authorities, including the FDA and other governmental agencies.

### **Intellectual Property**

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain the proprietary aspects of our technologies. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect our intellectual property.

Our patent portfolio includes rights to patents and patent applications that we own, whether wholly-owned or co-owned, or license from others. We seek patent protection in the United States and internationally for our products and technologies where and when we believe it is appropriate. United States patents are granted generally for a term of 20 years from the earliest effective priority date of the patent application. The actual protection afforded by a foreign patent, which can vary from country to country, depends on the type of patent, the scope of its claims and the availability of legal remedies in the country.

We also rely on other forms of intellectual property rights and measures, including trade secrets and nondisclosure agreements, to maintain and protect proprietary aspects of our products and technologies. We require our employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with us. We also require our employees and consultants to disclose and assign to us all inventions conceived during the term of their employment or engagement while using our property or which relate to our business.

### ***Owned Patents and Patent Applications***

As of March 31, 2010, we wholly owned seven issued United States patents, 25 pending United States patent applications (including four provisional applications), one issued foreign patent and 38 pending foreign patent applications (including seven patent cooperation treaty applications). In addition, as of March 31, 2010, we co-owned with third-parties a total of four issued United States patents, nine pending United States patent applications, one issued foreign patent and 22 pending foreign patent applications (including one patent cooperation treaty application).

Of those patents and patent applications, as of March 31, 2010, three issued United States patents, one pending United States patent application, one issued foreign patent and four pending foreign patent applications were co-owned by us and Johns Hopkins, one issued United States patent, seven pending United States patent applications and 17 pending foreign patent applications (including one patent cooperation treaty application) were co-owned by us and Boston Scientific, and one pending United States patent application and one pending foreign patent application were co-owned by us and other third parties.

We have licensing and cross-licensing arrangements in place with Boston Scientific with respect to the patent and patent applications we co-own with them. As a result of those arrangements, we have exclusive rights to all fields outside neuromodulation and implantable medical leads for cardiac applications, and we have licensed the fields of neuromodulation and implantable medical leads for cardiac applications to Boston Scientific. Our owned, issued patents expire at various dates beginning in 2020.

### ***Patents and Patent Applications Licensed from Third-Parties***

As of March 31, 2010, we had licensed rights to 11 United States and 12 foreign third-party issued patents, and we had licensed rights to eight United States and 14 foreign third-party pending patent applications. Our licensed, issued patents expire at various dates beginning in 2015.



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### ***License Arrangements***

#### *License Arrangements with The Johns Hopkins University*

Our principal licensing arrangement is with Johns Hopkins. Shortly following our formation in 1998, we entered into a license agreement with Johns Hopkins pursuant to which we obtained an exclusive, worldwide license to a number of technologies owned by Johns Hopkins relating to devices, systems and methods for performing MRI-guided interventions, such as MRI-guided cardiac EP procedures. The field of use for this exclusive license covers diagnostic or therapeutic methods, processes or devices using an intravascular, intralumen or intratissue miniature magnetic resonance coil detection probe. We are obligated to pay Johns Hopkins an annual maintenance fee, and we are also obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services covered by licensed patent. To the extent we sublicense any licensed intellectual property to a third-party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of the sublicense. Under our license agreements with Boston Scientific, we sublicensed intellectual property that is licensed from Johns Hopkins. Therefore, we are obligated to pay Johns Hopkins a percentage of any revenue we receive from sales by Boston Scientific of products covered by a sublicensed patent. This license agreement with Johns Hopkins will terminate upon the expiration of the last to expire of the licensed patents.

In December 2006, we entered into a second license agreement with Johns Hopkins under which we obtained an exclusive, worldwide license to certain MRI-safety technologies owned by Johns Hopkins. Under the agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services covered by a licensed patent, subject to a minimum annual payment. Likewise, to the extent we sublicense any intellectual property to a third party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of the sublicense. Under our license agreements with Boston Scientific, we sublicensed intellectual property that is licensed from Johns Hopkins. Therefore, we are obligated to pay Johns Hopkins a percentage of any revenue we receive from sales by Boston Scientific of products covered by a sublicensed patent. This license agreement with Johns Hopkins will terminate upon the expiration of the last to expire of the licensed patents.

We entered into three additional exclusive license agreements with Johns Hopkins in June 2008 as described below. Our development efforts with respect to the technologies we licensed under those agreements are at a very early stage.

- Under the first agreement, we obtained an exclusive, worldwide license to certain catheter technology owned by Johns Hopkins. Under this agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services incorporating the licensed technology and a contingent license fee in the event a United States patent issues covering the licensed technology. Likewise, to the extent we sublicense any licensed technology to a third party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of a sublicense of the licensed technology. This license agreement with Johns Hopkins will terminate upon the expiration of the last licensed patent or, if no patent issues, on June 30, 2028.
- Under the second agreement, we obtained an exclusive, worldwide license to certain technology owned by Johns Hopkins relating to catheter-based MRI probes. Under this agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services incorporating the licensed technology and a contingent license fee in the event a United States patent issues for the licensed technology. Likewise, to the extent we sublicense any licensed technology to a third party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of a sublicense of the licensed technology. This license agreement with Johns Hopkins will terminate upon the expiration of the last licensed patent or, if no patent issues, on June 30, 2028. In addition, Johns Hopkins has the option to terminate the license in the event that a commercial sale of a licensed product or a licensed service does not occur by June 30, 2012.

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- Under the third agreement, we obtained an exclusive, worldwide license to certain technology owned by Johns Hopkins to measure the amount of radio frequency absorption in the human body during an MRI scan. Under this agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services incorporating the licensed technology. Likewise, to the extent we sublicense any licensed technology to a third party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of a sublicense of the licensed technology. This license agreement with Johns Hopkins will terminate upon the expiration of the last licensed patent or, if no patent issues, on June 30, 2028.

#### *License Arrangements with Cedara Software Corp.*

In July 2007, we entered into a master service and license agreement with Cedara Software Corp. (d/b/a Merge OEM), or Cedara, for Cedara to develop on our behalf, based on our detailed specifications, a customized software solution for our ClearPoint system. Cedara is in the business of providing software development and engineering services on a contract basis to a number of companies. In developing our ClearPoint system software, Cedara utilized certain of its own pre-existing software code. Under our agreement with Cedara, we received a non-exclusive, worldwide license to that code as an integrated component of our ClearPoint system software. In return, we agreed to pay Cedara a license fee for each copy of our ClearPoint system software that we distribute. Except for Cedara's pre-existing software code, the work performed by Cedara was a "work-made-for-hire" and we exclusively own our ClearPoint system software. The agreement provides for annual minimum licensing fees. Our license from Cedara continues through July 2015, absent a mutual extension of the license term. If necessary, we could replace the licensed Cedara code.

#### *License Arrangements with the National Institutes of Health*

In April 2009, we entered into a patent license agreement with the National Institutes of Health, or NIH, that covers techniques for three dimensional renderings of the patient's anatomy from MRI data in real time. The techniques underlying this patent may be used in the development of the ClearTrace system. Under the terms of this agreement, we have a non-exclusive license to a pending United States patent application within the field of devices and systems for MRI-guided medical procedures. Our licensed territory includes Australia, Canada, China, Europe, Israel, Japan and the United States, although there is no patent or patent application pending for the licensed intellectual property outside the United States. Pursuant to this agreement, we are obligated to make royalty payments to NIH based on the sale of products and the practice of processes covered by the licensed intellectual property, whether by us or any sublicensee. In addition, NIH is entitled to receive a single milestone payment in the event we receive a regulatory clearance or approval of a product or process covered by the licensed intellectual property.

## **Competition**

### ***General***

The length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement clearance or approval is an important competitive factor. However, even if we are successful in obtaining regulatory clearances or approvals, the medical device industry is characterized by rapid and significant technological change. Thus, the development by others of new treatment methods, including novel drugs, medical devices or surgical techniques could render our product candidates non-competitive or obsolete. As a result, product development involves a high degree of risk and there can be no assurance that our current or new product development efforts will result in any commercially successful products.

### ***ClearPoint System***

Our success depends on convincing hospitals, neurosurgeons, neurologists and patients to utilize our ClearPoint system. Currently, we are not aware of any company that offers a direct MRI-guided stereotactic system for neurological interventions, although two companies, Monteris Medical Inc. and Visualase, Inc., do

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offer devices for laser ablation under direct MRI guidance. However, we do face competition from companies, such as BrainLAB AG, Elekta AB FHC Inc. and Medtronic, Inc., which offer instruments and systems for use in conventional stereotactic neurological procedures, such as surgical navigation workstation and frame-based and frameless stereotactic systems. Additionally, we could also face competition from other medical device and pharmaceutical companies that have the technology, experience and capital resources to develop alternative therapy methods, including MRI-guided technologies. Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we have.

#### ***ClearTrace System***

Our success depends on convincing hospitals, cardiologists and patients to utilize the ClearTrace system for performing cardiac ablation procedures. While we are not aware of any companies that currently offer a direct MRI-guided cardiac ablation system, companies such as GE Healthcare, Imricor Medical Systems, Inc. and Philips Healthcare may be in the process of developing such a system. If any of these companies obtains regulatory clearance or approval and commercial success, our products could be rendered non-competitive or obsolete, which could have a material adverse effect on our business, financial condition and results of operations.

We also will face competition from companies who are engaged in the development and marketing of conventional catheter-based cardiac ablation systems and devices. These products include mapping systems using contact mapping, single-point spatial mapping and non-contact, multi-site electrical mapping technologies and ablation systems using radio frequency, ultrasound, laser and cryoablation technologies. These products evolve rapidly, and their manufacturers are constantly attempting to make them easier to use or more efficacious in performing procedures. Today, the vast majority of minimally invasive catheter-based cardiac ablation procedures are performed with these products. Because these products are currently in use while the ClearTrace system remains under development, physician preferences will have to shift for the ClearTrace system to gain market acceptance.

We are aware of two companies, Hansen Medical, Inc. and Stereotaxis, Inc., that market systems that use magnets to control the working tip of catheters and other control catheters during interventional cardiac ablation and other procedures. Also, other manufacturers are attempting to market devices that access the heart through an endoscopic surgical technique called thoracoscopy to treat atrial fibrillation.

Additionally, we will face competition from large companies who are engaged in the development and marketing of products for other treatments of atrial fibrillation. Their treatments include drugs, external electrical cardioversion and defibrillation, implantable defibrillators, open-heart surgery and purposeful destruction of the atrio-ventricular node, followed by implantation of a pacemaker.

Many of our potential competitors have an established presence in the field of cardiac electrophysiology, including cardiac ablation, such as Biosense Webster Inc., a division of Johnson & Johnson, Boston Scientific, Medtronic, Inc. and St. Jude Medical, Inc. These potential competitors have substantially greater financial and other resources than we do, including larger research and development staffs and more experience and greater capabilities in conducting research and development activities, testing products in clinical trials, obtaining regulatory clearances or approvals, and manufacturing, marketing and distributing products.

#### ***SafeLead Development Program***

Because manufacturers studies have indicated that cardiologists identify “MRI-compatibility” of implantable medical leads as one of the main features that would drive a change in brand preference, we believe that other medical device companies are developing proprietary MRI-safe lead designs. For example, in some European countries, Medtronic is currently marketing a device called an “MR-conditional” pacemaker system, including a pacemaker and implantable leads, which is designed for use with MRI under certain conditions specified in product labeling. This product is relatively new to the market and therefore we are not able to determine the degree to which it has achieved market acceptance. We are working together with Boston

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Scientific to incorporate our MRI-safety technologies into Boston Scientific's implantable leads for cardiac and neurological applications. These development efforts for the SafeLead Development Program are ongoing and therefore we are unable to describe the way in which the Boston Scientific implantable leads will differ from the Medtronic leads. We believe that any Boston Scientific device developed from the SafeLead Development Program will compete with similar devices that may be commercialized by other manufacturers.

### **Regulatory Requirements of the United States Food and Drug Administration**

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to regulation as medical devices under the federal Food Drug and Cosmetic Act, as implemented and enforced by the FDA. The FDA governs the following activities that we perform or that are performed on our behalf, to ensure that the medical products we manufacture, promote and distribute domestically or exported internationally are safe and effective for their intended uses:

- product design, preclinical and clinical development and manufacture;
- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

### ***FDA Premarket Clearance and Approval Requirements***

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either premarket notification, or 510(k) clearance or approval of a premarket approval application, or PMA, from the FDA. The FDA classifies medical devices into one of three classes. Class I devices, considered to have the lowest risk, are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, which include compliance with the applicable portions of the FDA's QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials (General Controls). Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device (Special Controls). Manufacturers of most Class II and some Class I devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA.

### ***510(k) Clearance Pathway***

When a 510(k) clearance is required, we will be required to submit a 510(k) application demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

Once filed, the FDA has 90 days in which to review the 510(k) application and respond. Typically, the FDA's response after reviewing a 510(k) application is a request for additional data or clarification. Depending

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on the complexity of the application and the amount of data required, the process may be lengthened by several months or more. If additional data, including clinical data, are needed to support our claims, the 510(k) application process may be significantly lengthened.

If the FDA issues an order declaring the device to be Not Substantially Equivalent, or NSE, the device is placed into a Class III or PMA category. At that time, a company can request a de novo classification of the product. De novo generally applies where there is no predicate device and the FDA believes the device is sufficiently safe so that no PMA should be required. The request must be in writing and sent within 30 days from the receipt of the NSE determination. The request should include a description of the device, labeling for the device, reasons for the recommended classification and information to support the recommendation. The de novo process has a 60 day review period. If the FDA classifies the device into Class II, a company will then receive an approval order to market the device. This device type can then be used as a predicate device for future 510(k) submissions. However, if the FDA subsequently determines that the device will remain in the Class III category, the device cannot be marketed until the company has obtained an approved PMA. If we are required to follow a de novo process, an additional 60 to 90 days or more will be added on to the original 90 days required for the initial 510(k) review.

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA were to disagree with any of our determinations that changes did not require a new 510(k) submission, it could require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. If the FDA requires us to seek 510(k) clearance or PMA approval for any modifications, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance or PMA approval is obtained and we could be subject to significant regulatory fines or penalties.

There is no guarantee that the FDA will grant 510(k) clearance of our ClearPoint system for a general neurological intervention claim. Likewise, there is no guarantee that the FDA will grant 510(k) clearance or PMA approval of any future uses of our ClearPoint system or future products. Failure to obtain such clearances or approvals could adversely affect our ability to grow our business. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business.

### ***PMA Approval Pathway***

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process, or is not otherwise exempt from the FDA's premarket clearance and approval requirements. A PMA must generally be supported by extensive data, including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of our or our third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. Once a PMA is approved, the FDA may require that certain conditions of approval, such as conducting a post market clinical trial, be met.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a

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PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. We have not submitted any of our product candidates for a PMA approval. However, we may in the future develop devices which will require the approval of a PMA, or seek to add new indications for use of existing products that require the approval of a PMA. There is no guarantee that the FDA will grant PMA approval of these specific indications for use or for our future products and failure to obtain necessary approvals for our future products would adversely affect our ability to grow our business.

### ***Clinical Trials***

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. Such trials generally require an investigational device exemption application, or IDE, approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patient's informed consent in a form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Similarly, in Europe the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

### ***Pervasive and Continuing Regulation***

After a device is placed on the market, numerous regulatory requirements continue to apply. In addition to the requirements below, the MDR regulations require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Additional regulatory requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the device;

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- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

As a manufacturer, we are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA's QSR and other regulations. We have not yet been inspected by the FDA. We believe that we are in compliance with QSR and other regulations.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the United States Federal Trade Commission, or FTC, and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

Failure by us or by our third-party manufacturers and suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

### **International Marketing Approvals**

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ.

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Each European Union member state has implemented legislation applying these directives and standards at a national level. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Devices that comply with the requirements of the laws of the relevant member state applying

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the applicable European Union directive are entitled to bear CE conformity marking and, accordingly, can be distributed throughout the member states of the European Union and other countries that comply with or mirror those directives.

The method of assessing conformity with applicable regulatory requirements varies depending on the classification of the medical device, which may be Class I, Class IIa, Class IIb or Class III. Normally, the method involves a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a device complies with applicable regulatory requirements. An assessment by a Notified Body in one country with the European Union is required in order for a manufacturer to commercially distribute the device throughout the European Union. In addition, compliance with ISO 13485 issued by the International Organization for Standardization, among other standards, establishes the presumption of conformity with the essential requirements for CE marking. Certification to the ISO 13485 standard demonstrates the presence of a quality management system that can be used by a manufacturer for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

We intend to apply for CE marking approval for sale of our ClearPoint system during 2010, and we believe the components of our ClearPoint system will fall into different device classifications, including Class III. We intend to use KEMA as the Notified Body for our CE marking approval process.

## **Healthcare Laws and Regulations**

### ***Third-Party Reimbursement***

In the United States and elsewhere, healthcare providers that perform surgical procedures using medical devices such as ours generally rely on third-party payors, including governmental payors such as Medicare and Medicaid and private payors, to cover and reimburse all or part of the cost of the products. Consequently, sales of medical devices are dependent in part on the availability of reimbursement to the customer from third-party payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. In general, third-party payors will provide coverage and reimbursement for medically reasonable and necessary procedures and tests that utilize medical devices and may provide separate payments for the implanted or disposable devices themselves. Most payors, however, will not pay separately for capital equipment, such as our ClearPoint system. Instead, payment for the cost of using the capital equipment is considered to be covered as part of payments received for performing the procedure. In determining payment rates, third-party payors are increasingly scrutinizing the prices charged for medical products and services in comparison to other therapies. Our products, and the procedures in which our products will be used, may not be reimbursed by these third-party payors at rates sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in many foreign markets, including the countries in the European Union, pricing of medical devices is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to limit payments by governmental payors for medical devices, and the procedures in which medical devices are used. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

### ***Medicare and Medicaid***

The Medicare program is a federal health benefit program administered by CMS that covers and pays for certain medical care items and services for eligible elderly and certain disabled individuals, and individuals with end stage renal disease. The Medicaid program is a federal-state partnership under which states receive matching federal payments to fund healthcare services for the poor. Because some private commercial health insurers and



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some state Medicaid programs may follow the coverage and payment policies for Medicare, Medicare's coverage and payment policies are significant to our business. On July 30, 2008, CMS released a list of potential topics for national coverage determinations. This list included ablation for atrial fibrillation and specifically asked whether the evidence was adequate to demonstrate health benefits in patients who receive the procedure. On October 21, 2009, the Medicare Evidence Development and Coverage Advisory Committee, or MedCAC, held a meeting on the adequacy of the available evidence for catheter ablation for the treatment of atrial fibrillation. Although CMS has not formally opened a national coverage analysis on this topic, the agency clearly is interested in the clinical evidence of atrial fibrillation treatments and any national coverage decisions it makes could have a material effect on our potential business in this area.

Medicare coverage for the procedures in which our products would be used currently exists in the hospital inpatient setting, which falls under Part A of the Medicare program. Under Medicare Part A, Medicare reimburses acute care hospitals a prospectively determined payment amount for beneficiaries receiving covered inpatient services in an acute care hospital. This method of payment is known as the prospective payment system, or PPS. Under PPS, the prospective payment for a patient's stay in an acute care hospital is determined by the patient's condition and other patient data and procedures performed during the inpatient stay using a classification system known as DRGs. Payments also are adjusted to reflect regional variations in labor costs, indirect medical education expenses, payments for hospitals that treat a disproportionate share of poor patients, and other factors. As of October 1, 2007, CMS implemented a revised version of the DRG system that uses 745 Medicare Severity DRGs, or MS-DRGs, instead of the approximately 540 DRGs Medicare previously used. The MS-DRGs are intended to account more accurately for the patient's severity of illness when assigning each patient's stay to a payment classification. Medicare pays a fixed amount to the hospital based on the MS-DRG into which the patient's stay is classified, regardless of the actual cost to the hospital of furnishing the procedures, items and services that the patient's condition requires. Accordingly, acute care hospitals generally do not receive direct Medicare reimbursement under PPS for the specific costs incurred in purchasing medical devices. Rather, reimbursement for these costs is deemed to be included within the MS-DRG-based payments made to hospitals for the services furnished to Medicare-eligible inpatients in which the devices are utilized. For cases involving unusually high costs, a hospital may receive additional "outlier" payments above the pre-determined amount. In addition, there is a mechanism by which new technology services can apply to Medicare for additional payments above the pre-determined amount, although such requests have not been granted frequently.

Because PPS payments are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, acute care hospitals have incentives to lower their inpatient operating costs by utilizing products, devices and supplies that will reduce the length of inpatient stays, decrease labor or otherwise lower their costs. For each MS-DRG, a relative weight is calculated representing the average resources required to care for cases grouped in that particular MS-DRG relative to the average resources used to treat cases in all MS-DRGs. MS-DRG relative weights are recalculated every year to reflect changes in technology and medical practice in a budget neutral manner. Under the MS-DRG payment system, there can be significant delays in obtaining adequate reimbursement amounts for hospitals for new technologies such that reimbursement may be insufficient to permit broad acceptance by hospitals.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services. The American Medical Association, or AMA, has developed a coding system known as the Current Procedural Terminology, or CPT, codes, which have been adopted by the Medicare program to describe and develop payment amounts for certain physician services.

The Medicare physician fee schedule uses CPT codes (and other codes) as part of the determination of allowable payment amounts to physicians. In determining appropriate payment amounts for surgeons, CMS receives guidance from the AMA regarding the relative technical skill level, level of resources used, and complexity of a new surgical procedure. Generally, the designation of a new procedure code for a new procedure using a new product does not occur until after FDA clearance or approval of the product used in the procedure. Codes are assigned by either the AMA (for CPT codes) or CMS (for Medicare-specific codes) and new codes usually become effective on January 1st of each year.

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The Health Care Reform Law encourages hospitals and physicians to work collaboratively through shared savings programs, such as accountable care organizations, which may ultimately result in reduced medical device acquisition by hospitals and the consolidation of medical device suppliers available to hospital purchasers.

### ***Commercial Insurers***

In addition to the Medicare program, many private payors look to CMS policies as a guideline in setting their coverage policies and payment amounts. The current coverage policies of these private payors may differ from the Medicare program, and the payment rates they make may be higher, lower, or the same as the Medicare program. If CMS or other agencies decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare guidelines, and those payors may reimburse only a portion of the costs associated with the use of our products, or none at all.

### ***Fraud and Abuse Laws***

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws whose purpose is to eliminate fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws.

### ***Anti-Kickback Laws***

In the United States, there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes or other remuneration in exchange for the referral of patients or other health-related business. The United States federal healthcare programs' Anti-Kickback Statute makes it unlawful for individuals or entities knowingly and willfully to solicit, offer, receive or pay any kickback, bribe or other remuneration, directly or indirectly, in exchange for or to induce the purchase, lease or order, or arranging for or recommending purchasing, leasing, or ordering, any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program such as Medicare or Medicaid. The Anti-Kickback Statute covers "any remuneration," which has been broadly interpreted to include anything of value, including for example gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the arrangement can be found to violate the statute. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, several courts have permitted kickback cases brought under the Federal False Claims Act to proceed, as discussed in more detail below.

Because the Anti-Kickback Statute is broadly written and encompasses many harmless or efficient arrangements, Congress authorized the Office of Inspector General of the United States Department of Health and Human Services, or OIG, to issue a series of regulations, known as "safe harbors." For example, there are regulatory safe harbors for payments to bona fide employees, properly reported discounts, and payments for certain investment interests. Although an arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the statute. The failure of a transaction or arrangement to fit precisely within one or more of the exceptions or safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that arguably implicate the Anti-Kickback Statute but do not fully satisfy all the elements of an exception or safe harbor may be subject to increased scrutiny by government enforcement authorities such as the OIG. The Health Care Reform Law increases the investigatory authority of the OIG, clarifies that Anti-Kickback Statute claims can be brought under the federal civil False Claims Act, and provides for enhanced civil monetary penalties and expanded permissible exclusion authority.

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Many states have laws that implicate anti-kickback restrictions similar to the Anti-Kickback Statute. Some of these state prohibitions apply regardless of whether federal healthcare program business is involved such as for self-pay or private pay patients.

Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

### *Federal Civil False Claims Act and State False Claims Laws*

The federal civil False Claims Act imposes liability on any person or entity who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program, including Medicare and Medicaid. The “qui tam,” or “whistleblower,” provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. Medical device companies, like us, can be held liable under false claims laws, even if they do not submit claims to the government where they are deemed to have caused submission of false claims by, among other things, providing incorrect coding or billing advice about their products to customers that file claims, or by engaging in kickback arrangements with customers that file claims.

The False Claims Act also has been used to assert liability on the basis of misrepresentations with respect to the services rendered and in connection with alleged off-label promotion of products. Our future activities relating to the manner in which we sell our products and document our prices such as the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products, may be subject to scrutiny under these laws.

The Health Care Reform Law is likely to increase the number of cases asserting civil False Claims Act violations since it removes a significant defense to such claims and clarifies that a violation of the Anti-Kickback Statute or retention of a federal healthcare program overpayment are actionable under the civil False Claims Act.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. A number of states have enacted false claim laws analogous to the federal civil False Claims Act and many of these state laws apply where a claim is submitted to any state or private third-party payor. In this environment, our engagement of physician consultants in product development and product training and education could subject us to similar scrutiny. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

### *HIPAA Fraud and Other Regulations*

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created a class of federal crimes known as the “federal health care offenses,” including healthcare fraud and false statements relating to healthcare matters. The HIPAA healthcare fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, or to obtain by means of false or fraudulent pretenses, any money under the control of any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs. The Health Care Reform Law also provides for civil monetary penalties for knowingly participating in certain federal healthcare offenses and enhances sentences under the

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Federal Sentencing Guidelines for such offenses. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment. Entities that are found to have aided or abetted in a violation of the HIPAA federal health care offenses are deemed by statute to have committed the offense and are punishable as a principal.

We are also subject to the United States Foreign Corrupt Practices Act and similar anti-bribery laws applicable in non-United States jurisdictions that generally prohibit companies and their intermediaries from making improper payments to non-United States government officials for the purpose of obtaining or retaining business. Because of the predominance of government sponsored healthcare systems around the world, most of our customer relationships outside of the United States will be with governmental entities and therefore subject to such anti-bribery laws.

### *HIPAA and Other Privacy Regulations*

The regulations that implement HIPAA also establish uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses, which are referred to as “covered entities.” Several regulations have been promulgated under HIPAA’s regulations including: the Standards for Privacy of Individually Identifiable Health Information, or the Privacy Rule, which restricts the use and disclosure of certain individually identifiable health information, the Standards for Electronic Transactions, which establishes standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures, and the Security Standards for the Protection of Electronic Protected Health Information, or the Security Rule, which requires covered entities to implement and maintain certain security measures to safeguard certain electronic health information. Although we do not believe we are a covered entity and therefore are not currently directly subject to these standards, we expect that our customers generally will be covered entities and may ask us to contractually comply with certain aspects of these standards by entering into requisite business associate agreements. While the government intended this legislation to reduce administrative expenses and burdens for the healthcare industry, our compliance with certain provisions of these standards entails significant costs for us.

The Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, which was enacted in February 2009, strengthens and expands the HIPAA Privacy and Security Rules and the restrictions on use and disclosure of patient identifiable health information. HITECH also fundamentally changed a business associate’s obligations by imposing a number of Privacy Rule requirements and a majority of Security Rule provisions directly on business associates that were previously only directly applicable to covered entities. HITECH includes, but is not limited to, prohibitions on exchanging patient identifiable health information for remuneration, restrictions on marketing to individuals and obligations to agree to provide individuals an accounting of virtually all disclosures of their health information. Moreover, HITECH requires covered entities to report any unauthorized use or disclosure of patient identifiable health information, known as a breach, to the affected individuals, the United States Department of Health and Human Services, or HHS, and depending on the size of any such breach, the media for the affected market. Business associates are similarly required to notify covered entities of a breach. Most of the HITECH provisions became effective in February 2010 and it is expected that the HHS will issue regulations to clarify many of the new provisions. HHS has already issued regulations governing breach notification which were effective in September 2009.

HITECH has increased civil penalty amounts for violations of HIPAA by either covered entities or business associates up to an annual maximum of \$1.5 million for uncorrected violations based on willful neglect. Imposition of these penalties is more likely now because HITECH significantly strengthens enforcement. It requires HHS to conduct periodic audits to confirm compliance beginning in February 2010 and to investigate any violation that involves willful neglect which carries mandatory penalties beginning in February 2011.

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Additionally, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations of HIPAA Privacy and Security Rules that threaten the privacy of state residents.

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our planned operations and procedures to comply with the more stringent state laws. If we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions.

Federal and state consumer protection laws are being applied increasingly by the FTC and state attorneys general to regulate the collection, use, storage and disclosure of personal or patient information, through websites or otherwise, and to regulate the presentation of web site content. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Numerous other countries have or are developing laws governing the collection, use, disclosure and transmission of personal or patient information.

HIPAA as well as other federal and state laws apply to our receipt of patient identifiable health information in connection with research and clinical trials. We collaborate with other individuals and entities in conducting research and all involved parties must comply with applicable laws. Therefore, the compliance of the surgeons, hospitals or other providers or entities with whom we collaborate also impacts our business.

### **Employees**

As of March 31, 2010, we had 22 full time employees and one part time employee, 11 of whom were engaged in research and development, five in manufacturing and clinical sales, and seven (including six full time and one part time employee) in general administrative and finance functions. None of our employees is covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

### **Facilities**

We lease approximately 7,400 square feet of space in Irvine, California under a lease that expires in July 2012, which we use as our principal research and development facility and for the assembly of certain of our products. We have the right to extend our Irvine lease for three additional years upon prior written notice and the fulfillment of certain conditions.

We lease approximately 3,300 square feet of office space in Memphis, Tennessee, which we use as our executive offices. Our Memphis lease expires in November 2014. We also have a license to use approximately 1,400 square feet of space in Baltimore, Maryland, which we use as our advanced research and development facility. Our license agreement with respect to our Baltimore facility expires in February 2011.

We believe that our current facilities are sufficient to meet our needs for the foreseeable future.

### **Litigation**

From time to time we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any material litigation.

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**MANAGEMENT**

**Directors and Executive Officers**

The following table sets forth information about our directors, executive officers and other key employees as of March 31, 2010.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<b><i>Directors and Executive Officers</i></b>		
Kimble L. Jenkins <sup>(4)</sup>	48	President, Chief Executive Officer and Chairman of Board of Directors
John C. Thomas, Jr.	56	Chief Financial Officer and Director
Lenox D. Baker <sup>(3)</sup>	68	Director
Paul A. Bottomley	57	Director
Charles E. Koob <sup>(2)(3)(4)</sup>	65	Director
James K. Malemee, Jr. <sup>(1)(3)</sup>	62	Director
Wendelin C. Maners	47	Director
Michael A. Pietrangelo <sup>(1)(2)(4)</sup>	67	Director
John N. Spencer, Jr. <sup>(1)(2)(4)</sup>	69	Director
Peter G. Piferi	50	Chief Operating Officer
David W. Carlson	45	Vice President, Finance
Carol J. Barbre	49	Vice President, Product Management
Michael M. Moore	37	Vice President, Operations
Oscar L. Thomas	39	Vice President, Business Affairs and Secretary

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Corporate Governance and Nominating Committee

(4) Member of the Executive Committee

**Kimble L. Jenkins** joined our Board of Directors in September 2002 and presently serves as our Chairman. Mr. Jenkins has served as our President since January 2003, and he has also served as our Chief Executive Officer since September 2004. Mr. Jenkins served in those offices on a part-time basis until May 2008, at which time Mr. Jenkins began serving as our President and Chief Executive Officer on a full-time basis. Prior to May 2008, Mr. Jenkins was also a Managing Director with the investment bank Morgan Keegan & Company, Inc., where he founded that firm's Private Equity Group in 1998. Mr. Jenkins has over 20 years of experience building and working with growth stage companies. Mr. Jenkins holds a Bachelor of Arts from Brown University and a Juris Doctorate from Georgetown University Law Center. As our Chief Executive Officer, Mr. Jenkins offers unique insight and vision into our operations, our competition and the medical device industry.

**John C. Thomas, Jr.** joined our Board of Directors in April 2004. Since 1998, Mr. Thomas has served as our Chief Financial Officer on a part-time basis. Mr. Thomas also serves as a part-time chief financial officer and secretary for CorMatrix Cardiovascular, Inc. (2001 to present), a privately held medical device company, and Motion Reality, Inc. (2001 to present), a privately held motion capture and simulation company. Previously, Mr. Thomas served as a chief financial officer and secretary for the following companies: MiMedx Group, Inc. (2006 to 2009), a publicly traded biomedical products company; iVideotunes, Inc. (2005 to 2008) a privately held music company; and DARA Pharmaceuticals, Inc., or DARA (2002 to 2008). Mr. Thomas is a certified public accountant, and was formerly an auditor with Arthur Andersen & Company. There is no familial relationship between Mr. John C. Thomas, Jr. and Mr. Oscar L. Thomas. As our Chief Financial Officer, Mr. Thomas offers expertise in accounting, financial statement analysis, medical device company operations and the requirements of a growth stage company.

**Lenox D. Baker** joined our Board of Directors in December 1998. Pursuant to the terms of our First Amended and Restated Stockholders' Agreement, as amended, or the Stockholders' Agreement, which will terminate in connection with this offering, Dr. Baker is the designated nominee of Johns Hopkins to serve on our Board of Directors. He is Past-Chairman of the board of trustees for Johns Hopkins Medicine and Past Vice-

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Chairman of the board of trustees for Johns Hopkins. He currently serves on the executive committee and board of trustees of Johns Hopkins Medicine, as well as serving on the board of trustees of Johns Hopkins. Since 1979, Dr. Baker has practiced cardiothoracic surgery with Mid-Atlantic Cardiothoracic Surgeons and has served as its President since 2002. Since 1982, Dr. Baker has served as Chief of the Division of Cardiac and Thoracic Surgery at Sentara Norfolk General Hospital. In 1975, Dr. Baker founded Impru Inc., a manufacturer of prosthetic arterial grafts, and he served as its Chairman of the Board until Bard Cardiology acquired the company in 1996. Dr. Baker has served as the principal investigator in numerous studies and has written and published multiple articles in the field of cardiothoracic surgery. Dr. Baker also serves as a member of the board of directors of WellPoint, Inc., a publicly traded health benefits company. Dr. Baker offers a practicing physician's perspective on the design, development and commercialization of our product candidates.

**Paul A. Bottomley** is a SurgiVision founder and has been a member of our Board of Directors since December 1998. Pursuant to the terms of the Stockholders' Agreement, Dr. Bottomley is the designated nominee of the Scientific Founders, as such term is defined in the Stockholders' Agreement, to serve on our Board of Directors. Dr. Bottomley joined Johns Hopkins in 1994. Since 1997, Dr. Bottomley has served as the Director of the Division of MR Research in the Department of Radiology at Johns Hopkins. Previously, Dr. Bottomley worked at General Electric Company's Research and Development Center from 1980-1994 where he played a key role in the development of their MRI clinical product and was awarded the Center's highest honor, its Coolidge Medal and Fellowship, for these developments in 1990. He was awarded the Society of Magnetic Resonance in Medicine's Gold Medal for his contributions to MRI in 1989. He holds 34 U.S. patents and has written more than 150 scientific journal publications. Dr. Bottomley also serves as a consultant to us. As a pioneer in MR research, Dr. Bottomley offers expertise in the practical application of our technologies and the commercial opportunities for our product candidates.

**Charles E. Koob** joined our Board of Directors in August 2008. From 1970 to 2008, Mr. Koob practiced competition, trade regulation and antitrust law at the law firm of Simpson Thacher & Bartlett and served as the co-head of the firm's litigation department for a portion of his tenure. For much of his career, Mr. Koob served as a strategic advisor for the boards of directors of many public companies. Mr. Koob also serves on the board of directors of MiMedx Group, Inc., a publicly traded biomedical products company. As a byproduct of Mr. Koob's sophisticated former legal practice, Mr. Koob offers expertise in the areas of corporate governance, contract negotiation and organizational and strategic leadership.

**James K. Malernee, Jr.** joined our Board of Directors in March 2010. Dr. Malernee is a cofounder of Cornerstone Research, Inc., or Cornerstone Research, a consulting firm specializing in analytical support to attorneys in all phases of commercial litigation and regulatory proceedings, and he currently serves as Chairman and Managing Director of that firm. Over the last twenty years with Cornerstone Research, he has directed research on complex business issues related to a wide variety of cases. In recent years, Dr. Malernee has specialized in securities matters, supervising hundreds of cases dealing with material disclosure, loss causation, insider trading, mergers and acquisitions, targeted repurchases, minority buyouts, stock trading behavior, valuation and class certification. Dr. Malernee has served as a board member and consultant to major corporations, and he has taught finance at the University of Texas at Austin and business strategy at the Stanford Graduate School of Business. Through his academic and professional pursuits, Dr. Malernee offers expertise in finance and business strategy as well as an in-depth understanding of corporate disclosure and governance.

**Wendelin C. Maners** joined our Board of Directors in August 2008. Pursuant to the terms of the Stockholders' Agreement, Ms. Maners is the designated nominee of Boston Scientific Neuromodulation Corporation to serve on our Board of Directors. Ms. Maners has been employed by Boston Scientific since 1997 and currently is the Vice President, Strategy and Business Development. She is responsible for transaction and licensing activities for Boston Scientific's neuromodulation, electrophysiology and undeveloped markets. Prior to joining Boston Scientific, Ms. Maners was Head of Healthcare Investment Banking at Barrington Associates, a merger & acquisition advisory firm in Los Angeles. With her background, Ms. Maners offers insight into the medical device industry, particularly as it relates to neurological applications and catheter-based cardiac ablation.

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**Michael A. Pietrangelo** joined our Board of Directors in March 2010. From 1972 through 1989, Mr. Pietrangelo was employed by Schering-Plough Corporation in various capacities including President of the Personal Care Products Group. From 1989 to 1990, he served as President and Chief Operating Officer of Western Publishing Company. From 1990 to 1994, Mr. Pietrangelo was the President and Chief Executive Officer of CLEO, Inc., a subsidiary of Gibson Greetings, Inc. From 1994 until 1998, he served as President of Johnson Products Company, a subsidiary of IVAX Corporation. Since 1998, Mr. Pietrangelo has practiced law at Pietrangelo Cook PLC. Mr. Pietrangelo is also a director of Medicis Pharmaceutical Corporation, a publicly traded pharmaceutical company, serving on the executive committee (Chair), compliance committee (Chair), and nominating and governance committee. Mr. Pietrangelo also serves on the board of directors of the American Parkinson Disease Association, a not-for-profit organization focused on serving the Parkinson's community, and Universal Insurance Holdings, Inc., a publicly traded insurance holding company. Mr. Pietrangelo currently serves as the managing partner of Theraplex Company LLC, a privately held company. As a result of his diverse professional background, Mr. Pietrangelo offers a unique combination of legal expertise and operational acumen.

**John N. Spencer, Jr.** joined our Board of Directors in March 2010. Mr. Spencer is a certified public accountant and was a partner of Ernst & Young LLP where he spent more than 38 years until his retirement in 2000. Mr. Spencer serves on the board of directors of GeoVax Labs, Inc., a publicly traded biotechnology company, and until April 2009, served on the board of directors of Firstwave Technologies, Inc., formerly a publicly traded customer relationship management software company. In addition, he serves as a consultant to various companies, primarily relating to financial accounting and reporting matters. By virtue of his experience at Ernst & Young, where he was the partner in charge of its life sciences practice for the southeastern United States, which included a large number of publicly owned and privately held medical technology companies, together with his continuing expertise as a director of, and a consultant to, other publicly traded and privately held companies, Mr. Spencer offers expertise in accounting, finance and the medical device industry.

**Peter G. Piferi** joined us in December 2006 as our Chief Operating Officer. Mr. Piferi has 23 years of experience in the areas of product development, operations, engineering and production in the medical device industry. From March 2003 to December 2006, Mr. Piferi served as Vice President for Endovascular Technologies, Inc., a privately held medical device company. In addition, Mr. Piferi has served as Vice President at Edwards Lifesciences Corporation, Kriton Medical Inc. and Orbus Medical Technologies, Inc. and as Director of Advanced Engineering at Cordis Corporation.

**David W. Carlson** joined us in February 2010 as Vice President, Finance. Mr. Carlson has 17 years of experience in financial leadership roles in the medical device industry. From 1999 to 2009, he served in various financial management positions as a Vice President of Finance and Senior Finance Director at Medtronic, Inc., a global leader in medical technologies. He was serving as the Corporate Controller of Sofamor Danek, Inc., a then publicly traded medical device company, when it was acquired by Medtronic, Inc. in 1999. Mr. Carlson is a certified public accountant, and was formerly an auditor for PricewaterhouseCoopers LLP. We anticipate that Mr. Carlson will become our Chief Financial Officer prior to the completion of this offering.

**Carol J. Barbre** joined us in May 2008 as Vice President, Product Management. Ms. Barbre has 20 years of experience in the medical device industry in the areas of marketing and business development, with a focus on new medical therapies. From May 2007 to May 2008, Ms. Barbre served as Senior Director of Marketing for Edwards Lifesciences Corporation, a publicly traded medical device company. From 2002 to May 2007, Ms. Barbre served as Global Marketing Director for Bolton Medical, Inc., a privately held medical device company.

**Michael M. Moore** joined us in October 2008 as Senior Director, and he was promoted to Vice President, Operations in June 2009. Mr. Moore has 18 years of experience in medical device development and product realization. From January 2003 to March 2008, he was the Chief Technical Officer for Bolton Medical, Inc. In addition, Mr. Moore previously served as Director of R&D and Operations for AVE- Peripheral Vascular, a division of Medtronic, Inc., and in different operations and product development roles at Cordis Corporation and DePuy Orthopedics, Inc.



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*Oscar L. Thomas* joined us in April 2008 as Vice President, Business Affairs. In addition, Mr. Thomas serves as our Secretary. From January 2003 to April 2008, Mr. Thomas was a partner in the Corporate and Securities Practice Group of the law firm Bass, Berry & Sims PLC. There is no familial relationship between Mr. John C. Thomas, Jr. and Mr. Oscar L. Thomas.

**Board Composition**

Upon the completion of this offering, we will have an authorized Board of Directors consisting of nine members. In accordance with the terms of our certificate of incorporation and our bylaws, which will become effective upon completion of this offering, the Board of Directors will be divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms. Upon the completion of this offering, the members of the classes will be divided as follows:

- the Class I directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in 2011;
- the Class II directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in 2012; and
- the Class III directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in 2013.

Our certificate of incorporation that will become effective upon the completion of this offering provides that the authorized number of directors may be changed only by resolution of the Board of Directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the Board of Directors may have the effect of delaying or preventing changes in our control or management.

Our directors may be removed only for cause by the affirmative vote of the holders of a majority of our voting stock.

**Board Committees and Independence**

Rule 5605 of the Nasdaq Marketplace Rules requires a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, Nasdaq Marketplace Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Rule 5605(a)(2), a director will only qualify as an "independent director" if, in the opinion of our Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the Board of Directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

Our Board of Directors undertook a review of the composition of our Board of Directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that none of Drs. Baker, Bottomley or Malemee, Messrs. Koob, Spencer or Pietrangelo or Ms. Maners, representing seven of our nine directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. In making such determination, our Board of Directors considered the relationships that each such director has with

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us and all other facts and circumstances the Board of Directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each director.

### **Board Committees**

Our Board of Directors has an audit committee, a compensation committee, a corporate governance and nominating committee and an executive committee.

#### *Audit Committee*

Our audit committee consists of Messrs. Spencer (Chair) and Pietrangelo and Dr. Malemee. The functions of the audit committee include:

- appointing, determining the compensation of, and overseeing the work of the independent registered public accounting firm;
- pre-approving all auditing services and permitted non-audit services, including the fees and terms thereof, to be performed by the independent registered public accounting firm;
- reviewing and discussing with management and the independent registered public accounting firm the annual audited and quarterly unaudited financial statements and our disclosure under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 10-Qs and 10-Ks;
- reviewing and discussing the adequacy and effectiveness of our systems of internal accounting and financial controls;
- overseeing our risk assessment and risk management relative to our financial risk exposure;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters and the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters; and
- issuing the audit committee report for inclusion in our proxy statement for our annual meeting.

Our Board of Directors has determined that at this time, Mr. Spencer is an audit committee financial expert within the meaning of SEC regulations and the Nasdaq listing standards. Our Board of Directors has determined that each member of the audit committee satisfies the independence requirements for service on the audit committee. Both our independent registered public accounting firm and management will periodically meet privately with our audit committee.

Upon the effectiveness of the registration statement of which this prospectus forms a part, a copy of the charter for our audit committee will be posted on our website at [www.surgivision.com](http://www.surgivision.com). The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

#### *Compensation Committee*

Our compensation committee consists of Messrs. Pietrangelo (Chair), Koob and Spencer. The functions of the compensation committee include:

- determining the compensation of our executive officers and reviewing and approving the compensation goals and objectives relevant to such compensation;
- reviewing and approving the compensation programs, plans and awards for our executive officers;
- overseeing our risk assessment and risk management relative to our compensation structure and benefits plan administration;
- administering and implementing our incentive compensation plans and equity-based plans;

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- reviewing and discussing with management the information contained in the Compensation Discussion and Analysis section of our proxy statement; and
- issuing the compensation committee report on executive compensation for inclusion in our proxy statement for our annual meeting.

Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Code. Furthermore, our Board of Directors has determined that each member of our compensation committee satisfies the independence standards for compensation committees established by the Nasdaq Marketplace Rules.

Upon the effectiveness of the registration statement of which this prospectus forms a part, a copy of the charter for our compensation committee will be posted on our website at [www.surgivision.com](http://www.surgivision.com). The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

#### ***Corporate Governance and Nominating Committee***

Our corporate governance and nominating committee consists of Mr. Koob (Chair), Drs. Baker and Malernee. The functions of the corporate governance and nominating committee include:

- evaluating director performance on the Board of Directors and applicable committees of the Board of Directors;
- interviewing, evaluating, nominating and recommending individuals for membership on our Board of Directors;
- evaluating nominations by stockholders of candidates for election to our Board of Directors;
- reviewing and recommending to our Board of Directors any amendments to our corporate governance documents; and
- making recommendations to the Board of Directors regarding management succession planning.

Our Board of Directors has determined that each member of the corporate governance and nominating committee satisfies the independence standards for the corporate governance and nominating committees established by the Nasdaq Marketplace Rules.

Upon the effectiveness of the registration statement of which this prospectus forms a part, a copy of the charter for our corporate governance and nominating committee will be posted on our website at [www.surgivision.com](http://www.surgivision.com). The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

#### ***Executive Committee***

Our executive committee consists of Messrs. Jenkins, Koob, Pietrangelo and Spencer. The executive committee, which acts on behalf of the Board of Directors between regular meetings of the Board of Directors or at such times as our business so requires, has and may exercise all of the Board of Director's powers and authority in the management of our business and affairs, but the executive committee does not have the power or authority with respect to the following matters: (1) approving or adopting, or recommending to the stockholders, any action or matter expressly required by the Delaware General Corporation Law to be submitted to stockholders for approval; or (2) adopting, amending or repealing our bylaws.

Upon the effectiveness of the registration statement of which this prospectus forms a part, a copy of the charter for our executive committee will be posted on our website at [www.surgivision.com](http://www.surgivision.com). The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

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### ***Code of Business Conduct and Ethics***

Our Board of Directors intends to adopt a Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics will apply to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), agents and representatives, including directors and consultants. Upon the effectiveness of the registration statement of which this prospectus forms a part, the full text of our Code of Business Conduct and Ethics will be posted on our website at [www.surgivision.com](http://www.surgivision.com). We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of such provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors on our website identified above. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

### **Compensation Committee Interlocks and Insider Participation**

No member of our compensation committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our Board of Directors or compensation committee.

### **Compensation Risks**

We have assessed our compensation programs and have concluded that our compensation policies and practices do not create risks that are reasonably likely to have a material adverse effect on the company. Our compensation program is relatively simple and has only three material elements: base salary; annual bonus; and long-term equity compensation. Base salary represents a fixed amount of payment and therefore does not encourage any excessive risk taking. The compensation committee has determined annual bonus amounts by subjectively analyzing company and individual performance for the prior year and only rewarding individual and company performance that, in the opinion of the compensation committee, had a positive effect on stockholder value. The subjective nature of the compensation committee's determinations regarding both the award and the amount of annual bonuses and equity grants provides a significant control over the incentive of an employee to take undue risk in order to receive a larger annual bonus or equity grant. Finally, our long-term equity compensation program involves only the issuance of options to our employees. We believe that the equity component of our compensation program serves to align the interest of management with the interests of stockholders and does not encourage excessive risk taking. Based on the foregoing, we believe that our compensation policies and practices do not create inappropriate or unintended significant risk to the company as a whole. We also believe that our compensation arrangements provide incentives that do not encourage risk-taking beyond the organization's ability to effectively identify and manage significant risks; are compatible with effective internal controls and the risk management practices of the company; and are supported by the oversight and administration of the compensation committee with regard to executive compensation programs.

### **Director Compensation**

#### ***Retainer and Fees***

Historically, we have paid each non-employee director a retainer based on an annualized rate of \$6,000 a year. With respect to each standing committee of our Board of Directors, we have paid each non-employee director who serves on such a committee a retainer based on an annualized rate of \$1,000 a year, or \$1,500 a year for the committee chairperson. In addition, we have paid our non-employee directors \$1,000 per day for attending in person each Board of Directors meeting or \$250 for attending a Board of Directors meeting telephonically. We also reimburse directors for their reasonable expenses incurred in attending meetings of our Board of Directors. In connection with this offering, we expect to revise the compensation we pay to our non-employee directors but have yet to finalize these plans.

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### **Stock Options; Initial One-Time Grant**

Upon an individual becoming a director for the first time, we have historically granted stock options to purchase 15,000 shares of our common stock, which options vest immediately. The exercise price per share for the options granted has not been less than fair market value on the date of grant. In connection with this offering, we expect to revise the compensation we pay to our non-employee directors but have yet to finalize these plans.

### **Stock Options; Annual Grants**

Any individual who serves as a director on the day following our annual meeting of stockholders has historically been granted an option to purchase 10,000 shares of our common stock, which vests the earlier to occur of the first anniversary of the grant date or the day immediately preceding the next annual meeting of our stockholders. The exercise price per share for the options granted has not been less than fair market value on the date of grant. In connection with this offering we expect to revise the compensation we pay to our non-employee directors but have yet to finalize these plans.

Following the completion of this offering, all directors will be eligible to participate in our 2010 Incentive Compensation Plan and awards will be granted pursuant to the terms of that plan, as more fully described in the section entitled "Benefit Plans—2010 Incentive Compensation Plan."

The following table sets forth information with respect to the compensation of all our non-employee directors in 2009.

Name	Fees Earned or Paid in Cash (\$)	Option Awards \$( <sup>1</sup> )	All Other Compensation (\$)	Total (\$)
Lenox D. Baker	\$ 10,750	\$8,100	—	\$18,850
Paul A. Bottomley	10,500	8,100	\$ 60,000 <sup>(2)</sup>	78,600
Charles E. Koob	14,250	8,100	—	22,350
Wendelin Maners <sup>(3)</sup>	10,000	8,100	—	18,100
Parker H. Petit <sup>(4)</sup>	14,750	—	—	14,750

(1) Amounts represent the aggregate grant date fair value of such options as computed in accordance with ASC Topic 718 "Compensation—Stock Compensation," or ASC Topic 718. For a discussion of the assumptions made in the valuation of these awards, see note 7 to the financial statements included elsewhere in this prospectus and the discussion under "Managements Discussion and Analysis of Financial Condition and Results of Operations—Share-based Compensation".

(2) This amount was compensation paid under Dr. Bottomley's consulting agreement.

(3) Ms. Maners remits all fees received in connection with her service as a director to Boston Scientific, who designated her as a nominee to serve on our Board of Directors pursuant to the Stockholders' Agreement. In addition, Ms. Maners holds her options for the benefit of Boston Scientific.

(4) On December 22, 2009, Mr. Petit resigned from our Board of Directors. Like the other directors, Mr. Petit received an option to purchase 10,000 shares of our common stock on December 10, 2009; however, no award agreement was issued to Mr. Petit and the shares were forfeited upon Mr. Petit's resignation on December 22, 2009. Mr. Petit's resignation was not the result of any disagreement with us on any matter relating to our operations, policies or practices. Mr. Petit recently became the Chairman of the Board, Chief Executive Officer and President of MiMedx Group, Inc., a publicly traded biomedical products company. Mr. Petit advised us that, given the scope of his responsibilities at MiMedx, he did not believe that he would be able to devote sufficient time to serve on our Board of Directors.

## **Compensation Discussion and Analysis**

### **Introduction**

Our compensation discussion and analysis discusses the total compensation for our named executive officers, and it describes our overall compensation philosophy, objectives and practices. Our compensation philosophy and objectives generally apply to all of our employees and all of our employees are eligible to participate in the main components of our compensation program: salary; annual bonus; and equity compensation. The relative value of each of these components for individual employees varies based on job role and responsibility, as well as our financial performance.

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### ***Compensation Philosophy and Objectives***

Our compensation approach is necessarily tied to our stage of development. Our compensation philosophy is to offer our executive officers, including our named executive officers, compensation and benefits that meet our goals of attracting, retaining and motivating highly skilled management which is necessary to achieve our financial and strategic objectives and create long-term value for our stockholders. Accordingly, our executive officer compensation program is designed to link compensation to corporate and individual performance and to align executive officers' interests with stockholder value creation by subjectively analyzing both corporate and individual performance in determining appropriate base salary, bonus and equity compensation awards.

We believe compensation should be determined within a framework that is intended to reward individual contribution and the achievement of company objectives. Within this overall philosophy, our objectives are to:

- attract, retain and motivate our executives by providing a total compensation program that takes into consideration our strategic business needs;
- align the financial interests of the executive officers with those of our stockholders, both in the short and long term;
- provide incentives for achieving and exceeding performance expectations; and
- appropriately reward executive officers for creating long-term stockholder value.

Currently, each of our named executive officers is an "at-will" employee; however, some of our named executive officers have employment letters that set forth the basic terms of their employment. In connection with this offering, the compensation committee is considering the advisability of entering into formal employment agreements with each of our named executive officers.

On an annual basis, our compensation committee has utilized its business judgment to establish:

- base salaries for our named executive officers based on the recommendations of our Chief Executive Officer and the compensation committee's exercise of its subjective judgment;
- annual cash bonuses based on the recommendations of our Chief Executive Officer and a subjective analysis by the compensation committee of both our performance and each named executive officer's performance for the most recently completed fiscal year; and
- any long term equity compensation awards to the named executive officers based on the recommendations of the Chief Executive Officer and the compensation committee's exercise of its subjective judgment.

### ***Role of Directors and Executive Officers in Setting Compensation***

Prior to September 2008, we did not have a compensation committee and compensation decisions for our named executive officers were approved by our Board of Directors upon the recommendation of our Chief Executive Officer. The compensation recommendations of our Chief Executive Officer have been largely discretionary, based on our Chief Executive Officer's subjective assessment of the particular executive officer, publicly available data relating to compensation of executive officers at other medical device companies and input from our other executive officers. There is no particular mathematical formula for deriving executive compensation from these sources. As we gain experience as a public company, we expect that the specific direction, emphasis and components of our executive compensation program will continue to evolve. For example, over time, we expect to reduce our reliance upon subjective determinations made by our Chief Executive Officer in favor of a more empirically-based approach, that could involve benchmarking the compensation paid to our named executive officers against peer companies that we identify and the use of clearly defined, objective targets to determine incentive compensation awards.

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The compensation committee typically considers, but is not required to accept, the recommendations of our Chief Executive Officer regarding the performance and proposed base salary and bonus and equity awards for the other named executive officers, as well as himself. The compensation committee may also request the assistance of our Chief Financial Officer in evaluating the financial, accounting and tax implications of various compensation awards paid to the named executive officers. However, our Chief Financial Officer does not recommend or determine the amounts or types of compensation paid to the named executive officers. Our Chief Executive Officer and certain of our other named executive officers may attend compensation committee meetings, as requested by the compensation committee. None of our named executive officers, including our Chief Executive Officer, attend any portion of the compensation committee meetings during which his or her compensation is established and approved.

We believe that the levels of compensation we provide should be appropriate for our business needs and circumstances. To date, the compensation committee has not engaged a compensation consultant. Rather, the compensation committee and our Chief Executive Officer applied subjective discretion to make compensation decisions and they have not used a specific formula or matrix to set compensation in relation to compensation paid by other medical device companies. Our compensation committee designed our executive compensation program based on the compensation committee's general knowledge of compensation practices and the application of such knowledge to successfully attract and retain the named executive officers. Our compensation committee has not established any percentile targets for the levels of compensation provided to our named executive officers. To date, the compensation committee has not performed reviews of our compensation programs with those of similarly-situated companies, nor have we engaged in benchmarking of compensation paid to our named executive officers. Our historical approach has been to consider compensation practices and relevant factors rather than establishing compensation at specific benchmark percentiles. This enabled us to respond to dynamics in the labor market and provided us with flexibility in maintaining and enhancing our named executive officers' engagement, focus, motivation and enthusiasm for our future. However, as mentioned above, we expect to build some of these objective practices into our compensation approach over time.

The amount of past compensation, including annual discretionary bonus awards, and amounts realizable from prior stock option awards, is generally not a significant factor in the compensation committee's considerations, because these awards would have been earned based on prior years' performances or granted in connection with a named executive officer's initial hire.

Our named executive officers are not subject to mandated stock ownership or stock retention guidelines. It is the belief of the compensation committee that the equity component of our executive compensation program ensures that our named executive officers are also owners and those components to work align the named executive officers' goals with the best interests of stockholders.

### ***Elements of Our Executive Compensation Program***

The principal elements of our executive compensation program have been base salary, a discretionary cash bonus and long-term equity compensation in the form of stock options. Each of these compensation elements satisfies one or more of our compensation objectives.

We have not adopted any policies with respect to long-term versus currently-paid compensation, but feel that both elements are necessary for achieving our compensation objectives. Currently-paid compensation provides financial stability for each of our named executive officers and immediate reward for short-term company and individual performance, while long-term compensation rewards achievement of strategic long-term objectives and contributes toward overall stockholder value. Similarly, while we have not adopted any policies with respect to cash versus equity compensation, we feel that it is important to encourage or provide for a meaningful amount of equity ownership by our named executive officers as to help align their interests with those of stockholders, one of our compensation objectives. We combine the compensation elements for each named executive officer in a manner that the compensation committee believes, in its discretion and judgment, is consistent with the executive's contributions to our company and our overall goals with respect to executive compensation.

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### *Base Salary*

We believe that base salary is an important component of compensation as it provides a degree of financial stability for our named executive officers and is critical to recruiting and retaining our executives. Base salary is also designed to recognize the scope of responsibilities placed on each named executive officer and reward each executive for his or her unique leadership skills, management experience and contributions. We make a subjective determination of base salary after considering such factors collectively.

### *Annual Cash Bonuses*

Our cash bonus compensation is designed to motivate executives to achieve superior performance in their areas of responsibility. To date, we have awarded only discretionary annual cash bonuses based upon a subjective evaluation of corporate and individual performance by the compensation committee or, prior to its creation, our Board of Directors.

### *Long-Term Equity Compensation*

We grant stock options to our named executive officers, as we believe that such grants further our compensation objectives of aligning the interests of our named executive officers with those of our stockholders, encouraging long-term performance, and providing a simple and easy-to-understand form of equity compensation that promotes executive retention. We view such grants both as incentives for future performance and as compensation for past accomplishments.

We generally have used stock options, rather than other forms of long-term incentives, because they create value for the executive only if stockholder value is increased through an increased share price. Prior to this offering, all stock option grants were made pursuant to either our 1998 Stock Option Plan or our 2007 Stock Incentive Plan. Our Board of Directors determined the exercise price based on internal or third-party valuation reports. Following this offering, all option grants will be made pursuant to our 2010 Incentive Compensation Plan. The exercise price of stock options will be based on the fair market value of our common stock on the grant date.

In lieu of receiving an initial stock option grant upon initial hire, our Chief Executive Officer purchased 2,000,000 shares of our common stock in September 2004. Our Chief Financial Officer did not receive an equity grant upon initial hire in 1998. Our other named executive officers received equity grants in connection with their initial hire. The number of stock options granted to our named executive officers in connection with their initial hire was determined based upon negotiations with each executive, represented the number necessary to recruit each executive from their then-existing positions and reflected our Board of Directors' subjective evaluation of the executive's experience and potential for future performance. We have made discretionary grants of equity compensation, from time to time, as determined by the Board of Directors or after its creation, the compensation committee, taking into consideration such factors as individual performance and market conditions. The timing of any such equity grants was determined by the Board of Directors' determination of achievement by the named executive officer, and not any effort to time the grants in coordination with changes in our stock price.

### *Stock Ownership Guidelines*

We currently do not have stock ownership guidelines.

### *Perquisites and Other Benefits*

As a general matter, we do not intend to offer perquisites or other benefits to any executive officer, including the named executive officers, with an aggregate value in excess of \$10,000, because we believe we can provide better incentives for desired performance with compensation in the forms described above. We recognize that, from time to time, it may be appropriate to provide some perquisites or other benefits in order to attract, motivate and retain our executives, with any such decision to be reviewed and approved by the compensation committee as needed.



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Our executive officers are eligible to participate in standard employee benefit plans, including medical, dental, vision, life and any other employee benefit or insurance plan made available to employees. We maintain a 401(k) plan, which is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Internal Revenue Code, or the Code. In general, all of our U.S. employees are eligible to participate in this plan. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to 90% or the statutory limit, \$16,500 in 2009, whichever is less, and have the amount of the reduction contributed to the 401(k) plan. We made no matching contributions during 2009; however, we may add this benefit in the future for all employees.

*Analysis of 2009 Compensation for Named Executive Officers*

*Base Salary*

The base salary of Mr. Kimble L. Jenkins, our President and Chief Executive Officer, remained unchanged at \$325,000 per year.

The base salary of Mr. John C. Thomas, Jr., our Chief Financial Officer, was increased from \$60,000 per year to \$100,000 per year to reflect Mr. Thomas' agreement to devote additional time to our affairs. Mr. Thomas is a part-time employee.

The base salary of Mr. Peter G. Piferi, our Chief Operating Officer, remained unchanged in 2009 at \$250,000 per year.

The base salary of Mr. Oscar L. Thomas, our Vice President, Business Affairs, remained unchanged in 2009 at \$175,000 per year. Mr. Thomas is also entitled to receive guaranteed bonus payments equal to \$12,500 per calendar quarter in accordance with the initial terms of his hiring.

The base salary of Mr. Michael M. Moore, our Vice President, Operations, was increased from \$165,000 per year to \$175,000 per year in 2009 to reflect the additional roles and responsibilities of Mr. Moore resulting from his promotion from a Senior Director to Vice President, Operations.

*Annual Cash Bonuses*

In January 2010, our compensation committee authorized the payment of a discretionary one-time annual bonus as follows:

<u>Named Executive Officer</u>	<u>Discretionary Bonus</u>
Kimble L. Jenkins	\$ 110,000
John C. Thomas, Jr.	\$ 40,000
Peter G. Piferi	\$ 100,000
Oscar L. Thomas	\$ 80,000
Michael M. Moore	\$ 35,000

The bonuses were based upon recommendations made to the compensation committee by Mr. Jenkins. Mr. Jenkins described the performance of Messrs. John Thomas, Piferi, Oscar Thomas and Moore to the compensation committee and made a recommendation with respect to their annual bonus amounts, as well as his own. The bonus recommendations for Messrs. Jenkins, John Thomas and Oscar Thomas took into account the consummation of the co-development agreement with Siemens, the closing of the convertible note financing with Boston Scientific, and the filing of a registration statement for our initial public offering of common stock. In addition, Mr. Jenkins' bonus recommendation took into account the progress in obtaining 510(k) marketing clearance from the FDA for our ClearPoint system. The bonus recommendations for Messrs. Piferi and Moore took into account completion of development of our ClearPoint system, the successful design and implementation of our quality management system, and the progress in obtaining 510(k) marketing clearance from the FDA for our ClearPoint system.

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The compensation committee then discussed in executive session Mr. Jenkins' recommendations for the named executive officers, including an annual bonus for Mr. Jenkins. After subjectively evaluating both the performance of the company and the individuals under consideration, the compensation committee awarded to our named executive officers the annual cash bonuses indicated above.

### *Long-Term Equity Compensation*

None of the named executive officers received long term equity compensation in 2009 for their service as employees. Messrs. Jenkins and John Thomas received an option grant relating to their service as members of the Board of Directors that was identical to grants awarded to the non-employee directors. In addition, Mr. Jenkins received an option grant in connection with a stock purchase transaction with us in December 2009.

### *Effect of Accounting and Tax Treatment on Compensation Decisions*

In the review and establishment of our compensation programs, we consider the anticipated accounting and tax implications to us and our executives. While we consider the applicable accounting and tax treatment, these factors alone are not dispositive, and we also consider the cash and non-cash impact of the programs and whether a program is consistent with our overall compensation philosophy and objectives.

Section 162(m) of the Code imposes a limit on the amount of compensation that we may deduct in any one year with respect to covered employees, unless specific and detailed criteria are satisfied. Performance-based compensation, as defined in the Code, is fully deductible if the programs are approved by stockholders and meet other requirements. In general, we have determined that we will not seek to limit executive compensation so that all of such compensation is deductible under Section 162(m). However, from time to time, we monitor whether it might be in our interests to structure our compensation programs to satisfy the requirements of Section 162(m). We seek to maintain flexibility in compensating our executives in a manner designed to promote our corporate goals and, as a result, our compensation committee has not adopted a policy requiring all compensation to be deductible. Our compensation committee will continue to assess the impact of Section 162(m) on our compensation practices and determine what further action, if any, is appropriate.

### *Conclusion*

The compensation committee believes that our executive leadership is a key element to our success and that the compensation package offered to our named executive officers is a key element in attracting and retaining the appropriate personnel.

The Board of Directors and, since its creation, the compensation committee each believes it has maintained compensation for our named executive officers at levels that are reflective of the talent and success of the individuals being compensated, and with the inclusion of additional compensation directly tied to performance, the compensation committee believes executive compensation will be sufficiently comparable to its industry peers to allow us to retain our key personnel at costs which are appropriate for us.

The compensation committee will continue to develop, analyze and review its methods for aligning executive officers' long-term compensation with the benefits generated for stockholders. The compensation committee believes the idea of creating ownership helps align management's interests with the interests of stockholders. The compensation committee has no pre-determined timeline for implementing new or ongoing long-term incentive plans. New plans are reviewed, discussed and implemented as the compensation committee feels it is necessary or appropriate as a measure to incent, retain and reward our named executive officers.

**EXECUTIVE COMPENSATION****Summary Compensation Table**

The following table shows the compensation awarded or paid to, or earned by, our Chief Executive Officer, Chief Financial Officer and our three other most highly compensated executive officers for the fiscal year ended December 31, 2009. We refer to these executive officers in this prospectus as our “named executive officers”.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards \$( <sup>1</sup> )	All Other Compensation \$( <sup>2</sup> )	Total (\$)
Kimble L. Jenkins Chief Executive Officer and President	2009	\$325,000	\$110,000	\$192,060 <sup>(3)(4)</sup>	\$ 5,355	\$657,415 <sup>(4)</sup>
	2008	291,667	75,000	12,900	3,005	387,572
John C. Thomas, Jr. Chief Financial Officer	2009	91,667	40,000	8,100 <sup>(5)</sup>	—	139,767
	2008	40,000	18,000	12,900	—	70,900
Peter G. Piferi Chief Operating Officer	2009	250,000	100,000	—	2,860	352,860
	2008	250,000	125,000	—	2,609	377,609
Oscar L. Thomas VP, Business Affairs	2009	175,000	130,000 <sup>(6)</sup>	—	5,355	310,355
	2008	122,051	59,750	120,000	3,005	304,812
Michael M. Moore VP, Operations	2009	173,750	48,500 <sup>(7)</sup>	—	260	222,510
	2008	37,548	23,500	21,300	12	82,354

(1) Amounts represent grant date fair value of the option awards computed in accordance with ASC Topic 718. For a discussion of the assumptions made in the valuation of the awards, see note 7 to the financial statements included elsewhere in this prospectus and the discussion under “Managements Discussion and Analysis of Financial Condition and Results of Operations—Share-based Compensation”.

(2) These amounts consist of the group medical, life and disability premiums paid by us.

(3) Represents the grant date fair value in accordance with ASC Topic 718 for: (a) an option to purchase 10,000 shares of our common stock issued to Mr. Jenkins on December 10, 2009 (\$8,100); and (b) an option to purchase 266,608 shares of our common stock issued to Mr. Jenkins on December 22, 2009 (\$183,960).

(4) In September 2004, Mr. Jenkins purchased 2,000,000 shares of our common stock, which he paid for by delivering to us a non-recourse promissory note. Section 402(a) of the Sarbanes-Oxley Act required that the note be repaid prior to the filing of our registration statement for the initial public offering of our common stock. Our Board of Directors formed a special committee of independent directors to review and evaluate any potential transaction with Mr. Jenkins with respect to his loan. The special committee approved, and our Board of Directors ratified, a transaction pursuant to which, on December 22, 2009, Mr. Jenkins sold us 266,608 shares of common stock valued at \$2.41 per share and we issued to Mr. Jenkins an option to purchase 266,608 shares of common stock with an exercise price of \$2.41 per share. Our Board of Directors determined that the fair market value of our common stock as of December 22, 2009 was \$2.41 per share. We paid most of the stock purchase price for Mr. Jenkins’ shares by cancelling Mr. Jenkins’ promissory note and we paid the remaining portion of approximately \$48,000 in cash. See “Certain Relationships and Related Party Transactions – Related Person Transactions.” The purpose of the transaction was to satisfy Mr. Jenkins’ promissory note to enable us to file our registration statement for the initial public offering of our common stock while maintaining as closely as possible the original economics of Mr. Jenkins’ loan transaction. The December 22, 2009 stock option we issued to Mr. Jenkins, when computed in accordance with ASC Topic 718, resulted in \$183,960 of non-cash compensation to Mr. Jenkins.

(5) Represents the grant date fair value of the option award computed in accordance with ASC Topic 718 for an option to purchase 10,000 shares of our common stock issued to Mr. Thomas on December 10, 2009.

(6) This bonus amount includes non-discretionary quarterly bonuses totaling \$50,000, which was paid pursuant to Mr. Thomas’ employment letter.

(7) This bonus amount includes a non-discretionary one-time bonus of \$13,500, which was paid pursuant to Mr. Moore’s employment letter.

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**Grants of Plan-Based Awards**

The table below sets forth information concerning grants of plan based awards in 2009 to our named executive officers.

Name	Grant Date	All Other Option Awards:	Exercise Price Of Option Awards <sup>(1)</sup>	Grant Date Fair Value of Option Awards
		Number of Securities Underlying Options		
Kimble L. Jenkins	December 10, 2009	10,000 <sup>(2)</sup>	\$ 2.41	\$ 8,100
	December 22, 2009	266,608 <sup>(3)</sup>	2.41	183,960
John C. Thomas, Jr.	December 10, 2009	10,000 <sup>(2)</sup>	2.41	8,100

- (1) The exercise price of each stock option granted to our named executive officers is equal to the fair market value of one share of the underlying common stock on the grant date.
- (2) This option was awarded following our 2009 annual meeting of our stockholders in connection with the recipient's service as a director. These options vest on the earlier to occur of: (a) the one year anniversary of the grant date; or (b) the day immediately preceding the 2010 annual meeting of stockholders.
- (3) The shares subject to this option will vest ratably on the first, second and third anniversaries of the grant date, December 22, 2010, December 22, 2011 and December 22, 2012.

All the stock options granted to the named executive officers were granted under our 2007 Stock Incentive Plan. The compensation committee, which administers our 2007 Stock Incentive Plan, has general authority to accelerate, extend, or otherwise modify the benefits under the stock options in certain circumstances within overall plan and other limitations. The compensation committee has no present intention to exercise that authority with respect to these stock options.

**Outstanding Equity Awards at December 31, 2009**

The table below sets forth information regarding the outstanding equity awards held by our named executive officers at December 31, 2009.

Name	Option Awards			
	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable		
Kimble L. Jenkins	386,500 <sup>(1)</sup>	— <sup>(1)</sup>	\$ 0.80	December 1, 2011
	20,000 <sup>(2)</sup>	— <sup>(2)</sup>	0.80	March 28, 2017
	10,000 <sup>(3)</sup>	— <sup>(3)</sup>	2.41	September 16, 2018
	10,000 <sup>(4)</sup>	— <sup>(4)</sup>	2.41	November 8, 2018
	— <sup>(5)</sup>	10,000 <sup>(5)</sup>	2.41	December 10, 2019
	— <sup>(6)</sup>	266,608 <sup>(6)</sup>	2.41	September 1, 2013
John C. Thomas, Jr.	400,000 <sup>(7)</sup>	— <sup>(7)</sup>	0.22	April 12, 2014
	20,000 <sup>(2)</sup>	— <sup>(2)</sup>	0.80	March 28, 2017
	10,000 <sup>(3)</sup>	— <sup>(3)</sup>	2.41	September 16, 2018
	10,000 <sup>(4)</sup>	— <sup>(4)</sup>	2.41	November 8, 2018
	— <sup>(5)</sup>	10,000 <sup>(5)</sup>	2.41	December 10, 2019
Peter G. Piferi	300,000 <sup>(8)</sup>	— <sup>(8)</sup>	0.80	December 1, 2017
Oscar L. Thomas	83,334 <sup>(9)</sup>	166,666 <sup>(9)</sup>	1.51	April 30, 2018
Michael M. Moore	10,000 <sup>(10)</sup>	20,000 <sup>(10)</sup>	1.51	November 7, 2018

- (1) This warrant was immediately exercisable on the date of grant, December 1, 2006.
- (2) The vesting of shares subject to this option occurred on the date of grant, March 28, 2007.

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- (3) The vesting of shares subject to this option occurred on the date of grant, September 16, 2008.
- (4) The vesting of shares subject to this option occurred on the first anniversary of the date of grant, November 8, 2009.
- (5) The vesting of shares subject to this option will occur on the earlier of: (a) the first anniversary of the grant date, December 10, 2010; or (b) the day immediately preceding the 2010 annual meeting of our stockholders.
- (6) The shares subject to this option will vest ratably on the first, second and third anniversaries of the grant date, December 22, 2010, December 22, 2011 and December 22, 2012.
- (7) The vesting of shares subject to this option occurred on the date of grant, April 12, 2004.
- (8) One-third of the shares subject to this option vested upon the first anniversary of Mr. Piferi's hire date, December 1, 2007, one-third vested on the second anniversary, December 1, 2008, and the remaining one-third vested on December 1, 2009.
- (9) One-third of the shares subject to this option vested on the first anniversary of Mr. Thomas' hire date, April 18, 2009. The remaining shares subject to this option will vest ratably on the second and third anniversaries of Mr. Thomas' hire date, April 18, 2010 and April 18, 2011.
- (10) One-third of the shares subject to this option vested on the first anniversary of Mr. Moore's hire date, October 9, 2009. The remaining shares subject to this option will vest ratably on the second and third anniversaries of Mr. Moore's hire date, October 9, 2010 and October 9, 2011.

### **Option Exercises**

None of our named executive officers exercised stock options in 2009.

### **Employment Agreements**

Currently, each of our named executive officers is an "at-will" employee; however some of them have employment letters setting forth the basic terms of their employment. In connection with this offering, the compensation committee is considering the advisability of entering into formal employment agreements with each of our named executive officers.

### **Potential Payments Upon Change in Control**

The following table sets forth the benefits payable to our named executive officers based upon a hypothetical change in control date of December 31, 2009. Our compensation committee may, in its discretion, revise, amend, or add to the benefits if it deems advisable.

<u>Name</u>	<u>Benefit</u>	<u>Change in Control</u>
Kimble L. Jenkins	Stock option acceleration <sup>(1)</sup>	\$
John C. Thomas, Jr.	Stock option acceleration <sup>(1)</sup>	
Peter G. Piferi	Stock option acceleration <sup>(1)</sup>	
Oscar L. Thomas	Stock option acceleration <sup>(1)</sup>	
Michael M. Moore	Stock option acceleration <sup>(1)</sup>	

- (1) Stock option acceleration is calculated as the intrinsic value of the unvested options on December 31, 2009. The intrinsic value is calculated as the difference between the market value of our common stock as of December 31, 2009, and the exercise price of the stock option. The fair market value as of December 31, 2009, is deemed to have been \$ \_\_\_\_\_ per share (the mid-point of the offering range).

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For purposes of these benefits, a change in control is deemed to occur, in general, if (a) a stockholder or group of stockholders acquires 50% or more of the total fair market value or the total voting power of our outstanding capital stock, or (b) a majority of the members of the Board of Directors are replaced in any twelve month period by directors whose election is not endorsed by a majority of the members of the Board of Directors prior to the date of the election.

### **Benefit Plans**

#### ***1998 Stock Option Plan***

We adopted the 1998 Stock Option Plan on June 24, 1998 to enable us to attract, retain and motivate our officers, directors, employees and consultants. Of the 1,500,000 shares of common stock that were eligible for issuance pursuant to awards made under this plan, 1,170,000 shares of common stock were subject to options outstanding as of March 31, 2010. As of such date, the outstanding options had a weighted average exercise price of \$0.30 per share and had expiration dates ranging from January 1, 2010 to October 21, 2014. We terminated this plan, effective June 24, 2008, with respect to future grants such that no new options may be awarded under this plan.

#### ***2007 Stock Incentive Plan***

We adopted the 2007 Stock Incentive Plan on March 28, 2007 to enable us to attract, retain and motivate our officers, directors, employees and consultants. Of the 2,500,000 shares of common stock that were eligible for issuance pursuant to awards made under this plan, 1,232,500 shares of common stock were subject to options outstanding as of March 31, 2010. As of such date, the outstanding options had a weighted average exercise price of \$1.45 per share and had expiration dates ranging from March 28, 2017 to December 10, 2019. Although this plan remains in effect and options under the plan remain outstanding, we will cease making awards under the plan as of the adoption and effectiveness of our 2010 Incentive Compensation Plan.

#### ***2010 Incentive Compensation Plan***

We intend to adopt a 2010 Incentive Compensation Plan, or the 2010 Plan. The principal purpose of the 2010 Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The 2010 Plan is also designed to permit us to make cash-based awards and equity-based awards intended to qualify as “performance-based compensation” under Section 162(m) of the Code.

This following summary is qualified in its entirety by reference to the text of the 2010 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

*Eligibility.* Awards may be granted under the 2010 Plan to officers, directors (including non-employee directors) and other employees of our company or any of our subsidiaries or other affiliates, to any individual who is an advisor, consultant or other provider of services to us or any of our subsidiaries or other affiliates and to any other individuals who are approved by our Board of Directors as eligible to participate in the plan. Only our employees or those of any of our subsidiaries are eligible to receive incentive stock options.

*Administration, Amendment and Termination.* Our compensation committee will have the power and authority to administer the 2010 Plan. The compensation committee will have the authority to interpret the terms and intent of the 2010 Plan, determine eligibility for and terms of awards for participants and make all other determinations necessary or advisable for the administration of the 2010 Plan. To the extent permitted by law, our compensation committee may delegate authority under the 2010 Plan to our Chief Executive Officer or to our other executive officers under conditions and limitations the compensation committee may establish.

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The compensation committee may amend, suspend or terminate the 2010 Plan at any time with respect to any shares of common stock as to which awards have not been made. No such action may amend the 2010 Plan without the approval of stockholders if the amendment is required to be submitted for stockholder approval by applicable law, rule or regulation.

*Awards.* Awards under the 2010 Plan may be made in the form of: options, SARs, stock awards, restricted share units, cash bonuses or other incentive award granted under the 2010 Plan, whether singly, in combination, or in tandem. Any of the foregoing awards may be made subject to attainment of performance goals over any applicable performance period.

*Shares Subject to the Plan.* Following this offering, the aggregate number of shares of our common stock that may be issued initially pursuant to stock awards under the 2010 Plan is 5,000,000 shares. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2010 Plan is 2,500,000. Shares issued under the 2010 Plan may be authorized but unissued shares or treasury shares. Any shares covered by an award, or portion of an award, granted under the 2010 Plan that is forfeited or canceled, expires or is settled in cash will be deemed not to have been issued for purposes of determining the maximum number of shares available for issuance under the 2010 Plan.

*Adjustment of Shares Subject to 2010 Plan.* In the event of certain changes in our capitalization, the compensation committee will adjust, among other award terms, the number and kind of shares or property that may be delivered in connection with awards and the exercise price, grant price or purchase price relating to any award in such manner as the compensation committee determines to be necessary to prevent dilution or enlargement of the rights of participants.

*Effect of a Change of Control.* Upon the occurrence of a change of control, the compensation committee may:

- accelerate, vest or cause the restrictions to lapse with respect to all or any portion of an award under the 2010 Plan;
- cancel such awards for fair value (as determined by the compensation committee);
- provide for the issuance of substitute awards that will substantially preserve the otherwise applicable terms of any affected awards previously granted under the 2010 Plan, as determined by the compensation committee; or
- provide that for a period of at least 10 days prior to the change of control, option awards will be exercisable as to all shares of common stock subject thereto and that upon the occurrence of the change of control, such awards will terminate and be of no further force or effect.

*Corporate Performance Objectives.* Section 162(m) of the Code limits public companies to an annual deduction for federal income tax purposes of \$1,000,000 for compensation paid to their Chief Executive Officer and, based on recent IRS interpretation, the three most highly compensated executive officers determined at the end of each year. Performance-based compensation is excluded from this limitation. The 2010 Plan is designed to permit the compensation committee to grant awards that qualify as performance-based for purposes of satisfying the conditions of Section 162(m) at such time as the 2010 Plan becomes subject to Section 162(m).

### ***Key Personnel Incentive Program***

We have adopted the Key Personnel Incentive Program to enable us to provide certain key employees and consultants with financial rewards in the event of our sale. In the event of our sale, we will allocate funds to a bonus pool for the participants in this program. Participants are selected by the committee of our Board of

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Directors responsible for administering the program, which is now our compensation committee. The aggregate size of the bonus pool will be determined as follows:

- If the “net proceeds”, as described below, from a sale transaction exceed \$50,000,000, the aggregate bonus pool will equal the lesser of (1) \$3,000,000 or (2) 6% of the amount by which the “net proceeds” exceed \$50,000,000.
- If the “net proceeds” from a sale transaction do not exceed \$50,000,000, the aggregate bonus pool will equal \$0.

The “net proceeds” will be the portion of the aggregate cash and non-cash consideration paid or payable in connection with the consummation of the sale transaction that is distributed, or otherwise available for distribution, to holders of our common stock.

Currently, the participants in the pool are Paul A. Bottomley and Parag Karmarkar, each with a 33 1/3% interest, with the remainder being unallocated. Unless extended by the compensation committee, this program will terminate on September 14, 2011.

#### **401(k) Plan**

We offer a 401(k) Plan pursuant to Section 401(k) of the Code. All full time United States employees are eligible to participate in the plan. The plan permits pretax contributions by participants not to exceed annual amounts allowable under the Code. Participants are fully vested in their contributions.

#### **Limitations on Directors’ Liability and Indemnification Agreements**

As permitted by Delaware law, we have adopted provisions in our certificate of incorporation and bylaws, both of which will become effective upon the completion of this offering, that limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director’s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder’s rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director’s liability under federal securities laws. Our certificate of incorporation that will become effective upon the completion of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our bylaws also provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we may advance expenses to our directors, officers, employees and other agents in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our bylaws are not exclusive.



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We believe that indemnification under our bylaws covers at least negligence and gross negligence on the part of indemnified parties. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification provided for in our certificate of incorporation and bylaws, we intend to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in Delaware law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his or her service as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers. There is no pending litigation or proceeding involving any of our directors or executive officers to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

### Policies and Procedures for Related Person Transactions

Prior to the completion of this offering, we will adopt a related person transactions policy to be effective upon completion of this offering pursuant to which our executive officers, directors and principal stockholders, including their immediate family members, are not permitted to enter into a related person transaction with us without the consent of our audit committee, other independent committee of our Board of Directors or the full Board of Directors. Any request for us to enter into a transaction with an executive officer, director, principal stockholder or any of such persons' immediate family members, in which the amount involved exceeds \$120,000 must be presented to our audit committee for review, consideration and approval. All of our directors, executive officers and employees are required to report to our audit committee any such related person transaction. In approving or rejecting the proposed agreement, our audit committee will take into account, among other factors it deems appropriate, whether the proposed related person transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the person's interest in the transaction and, if applicable, the impact on a director's independence. After consideration of these and other factors, the audit committee may approve or reject the transaction. Under the policy, if we should discover related person transactions that have not been approved, the audit committee will be notified and will determine the appropriate action, including ratification, rescission or amendment of the transaction.

### Related Person Transactions

The following is a description of transactions since January 1, 2009 to which we have been a party, in which the amount involved in the transaction exceeds \$120,000, and in which any of our executive officers, directors and principal stockholders, including their immediate family members had or will have a direct or indirect material interest.

In September 2004, Mr. Jenkins, our Chief Executive Officer, purchased 2,000,000 shares of our common stock for an aggregate purchase price of \$480,000. Mr. Jenkins paid the purchase price by delivering to us a non-recourse promissory note in the principal amount of \$480,000, and Mr. Jenkins pledged the purchased shares as security for the note. The note was amended and restated on September 30, 2008 to extend the maturity date. As of December 22, 2009, the outstanding balance on the note was \$594,687 (including \$114,687 of accrued interest). Section 402(a) of the Sarbanes-Oxley Act required that the note be repaid prior to the filing of our registration statement for the initial public offering of our common stock. Our Board of Directors formed a special committee of independent directors to review and evaluate any potential transaction with Mr. Jenkins with respect to his loan. The special committee approved, and our Board of Directors ratified, a transaction pursuant to which, on December 22, 2009, Mr. Jenkins sold us 266,608 shares of common stock valued at \$2.41 per share and we issued to Mr. Jenkins an option to purchase 266,608 shares of common stock with an exercise price of \$2.41 per share. Our Board of Directors determined that the fair market value of our common stock as of December 22, 2009 was \$2.41 per share. We paid a portion of the stock purchase price, approximately \$594,687, by cancelling Mr. Jenkins' promissory note and the remainder, approximately \$48,000, was paid in cash. The purpose of the transaction was to satisfy Mr. Jenkins' promissory note to enable us to file of our registration statement for the initial public offering of our common stock while maintaining as closely as possible the original economics of Mr. Jenkins' loan transaction.

Between January 2006 and August 2007, Boston Scientific, one of our 5% common stockholders and the employer of one of our directors, loaned us \$1,500,000 in six equal quarterly installments pursuant to a convertible promissory note. This note matured on June 30, 2008, at which time Boston Scientific converted the note into 1,671,838 shares of our common stock and a warrant to purchase 1,671,838 shares of our common stock, which warrant has since expired. As such, we have no remaining obligations under the note.

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On January 30, 2009, we repurchased 500,000 shares of our common stock from DARA, one of our 5% common stockholders, for \$500,000. In connection with this repurchase, we also loaned \$500,000 to DARA pursuant to a secured promissory note, which bears interest at 8% annually and becomes due and payable on July 31, 2010. The secured promissory note is collateralized by 500,000 shares of our common stock held by DARA. On December 31, 2009, DARA repaid the \$500,000 loan plus accrued interest of \$36,712 by tendering to us an additional 536,712 shares of our common stock in full satisfaction of the note.

During 2009, Boston Scientific loaned us \$3,500,000 pursuant to the terms of three convertible promissory notes. Interest on the loans accrues at 10% per annum and compounds annually. The Boston Scientific loans are secured by a first priority security interest in all of our assets. Each loan matures on the second anniversary of the date on which the funds were advanced; however we can repay each loan at anytime prior to its respective maturity date. At the option of Boston Scientific, these loans are convertible into one share of our preferred stock for every \$2.00 of principal and interest outstanding at the time of conversion. To the extent that Boston Scientific has not exercised its conversion right prior to the completion of this offering, Boston Scientific will no longer have the right to convert the notes into shares of stock.

In addition to the disclosure above, the terms of the Key Personnel Incentive Plan, which is more fully described in the section entitled “Benefit Plans—Key Personnel Incentive Plan,” is incorporated and restated herein.

#### **Third Amended and Restated Investors Rights’ Agreement**

Pursuant to our Third Amended and Restated Investors Rights’ Agreement, or Rights Agreement, certain of our stockholders and their affiliates and transferees have registration rights. Pursuant to the Rights Agreement, holders of registrable shares may require us, on not more than two occasions at any time beginning six months from the date of the closing of this offering, to file a registration statement under the Securities Act to register for resale their shares of common stock. As of March 31, 2010, the holders of approximately 23,600,000 shares of our common stock or convertible preferred stock have registration rights pursuant to the Rights Agreement. For more information concerning the Rights Agreement, please see “Description of Capital Stock—Registration Rights.”

#### **Indemnification Agreements**

Prior to this offering, we expect to enter into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our certificate of incorporation and bylaws. See “Management—Limitations on Directors’ Liability and Indemnification Agreements.”

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**PRINCIPAL STOCKHOLDERS**

The following table sets forth information as of March 31, 2010 regarding the beneficial ownership of our common stock by:

- each person, or group of affiliated persons, who is known by us to own beneficially five percent or more of our common stock;
- each of our directors;
- each of our named executive officers; and
- all our directors and executive officers as a group.

The number of shares owned and percentage ownership in the following table is based on 20,517,120 shares of common stock outstanding on March 31, 2010, the effectuation of the 1-for- reverse stock split, the conversion of all outstanding shares of our preferred stock into 7,965,000 shares of common stock, the conversion of our bridge notes into shares of common stock and the issuance of shares in this offering. The information assumes no exercise of the underwriters' over-allotment option.

Each individual or entity shown on the table has furnished information with respect to beneficial ownership. Except as otherwise indicated below, the address of each officer, director and five percent stockholder listed below is c/o SurgiVision, Inc., One Commerce Square, Suite 2550, Memphis, TN 38103.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of March 31, 2010. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

Beneficial Owner (Name and Address)	Number of Shares Owned	Percentage of Shares Outstanding	
		Before Offering	After Offering
<b>5% Stockholders</b>			
Entities affiliated with Boston Scientific Neuromodulation Corporation <sup>(1)</sup> One Boston Scientific Plaza Natick, MA 01760	3,491,975	%	%
Bruce Conway <sup>(2)</sup> 5514 Wenonah Dr Dallas, TX 75209	2,026,907		
DARA Pharmaceuticals, Inc. <sup>(3)</sup> 8601 Six Forks Road, Suite 160 Raleigh, NC 27615	2,018,258		
<b>Directors and Named Executive Officers</b>			
Kimble L. Jenkins <sup>(4)</sup>	2,164,892		
John C. Thomas, Jr. <sup>(5)</sup>	760,923		
Lenox D. Baker <sup>(6)</sup>	60,000	*	*
Paul A. Bottomley <sup>(7)</sup>	468,665		
Charles E. Koob <sup>(8)</sup>	105,000	*	*
Wendelin C. Maners <sup>(9)</sup>	25,000	*	*
James K. Malemee, Jr.	—	*	*
Michael A. Pietrangelo	—	*	*
John N. Spencer, Jr.	—	*	*
Peter G. Piferi <sup>(10)</sup>	300,000		*
Oscar L. Thomas <sup>(11)</sup>	83,334	*	*
Michael M. Moore <sup>(12)</sup>	10,000	*	*
All executive officers and directors as a group (14 persons) <sup>(13)</sup>	3,987,814		

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\* Represents beneficial ownership of less than 1% of our outstanding common stock.

- (1) Includes 1,820,137 shares issuable upon the conversion of convertible promissory notes, the outstanding balance of which, including principal and accrued interest, was approximately \$3,640,274 as of March 31, 2010. Also includes 25,000 shares that Ms. Maners has the right to acquire through the exercise of options, which she holds for the benefit of Boston Scientific Neuromodulation Corporation. Pursuant to the terms of the Stockholders' Agreement, which terminates upon closing of this offering, Boston Scientific Neuromodulation Corporation designated Ms. Maners as their nominee to serve on our Board of Directors. Boston Scientific is a reporting company under the Exchange Act, the shares of which are traded on the New York Stock Exchange and are widely held.
- (2) Includes 25,000 shares jointly held with his spouse, 100,000 shares held solely by his spouse and 25,000 shares issuable upon the optional conversion of a bridge note in the principal amount of \$50,000.
- (3) Includes 405,000 shares that DARA Pharmaceuticals, Inc. has the right to acquire through the exercise of warrants. DARA Pharmaceuticals, Inc. is a reporting company under the Exchange Act, the shares of which are traded on the Nasdaq Capital Market and are widely held.
- (4) Includes 386,500 shares that Mr. Jenkins has the right to acquire through the exercise of warrants and 40,000 shares that Mr. Jenkins has the right to acquire through the exercise of options.
- (5) Includes 72,740 shares held by a family limited partnership of which Mr. Thomas is the general partner, 364 shares owned by Mr. Thomas' daughter, and 440,000 shares that Mr. Thomas has the right to acquire through the exercise of stock options. Does not include 727 shares beneficially owned by Mr. Thomas' spouse of which Mr. Thomas disclaims beneficial ownership.
- (6) Includes 60,000 shares that Dr. Baker has the right to acquire through the exercise of options.
- (7) Includes 280,000 shares that Dr. Bottomley has the right to acquire through the exercise of options.
- (8) Includes 80,000 shares jointly held with his spouse and 25,000 shares that Mr. Koob has the right to acquire through the exercise of options.
- (9) Includes 25,000 shares that Ms. Maners has the right to acquire through the exercise of options. Ms. Maners holds her options for the benefit of Boston Scientific Neuromodulation Corporation. Pursuant to the terms of the Stockholders' Agreement, which terminates upon closing of this offering, Boston Scientific Neuromodulation Corporation designated Ms. Maners as its nominee to serve on our Board of Directors.
- (10) Includes 300,000 shares that Mr. Piferi has the right to acquire through the exercise of options.
- (11) Includes 83,334 shares that Mr. Thomas has the right to acquire through the exercise of options.
- (12) Includes 10,000 shares that Mr. Moore has the right to acquire through the exercise of options.
- (13) Includes 1,659,834 shares exercisable through the exercise of options or warrants and 72,740 held by an entity controlled by an executive officer and director.

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## DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock gives effect to the amendment and restatement of our certificate of incorporation and bylaws, which will occur before the closing of this offering, a 1-for- reverse stock split, which will occur before the closing of this offering, and the conversion of our preferred stock and bridge notes into shares of common stock, which will occur upon the closing of this offering, as if such conversion had occurred on March 31, 2010.

Upon completion of this offering, our authorized capital stock will consist of shares of common stock, \$0.01 par value per share, and shares of preferred stock, \$0.01 par value per share.

### Common Stock

#### *Outstanding Shares*

As of March 31, 2010, we had 20,517,120 shares of common stock outstanding and 7,965,000 shares of preferred stock issued and outstanding that are convertible into 7,965,000 shares of common stock and approximately \$4.1 million of bridge notes that are convertible into shares of common stock. As of March 31, 2010, we had approximately 500 stockholders, assuming the conversion of all outstanding shares of our preferred stock and bridge notes into shares of our common stock. In addition, as of March 31, 2010, options and warrants to purchase 4,413,050 shares of common stock were issued and outstanding and we had outstanding convertible promissory notes that were convertible into 1,820,137 shares of common stock. Based on our outstanding capital stock as of March 31, 2010, upon the completion of this offering, there will be shares of common stock outstanding assuming conversion of all preferred stock into 7,965,000 shares of common stock, conversion of the bridge notes into shares of common stock, no exercise of the underwriters' over-allotment option, no exercise of outstanding stock options or warrants and no conversion of outstanding convertible promissory notes (other than the bridge notes).

#### *Voting Rights*

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our certificate of incorporation and bylaws, our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

#### *Dividends*

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the Board of Directors out of legally available funds.

#### *Liquidation*

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

#### *Rights and Preferences*

Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

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### ***Fully Paid and Nonassessable***

All of our outstanding shares of common stock are, and the shares of common stock to be issued pursuant to this offering will be, fully paid and nonassessable.

### **Preferred Stock**

Upon the closing of this offering, the Board of Directors will have the authority, without further action by the stockholders, to issue up to 30,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. The Board of Directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of SurgiVision and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock.

### **Registration Rights**

In 1998 shortly following our formation, some of our initial investors entered into an investor rights agreement with us, which, among other things, provided demand and piggyback registration rights. As our operations to date have been funded primarily through the sale of our equity securities, we have amended the investor rights agreement with each offering of equity securities to extend the respective rights thereunder to the new investors. The investor rights agreement was most recently amended in 2006 in connection with a preferred stock offering, and it remains in place as the Rights Agreement.

### ***Demand and Form S-3 Registration Rights***

Pursuant to the Rights Agreement, at any time beginning six months after the consummation of this offering, the holders of approximately 23,600,000 shares of our common stock or preferred stock convertible into common stock, or registrable shares, will have the right to require us to register the registrable shares under the Securities Act under specified circumstances. We will not be required to effect a demand registration for 120 days following the effectiveness of a registration statement relating to an underwritten public offering of our securities. Under specified circumstances, we also have the right to defer filing of a requested registration statement for a period of not more than 120 days, which right may not be exercised more than twice during any period of 12 consecutive months. These registration rights are subject to additional conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances.

If we are eligible to file a registration statement on Form S-3, each holder of registrable shares of our common stock has the right to demand that we file additional registration statements, including a shelf registration statement, for such holders on Form S-3. We will not be required to effect more than four demand registrations in total, of which no more than two may be required to be effected by us at any time after the second anniversary of this offering and then only on Form S-3.

### ***Piggyback Registration Rights***

Pursuant to the Rights Agreement, at any time beginning six months after the consummation of this offering, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit plans, debt securities, or corporate reorganizations, the holders of registrable shares are entitled to notice of the registration and have the right to include their registrable shares in such a registration. In addition, two of our warrant holders, pursuant to the terms of their respective warrants, have similar piggyback registration rights. As of March 31, 2010, the holders of approximately 24,216,000 shares of our common stock, common stock issuable on the exercise of warrants and preferred stock convertible into common stock will be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration statement. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement.

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### *Expenses of Registration*

We are required to pay all expenses relating to any demand or piggyback registration, other than underwriting discounts and commissions.

### **Delaware Anti-Takeover Law and Certain Provisions of our Certificate of Incorporation and Bylaws**

#### *Delaware Law*

We are governed by Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years, did own, 15% or more of the corporation’s outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

#### *Certificate of Incorporation and Bylaw Provisions*

Our certificate of incorporation that will become effective upon the completion of this offering:

- provides for a staggered Board of Directors;
- permits our Board of Directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provides that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provides that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- requires that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provides that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder’s notice;
- does not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provides that special meetings of our stockholders may be called only by the chairman of the Board of Directors, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provides that stockholders will be permitted to amend our amended and restated bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

These and other provisions contained in our certificate of incorporation and bylaws could delay or discourage some types of transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.



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**Nasdaq Capital Market Listing**

We intend to apply to the Nasdaq Capital Market to quote our common stock under the proposed trading symbol “SRGV”.

**Transfer Agent and Registrar**

The Transfer Agent and Registrar for our common stock is Continental Stock Transfer and Trust Company. The transfer agent’s address is 17 Battery Place, New York, New York 10004 and its telephone number is (212) 845-3212.

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**SHARES ELIGIBLE FOR FUTURE SALE**

Prior to this offering, there has been no public market for our common stock. Market sales of shares or the availability of shares for sale may decrease the market price of our common stock prevailing from time to time. As described below, only a portion of our outstanding shares of common stock will be available for sale shortly after this offering due to contractual and legal restrictions to resale. Nevertheless, sales of substantial amounts of common stock in the public market after these restrictions lapse, or the perception that such sales could occur, adversely affect the market price of the common stock and impair our future ability to raise capital through the sale of our equity securities.

Upon completion of this offering, \_\_\_\_\_ shares of common stock will be outstanding. All of the shares sold in this offering will be freely tradable. Except as set forth below, the remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. These remaining shares will be available for sale in the public market roughly as follows:

<b>Date of Availability of Sales</b>	<b>Approximate Number of Shares</b>
As of the date of this prospectus	
90 days after the date of this prospectus	
180 days after the date of this prospectus, not subject to volume limitations pursuant to Rule 144	
180 days after the date of this prospectus, subject to volume limitations pursuant to Rule 144	

**Rule 144**

Under Rule 144, any non-affiliate, who has not been an affiliate of ours during the preceding three months and has held their securities for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. In addition, Rule 144 provides that once we have been subject to the reporting requirements of the Exchange Act for a period of at least 90 days, non-affiliates that have held restricted securities of a reporting company for at least six months and have not had an affiliate relationship with us during the preceding three months may sell their securities without restriction or limitation, other than that Rule 144's public information requirements must be satisfied. Rule 144 does not permit affiliates to sell restricted securities until we have been subject to the reporting requirements of the Exchange Act for a period of 90 days. After such 90 day period, Rule 144 permits affiliates that have held restricted securities for at least six months to sell such restricted securities in accordance with the traditional conditions of Rule 144, including the current public information requirement, the volume limitations, manner of sale provisions and notice requirements. In particular, an affiliate who has beneficially owned shares of our common stock for at least six months would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our common stock on the Nasdaq Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

**Rule 701**

In general, under Rule 701 of the Securities Act, any of our employees, directors, officers, consultants or advisors who purchased shares from us in connection with a compensatory stock or option plan or other written agreement is eligible to resell those shares in reliance on Rule 144, but without compliance with certain

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restrictions, including the holding period contained in Rule 144. However, a substantial portion of the shares issued under Rule 701 will be subject to lock-up agreements and will only become eligible for sale at the expiration of such agreements.

### **Lock-Up Agreements**

Upon completion of this offering, each of our officers and directors and certain of our stockholders will have agreed, subject to specified exceptions, that, without the prior written consent of the underwriters, they will not, directly or indirectly, sell, offer, contract to sell, transfer the economic risk of ownership in, make any short sale, pledge or otherwise dispose of any shares of our capital stock or any securities convertible into or exchangeable or exercisable for or any other rights to purchase or acquire our capital stock for a period of 180 days from the date of this prospectus. The underwriters may, in their sole discretion, permit early release of shares subject to the lock-up agreements. See “Underwriting—Lock-ups” for a more detailed discussion of the lock-up agreements.

### **Registration Rights**

Upon completion of this offering, the holders of the registrable shares, or their transferees, will be entitled to registration rights with respect to the registrable shares under the Securities Act. Registration of the registrable shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of this registration. See “Description of Capital Stock—Registration Rights.”

### **Stock Options**

Immediately after this offering, we intend to file with the SEC a registration statement under the Securities Act covering the shares of common stock reserved for issuance under our stock option plans. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will, subject to Rule 144 volume limitations applicable to affiliates and the lock-up agreements described above, be available for sale in the open market.

**MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS  
FOR NON-UNITED STATES HOLDERS OF COMMON STOCK**

The following is a summary of some United States federal income and estate tax consequences of the acquisition, ownership and disposition of shares of our common stock purchased pursuant to this offering by a holder that, for United States federal income tax purposes, is not a “United States person,” as we define that term below. A beneficial owner of our common stock who is not a United States person is referred to below as a “non-United States holder.” This summary is based upon current provisions of the Internal Revenue Code of 1986, as amended, Treasury regulations promulgated thereunder, judicial opinions, administrative pronouncements and published rulings of the United States Internal Revenue Service, or IRS, all as in effect as of the date hereof. These authorities may be changed, possibly retroactively, resulting in United States federal tax consequences different from those set forth below. We have not sought, and will not seek, any ruling from the IRS or opinion of counsel with respect to the statements made in the following summary, and there can be no complete assurance that the IRS will not take a position contrary to such statements or that any such contrary position taken by the IRS would not be sustained.

This summary is limited to non-United States holders who purchase shares of our common stock issued pursuant to this offering and who hold our common stock as a capital asset for United States federal income tax purposes. This summary also does not address the tax considerations arising under the laws of any state, local or non-United States jurisdiction, or under United States federal estate or gift tax laws, except as specifically described below. In addition, this summary does not address tax considerations that may be applicable to an investor’s particular circumstances nor does it address the special tax rules applicable to special classes of non-United States holders, including, without limitation:

- banks, insurance companies or other financial institutions;
- partnerships or other entities treated as partnerships for United States federal income tax purposes;
- United States expatriates;
- tax-exempt organizations;
- tax-qualified retirement plans;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings; or
- persons that will hold common stock as a position in a hedging transaction, “straddle,” “conversion,” or other integrated transaction for tax purposes.

If a partnership, including any entity treated as a partnership for United States federal income tax purposes, is a holder, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. A holder that is a partnership, and partners in such partnership, should consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of shares of our common stock.

For purposes of this discussion, a United States person means a person who is for United States federal income tax purposes:

- a citizen or resident of the United States;
- a corporation, including any entity treated as a corporation for United States federal income tax purposes created or organized under the laws of the United States, any state within the United States, or the District of Columbia;
- an estate the income of which is subject to United States federal income taxation regardless of its source; or

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- a trust, if its administration is subject to the primary supervision of a United States court and one or more United States persons have the authority to control all of its substantial decisions, or other trusts considered United States persons for United States federal income tax purposes.

**YOU ARE URGED TO CONSULT YOUR TAX ADVISOR WITH RESPECT TO THE APPLICATION OF THE UNITED STATES FEDERAL INCOME TAX LAWS TO YOUR PARTICULAR SITUATION AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE FEDERAL ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY STATE, LOCAL, NON-UNITED STATES OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.**

#### **Dividends**

If distributions are paid on shares of our common stock, the distributions will constitute dividends for United States federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. To the extent a distribution exceeds our current and accumulated earnings and profits, it will constitute a return of capital that is applied against and reduces, but not below zero, the adjusted tax basis of your shares in our common stock. Any remainder will constitute gain on the common stock. Dividends paid to a non-United States holder generally will be subject to withholding of United States federal income tax at the rate of 30% or such lower rate as may be specified by an applicable income tax treaty, the benefits of which a non-United States holder is eligible. If the dividend is effectively connected with the non-United States holder's conduct of a trade or business in the United States or, if a tax treaty requires, attributable to a United States permanent establishment maintained by such non-United States holder, the dividend will not be subject to any withholding tax, provided certification requirements are met, as described below, but will be subject to United States federal income tax imposed on net income on the same basis that applies to United States persons generally. A corporate holder under certain circumstances also may be subject to a branch profits tax equal to 30%, or such lower rate as may be specified by an applicable income tax treaty, the benefits of which a non-United States holder is eligible, on a portion of its effectively connected earnings and profits for the taxable year. Non-United States holders should consult their own tax advisors regarding the potential applicability of any income tax treaty.

To claim the benefit of a tax treaty or to claim exemption from withholding because the income is effectively connected with the conduct of a trade or business in the United States, a non-United States holder must provide a properly executed IRS Form W-8BEN for treaty benefits or W-8ECI for effectively connected income, or such successor forms as the IRS designates, prior to the payment of dividends. These forms must be periodically updated. Non-United States holders may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund.

#### **Gain on Disposition**

A non-United States holder generally will not be subject to United States federal income tax, including by way of withholding, on gain recognized on a sale or other disposition of shares of our common stock unless any one of the following is true:

- the gain is effectively connected with the non-United States holder's conduct of a trade or business in the United States or, if a tax treaty applies, attributable to a United States permanent establishment or a fixed base maintained by such non-United States holder;
- the non-United States holder is a nonresident alien individual present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation," or USRPHC, for United States federal income tax purposes at any time during the shorter of (1) the period during which you hold our common stock or (2) the five-year period ending on the date you dispose of our common stock.

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We believe that we are not currently, and will not become, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other business assets, we cannot assure you that we will not become a USRPHC in the future. As a general matter, as long as our common stock is regularly traded on an established securities market, however, it will not be treated as a United States real property interest with respect to any non-United States holder that holds no more than 5% of such regularly traded common stock. If we are determined to be a USRPHC and the foregoing exception does not apply, among other things, a purchaser may be required to withhold 10% of the proceeds payable to a non-United States holder from a disposition of our common stock, and the non-United States holder generally will be taxed on its net gain derived from the disposition at the graduated United States federal income tax rates applicable to United States persons.

Unless an applicable treaty provides otherwise, gain described in the first bullet point above will be subject to the United States federal income tax imposed on net income on the same basis that applies to United States persons generally but will generally not be subject to withholding. Corporate holders also may be subject to a branch profits tax on such gain. Gain described in the second bullet point above will be subject to a flat 30% United States federal income tax, which may be offset by certain United States source capital losses. Non-United States holders should consult any potentially applicable income tax treaties that may provide for different rules.

#### **United States Federal Estate Taxes**

Shares of our common stock owned or treated as owned by an individual who at the time of death is a non-United States holder are considered United States situs assets and will be included in the individual's estate for United States federal estate tax purposes, unless an applicable estate tax treaty provides otherwise.

#### **Information Reporting and Backup Withholding**

Information reporting and backup withholding (currently at a 28% rate of tax) may apply to dividends paid with respect to our common stock and to proceeds from the sale or other disposition of our common stock. If we cannot determine whether a distribution will qualify as a dividend, in whole or in part, at the time the distribution is made, then the distribution will be subject to backup withholding. In certain circumstances, non-United States holders may avoid information reporting and backup withholding if they certify under penalties of perjury as to their status as non-United States holders or otherwise establish an exemption and certain other requirements are met. Non-United States holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules from a payment to a non-United States holder can be refunded or credited against the non-United States holder's United States federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

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**UNDERWRITING**

Canaccord Adams Inc., or Canaccord Adams, and Rodman & Renshaw, LLC, or Rodman, or collectively, the underwriters, are acting as the joint book running underwriters of this offering. Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, the underwriters have agreed to purchase, and we have agreed to sell to them, all shares of common stock offered by this prospectus as set forth below:

<u>Underwriter</u>	<u>Shares</u>
Canaccord Adams Inc.	
Rodman & Renshaw, LLC	

**Nature of Underwriting Commitment**

The underwriters are offering the shares of common stock subject to its acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the over-allotment option described below, unless and until the option is exercised. The underwriters initially propose to offer part of the shares of common stock directly to the public at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions, and part to certain dealers at a price that represents a concession not in excess of \$ \_\_\_\_\_ a share under the public offering price. The underwriters may allow, and the dealers may reallow, a discount not in excess of \$ \_\_\_\_\_ per share to other dealers. After the initial offering, the public offering price or any other term of the offering may be changed.

**Option to Purchase Additional Shares**

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of \_\_\_\_\_ additional shares of common stock at the public offering price, less underwriting discounts and commissions. The underwriters may exercise this option, in whole or in part, solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. If the over-allotment option is exercised in full, the total price to the public would be \$ \_\_\_\_\_, the total underwriter discounts and commissions would be \$ \_\_\_\_\_ and the total proceeds to us would be \$ \_\_\_\_\_.

**Discounts and Commissions**

The following table shows the per share and total underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

	<u>Total</u>		
	<u>Per Share</u>	<u>No Exercise</u>	<u>Full Exercise</u>
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Non-accountable expense allowance	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

In addition, we estimate that the expenses of this offering other than underwriting discounts and commissions payable by us will be approximately \$ \_\_\_\_\_ million.

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We have agreed to pay the underwriters a non-accountable expense allowance equal to 1% of the public offering price or \$ . We have also agreed to issue to the underwriters common stock purchase warrants to purchase up to shares of our common stock. The warrants will have an exercise price equal to \$ per share. The warrants are exercisable commencing one (1) year after the effective date of the registration statement of which the prospectus forms a part, and will be exercisable for four (4) years thereafter. The warrants also provides for unlimited “piggyback” registration rights at our expense with respect to the underlying shares of common stock. Pursuant to the rules of the Financial Industry Regulatory, Inc., or FINRA, and in particular Rule 5110, the warrants (and underlying shares) issued to the underwriters may not be sold, transferred, assigned, pledged, or hypothecated, or the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective disposition of the securities by any person for a period of 180 days immediately following the date of delivery and payment for the shares offered; provided, however, that the warrants (and underlying shares) may be transferred to officers or partners of the underwriters as long as the warrants (and underlying shares) remain subject to the lockup.

### **Lock-ups**

Upon completion of this offering, each of our officers and directors and certain stockholders will have agreed that, subject to specified exceptions, without the prior written consent of the underwriters through their representative Canaccord Adams, they will not, during the period beginning on the date of this prospectus and ending 180 days thereafter:

- offer, pledge, sell, announce the intention to sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock;
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of common stock; or
- make any demand for or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise.

The restrictions described in the preceding paragraphs do not apply to:

- the sale by us of shares to the underwriter in connection with the offering;
- options issued pursuant to employee benefit plans;
- transactions by any person other than us relating to shares of common stock or other securities convertible or exchangeable into common stock acquired in open market transactions after the completion of the offering of the shares; or
- the transfer of shares of common stock or any security convertible or exchangeable into shares of common stock as a bona fide gift, as a distribution to general or limited partners, stockholders, members or affiliates of our stockholders, or by will or intestate succession to a member of the immediate family of our stockholders, or to a trust for the benefit of such immediate family member.

With respect to the last bullet, it shall be a condition to the transfer or distribution that the transferee provide prior written notice of such transfer or distribution to Rodman, execute a copy of the lock-up agreement, that no filing by any donee or transferee with the SEC shall be required or shall be made voluntarily in connection with such transfer or distribution, other than a filing on Form 5, and no such transfer or distribution may include a disposition for value.

The 180-day restricted period described in the preceding paragraph will be extended if:

- during the last 17 days of the 180-day restricted period we issue an earnings release or material news or a material event relating to us occurs; or



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- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

### **Stabilization**

In order to facilitate this offering of common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or by purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. In addition, to stabilize the price of the common stock, the underwriters may bid for and purchase shares of common stock in the open market. Finally, the underwriters may reclaim selling concessions allowed for distributing the common stock in the offering if the syndicate repurchases previously distributed common stock to cover syndicate short positions or to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

### **Other Terms**

We will apply to have our common stock approved for quotation on the Nasdaq Capital Market under the symbol "SRGV."

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

Prior to this offering, there has been no public market for the shares of common stock. The initial public offering price will be determined by negotiations between us and the underwriters. Among the factors to be considered in determining the initial public offering price will be our future prospects and those of our industry in general; sales, earnings and other financial operating information in recent periods; and the price-earnings ratios, price-sales ratios and market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. The estimated initial public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors. An active trading market for the shares may not develop, and it is possible that after the offering the shares will not trade in the market above their initial offering price. A prospectus in electronic format may be made available on a web site maintained by the underwriters, and the underwriters may distribute prospectuses electronically.

### **Foreign Regulatory Restrictions on Purchase of Our Common Stock**

We have not taken any action to permit a public offering of our common stock outside the United States or to permit the possession or distribution of this prospectus outside the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about and observe any restrictions

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relating to this offering and the distribution of the prospectus outside the United States. In addition to the public offering of our common stock in the United States, the underwriters may, subject to applicable foreign laws, also offer our common stock to certain institutions or accredited persons in other countries.

### **Italy**

The offering of shares of common stock pursuant to this prospectus has not been cleared by Consob, the Italian Stock Exchange's regulatory agency of public companies, pursuant to Italian securities legislation and, accordingly, no shares may be offered, sold or delivered, nor may copies of this prospectus or of any other document relating to our common stock be distributed in Italy, except (1) to professional investors (*operatori qualificati*); or (2) in circumstances which are exempted from the rules on solicitation of investments pursuant to Decree No. 58 and Article 33, first paragraph, of Consob Regulation No. 11971 of May 14, 1999, as amended. Any offer, sale or delivery of our common stock or distribution of copies of this prospectus or any other document relating to our common stock in Italy under (1) or (2) above must be (i) made by an investment firm, bank or financial intermediary permitted to conduct such activities in Italy in accordance with the Decree No. 58 and Legislative Decree No. 385 of September 1, 1993, or the Banking Act; and (ii) in compliance with Article 129 of the Banking Act and the implementing guidelines of the Bank of Italy, as amended from time to time, pursuant to which the issue or the offer of securities in Italy may need to be preceded and followed by an appropriate notice to be filed with the Bank of Italy depending, inter alia, on the aggregate value of the securities issued or offered in Italy and their characteristics; and (iii) in compliance with any other applicable laws and regulations.

### **Germany**

The offering of our common stock is not a public offering in the Federal Republic of Germany. The shares may only be acquired in accordance with the provisions of the Securities Sales Prospectus Act (*Wertpapier-Verkaufsgesetz*), as amended, and any other applicable German law. No application has been made under German law to publicly market our common stock in or out of the Federal Republic of Germany. Our common stock is not registered or authorized for distribution under the Securities Sales Prospectus Act and accordingly may not be, and are not being, offered or advertised publicly or by public promotion. This prospectus is strictly for private use and the offering is only being made to recipients to whom the document is personally addressed and does not constitute an offer or advertisement to the public. Our common stock will only be available to persons who, by profession, trade or business, buy or sell securities for their own or a third party's account.

### **France**

Our common stock offered by this prospectus may not be offered or sold, directly or indirectly, to the public in France. This prospectus has not been, and will not be, submitted to the clearance procedure of the *Autorité des Marchés Financiers*, or the AMF, and may not be released or distributed to the public in France. Investors in France may only purchase the common stock offered by this prospectus for their own account and in accordance with articles L. 411-1, L. 441-2 and L. 412-1 of the *Code Monétaire et Financier* and decree no. 98-880 dated October 1, 1998, provided they are "qualified investors" within the meaning of said decree. Each French investor must represent in writing that it is a qualified investor within the meaning of the aforesaid decree. Any resale, directly or indirectly, to the public of the common stock offered by this prospectus may be effected only in compliance with the above mentioned regulations. "Les actions offertes par ce document d'information ne peuvent pas être, directement ou indirectement, offertes ou vendues au public en France. Ce document d'information n'a pas été ou ne sera pas soumis au visa de l'Autorité des Marchés Financiers et ne peut être diffusé ou distribué au public en France. Les investisseurs en France ne peuvent acheter les actions offertes par ce document d'information que pour leur compte propre et conformément aux articles L. 411-1, L. 441-2 et L. 412-1 du Code Monétaire et Financier et du décret no. 98-880 du 1 octobre 1998, sous réserve qu'ils soient des investisseurs qualifiés au sens du décret susvisé. Chaque investisseur doit déclarer par écrit qu'il est un investisseur qualifié au sens du décret susvisé. Toute revente, directe ou indirecte, des actions offertes par ce document d'information au public ne peut être effectuée que conformément à la réglementation susmentionnée."

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### *Greece*

This prospectus has been submitted for approval by the SEC and not the Greek Capital Market Committee. All information contained in this prospectus is true and accurate. The offering of our common stock does not constitute an initial public offering in Greece according to CL. 2190/1920 and L. 3401/2005 as amended and in force. This prospectus is strictly for the use of the person or entity to which it has been addressed to by us and not to be circulated in Greece or any other jurisdiction.

This information and documentation is true and accurate and in conformity with the information contained in the prospectus for the offer of common stock, which is being reviewed for approval only by the SEC, and does not constitute provision of the investment service of investment advice according to L. 3606/2007. Any recipient of this material has stated to be a qualified and experienced investor and will evaluate the contents and decide on his/her own discretion whether to participate or not in the offering pursuant to this prospectus.

### *United Kingdom*

In the United Kingdom, the shares of common stock offered by this prospectus are directed to and will only be available for purchase to a person who is an exempt person in accordance with clause (c) below and who warrants, represents and agrees that: (a) it has not offered or sold, will not offer or sell, any shares offered by this prospectus to any person in the United Kingdom except in circumstances that do not constitute an offer to the public in the United Kingdom for the purposes of the section 85 of the Financial Services and Markets Act 2000 (as amended), or the FSMA; and (b) it has complied and will comply with all applicable provisions of FSMA and the regulations made thereunder in respect of anything done by it in relation to the common stock offered by this prospectus in, from or otherwise involving the United Kingdom; and (c) it is a person who falls within the exemptions to Section 21 of the FSMA as set out in The Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, being either an investment professional as described under Article 19 or any body corporate (which itself has or a group undertaking has a called up share capital or net assets of not less than £500,000 (if more than 20 members) or otherwise £5 million) or an unincorporated association or partnership (with net assets of not less than £5 million) or is a trustee of a high value trust or any person acting in the capacity of director, officer or employee of such entities as defined under Article 49(2)(a) to (d) of the Order, or a person to whom the invitation or inducement may otherwise lawfully be communicated or cause to be communicated. The investment activity to which this document relates will only be available to and engaged in only with exempt persons referred to above. Persons who are not investment professionals and do not have professional experience in matters relating to investments or are not an exempt person as described above, should not review nor rely or act upon this document and should return this document immediately. It should be noted that this document is not a prospectus in the United Kingdom as defined in the Prospectus Regulations 2005 and has not been approved by the Financial Services Authority or any competent authority in the United Kingdom.

### *Sweden*

Neither this prospectus nor the common stock offered hereunder has been registered with or approved by the Swedish Financial Supervisory Authority under the Swedish Financial Instruments Trading Act (1991:980) (as amended), nor will such registration or approval be sought. Accordingly, this prospectus may not be made available nor may the shares of common stock offered hereunder be marketed or offered for sale in Sweden other than in circumstances that are deemed not to be an offer to the public in Sweden under the Financial Instruments Trading Act. This prospectus may not be distributed to the public in Sweden and a Swedish recipient of this prospectus may not in any way forward this prospectus to the public in Sweden.

### *Norway*

This prospectus has not been produced in accordance with the prospectus requirements laid down in the Norwegian Securities Trading Act 1997, as amended. This prospectus has not been approved or disapproved by, or registered with, either the Oslo Stock Exchange or the Norwegian Registry of Business Enterprises. This prospectus may not, either directly or indirectly, be distributed to Norwegian potential investors.

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#### **Denmark**

This prospectus has not been prepared in the context of a public offering of securities in Denmark within the meaning of the Danish Securities Trading Act No. 171 of 17 March 2005, as amended from time to time, or any Executive Orders issued on the basis thereof and has not been and will not be filed with or approved by the Danish Financial Supervisory Authority or any other public authority in Denmark. The offering of the shares of common stock pursuant to this prospectus will only be made to persons pursuant to one or more of the exemptions set out in Executive Order No. 306 of 28 April 2005 on Prospectuses for Securities Admitted for Listing or Trade on a Regulated Market and on the First Public Offer of Securities exceeding EUR 2,500,000 or Executive Order No. 307 of 28 April 2005 on Prospectuses for the First Public Offer of Certain Securities between EUR 100,000 and EUR 2,500,000, as applicable.

#### **The Netherlands**

The underwriters may not offer, distribute, sell, transfer or deliver any of our securities, directly or indirectly, in The Netherlands, as a part of their initial distribution or at any time thereafter, to any person other than our employees or employees of our subsidiary, individuals who or legal entities which trade or invest in securities in the conduct of their profession or business within the meaning of article 2 of the Exemption Regulation issued under the Securities Transactions Supervision Act 1995 (*Vrijstellingsregeling Wet toezicht effectenverkeer 1995*), which includes banks, brokers, pension funds, insurance companies, securities institutions, investment institutions, and other institutional investors, including, among others, treasuries of large enterprises who or which regularly trade or invest in securities in a professional capacity.

#### **Cyprus**

The underwriters have represented, warranted and agreed that: (i) they will not be providing from or within Cyprus any “Investment Services,” “Investment Activities” and “Non-Core Services” (as such terms are defined in the Investment Firms Law 144(I) of 2007, or the IFL) in relation to the shares of common stock, or will be otherwise providing Investment Services, Investment Activities and Non-Core Services to residents or persons domiciled in Cyprus. The underwriters have represented, warranted and agreed that it will not be concluding in Cyprus any transaction relating to such Investment Services, Investment Activities and Non-Core Services in contravention of the IFL and/or applicable regulations adopted pursuant thereto or in relation thereto; and (ii) they have not and will not offer any of the common stock other than in compliance with the provisions of the Public Offer and Prospectus Law, Law 114(I)/2005.

#### **Switzerland**

This prospectus may only be used by those persons to whom it has been directly handed out by the offeror or its designated distributors in connection with the offer described therein. The common stock is only offered to those persons and/or entities directly solicited by the offeror or its designated distributors, and are not offered to the public in Switzerland. This prospectus constitutes neither a public offer in Switzerland nor an issue prospectus in accordance with the respective Swiss legislation, in particular but not limited to Article 652A Swiss Code Obligations. Accordingly, this prospectus may not be used in connection with any other offer, whether private or public and shall in particular not be distributed to the public in Switzerland.

#### **Israel**

The common stock offered by this prospectus has not been approved or disapproved by the Israeli Securities Authority, or ISA. The shares may not be offered or sold, directly or indirectly, to the public in Israel. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the common stock being offered. Any resale, directly or indirectly, to the public of the common stock offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

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#### ***Oman***

For the attention of the residents of Oman:

The information contained in this prospectus neither constitutes a public offer of securities in the Sultanate of Oman, or Oman, as contemplated by the Commercial Companies Law of Oman (Sultani Decree 4/74) or the Capital Market Law of Oman (Sultani Decree 80/98), nor does it constitute an offer to sell, or the solicitation of any offer to buy non-Omani securities in Oman as contemplated by Article 6 of the Executive Regulations to the Capital Market Law of Oman (issued vide Ministerial Decision No 4/2001), and nor does it constitute a distribution of non-Omani securities in Oman as contemplated under the Rules for Distribution of Non-Omani Securities in Oman issued by the Capital Market Authority of Oman, or CMA. Additionally, this prospectus is not intended to lead to the conclusion of any contract of whatsoever nature within the territory of Oman.

This prospectus has been sent at the request of the investor in Oman, and by receiving this prospectus, the person or entity to whom it has been issued and sent understands, acknowledges and agrees that this prospectus has not been approved by the CMA or any other regulatory body or authority in Oman, nor has any authorization, license or approval been received from the CMA or any other regulatory authority in Oman, to market, offer, sell, or distribute the shares within Oman.

No marketing, offering, selling or distribution of any financial or investment products or services has been or will be made from within Oman and no subscription to any securities, products or financial services may or will be consummated within Oman. Neither of the underwriters are a company licensed by the CMA to provide investment advisory, brokerage, or portfolio management services in Oman, nor a bank licensed by the Central Bank of Oman to provide investment banking services in Oman. Neither of the underwriters advise persons or entities resident or based in Oman as to the appropriateness of investing in or purchasing or selling securities or other financial products.

Nothing contained in this prospectus is intended to constitute Omani investment, legal, tax, accounting or other professional advice. This prospectus is for your information only, and nothing herein is intended to endorse or recommend a particular course of action. You should consult with an appropriate professional for specific advice on the basis of your situation.

#### ***United Arab Emirates***

This document has not been reviewed, approved or licensed by the Central Bank of the United Arab Emirates, or the UAE, Emirates Securities and Commodities Authority or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai International Financial Services Authority, or the DFSA, a regulatory authority of the Dubai International Financial Centre, or the DIFC. The sale of the shares does not constitute a public offer of securities in the UAE, DIFC and/or any other free zone in accordance with the Commercial Companies Law, Federal Law No. 8 of 1984 (as amended), DFSA Offered Securities Rules and the Dubai International Financial Exchange Listing Rules, accordingly, or otherwise.

The shares may not be offered to the public in the UAE and/or any of the free zones including, in particular, the DIFC. The shares may be offered and this document may be issued, only to a limited number of investors in the UAE or any of its free zones (including, in particular, the DIFC) who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned. Our management and the underwriters represent and warrant that the shares will not be offered, sold, transferred or delivered to the public in the UAE or any of its free zones including, in particular, the DIFC.

#### ***People's Republic of China***

This prospectus may not be circulated or distributed in the People's Republic of China, or PRC, and our common stock may not be offered or sold to any person for re-offering or resale, directly or indirectly, to any

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resident of the PRC except pursuant to applicable laws and regulations of the PRC. For the purpose of this paragraph, PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

### ***Botswana***

We hereby represent and warrant that we have not offered for sale or sold, and will not offer or sell, directly or indirectly our common stock to the public in the Republic of Botswana, and confirms that the offering will not be subject to any registration requirements as a prospectus pursuant to the requirements and/or provisions of the Companies Act, 2003 or the Listing Requirements of the Botswana Stock Exchange.

### ***Hong Kong***

The shares of common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that ordinance. No advertisement, invitation or document, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) has been issued or will be issued in Hong Kong or elsewhere other than with respect to the shares of common stock that are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that ordinance.

The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this document, you should obtain independent professional advice.

### ***Singapore***

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of common stock may not be circulated or distributed, nor may the shares of common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries’ rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

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*Canada*

**NOTICE TO CANADIAN INVESTORS**

**Resale Restrictions**

The distribution of our common stock in Canada is being made only on a private placement basis exempt from the requirement that we prepare and file a prospectus with the applicable securities regulatory authorities. We are not a reporting issuer (or equivalent) in any province or territory in Canada and our common stock is not listed on any stock exchange in Canada and there is currently no public market for our common stock in Canada. We currently have no intention of becoming a reporting issuer in Canada, filing a prospectus with any common stock regulatory authority in Canada to qualify the resale of the common stock to the public, or listing our common stock on any stock exchange in Canada. Accordingly, to be made in accordance with securities laws, any resale of the common stock in Canada must be made under available statutory exemptions from registration and prospectus requirements or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Canadian purchasers are advised to seek legal and tax advice prior to any purchase or resale of our common stock.

*European Economic Area*

**NOTICE TO PROSPECTIVE INVESTORS IN THE EEA**

In relation to each member state of the European Economic Area, or EEA, which has implemented the Prospectus Directive (each, a “Relevant Member State”) an offer to the public of any shares of our common stock which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- (c) by the underwriters to fewer than 100 natural or legal persons (other than “qualified investors” as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives for any such offer; or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive; provided that no such offer of shares shall result in a requirement for the publication by us or any representative of a prospectus pursuant to Article 3 of the Prospectus Directive.

Any person making or intending to make any offer of shares within the EEA should only do so in circumstances in which no obligation arises for us or the underwriters to produce a prospectus for such offer. Neither we nor the underwriters have authorized, nor do they authorize, the making of any offer of shares through any financial intermediary, other than offers made by the underwriters which constitute the final offering of shares contemplated in this prospectus.

For the purposes of this provision, and your representation below, the expression of an “offer to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

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Each person in a Relevant Member State who receives any communication in respect of, or who acquires any shares under, the offer of shares of our common stock contemplated by this prospectus will be deemed to have represented, warranted and agreed to and with us and the underwriters that:

(A) it is a “qualified investor” within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive; and

(B) in the case of any shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) the shares acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than “qualified investors” (as defined in the Prospectus Directive), or in circumstances in which the prior consent of the representatives has been given to the offer or resale; or (ii) where shares have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those shares to it is not treated under the Prospectus Directive as having been made to such persons.

#### **VALIDITY OF THE COMMON STOCK**

The validity of the shares of common stock offered hereby and certain other legal matters will be passed upon for us by Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, Memphis, Tennessee. Certain legal matters will be passed upon for the underwriters by Andrews Kurth LLP, Austin, Texas.

#### **EXPERTS**

The financial statements of SurgiVision, Inc. as of December 31, 2009 and 2008 and for each of the three years in the period ended December 31, 2009 appearing in this prospectus and registration statement, have been audited by Cherry, Bekaert & Holland, L.L.P., independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report, given on the authority of such firm as experts in accounting and auditing.



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#### **WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to SurgiVision, Inc. and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at <http://www.surgivision.com>, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

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**SurgiVision, Inc.**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
SurgiVision, Inc.

We have audited the accompanying balance sheets of SurgiVision, Inc., a Delaware corporation (the "Company"), as of December 31, 2009 and 2008, and the related statements of operations, stockholders' equity (deficit) and cash flows for the years ended December 31, 2009, 2008, and 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of SurgiVision, Inc. as of December 31, 2009 and 2008 and the results of its operations and its cash flows for the years ended December 31, 2009, 2008, and 2007 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company incurred net losses during the three years ended December 31, 2009 of approximately \$16,200,000 and will require additional financing to fund the continued development of the Company's products. The availability of such financing cannot be assured. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans with regard to these matters are described in Note 3. The financial statements do not include any adjustments with respect to the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

/s/ Cherry, Bekaert & Holland, L.L.P.

Tampa, Florida  
April 6, 2010

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## SURGIVISION, INC.

## Balance Sheets

	December 31,	
	2009	2008
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 2,569,129	\$ 9,920,801
Due from related parties	204	8,317
Inventory	569,350	—
Prepaid expenses and other current assets	54,823	21,440
Total current assets	3,193,506	9,950,558
<b>Furniture, software and equipment, net</b>	992,158	860,506
<b>Deferred offering costs</b>	366,503	—
<b>Licenses, net</b>	63,000	81,000
<b>Deposits</b>	58,521	63,296
Total assets	<u>\$ 4,673,688</u>	<u>\$ 10,955,360</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 473,484	\$ 742,498
Accrued compensation	539,865	180,852
Other accrued liabilities	704,000	111,272
Income taxes payable	49,250	—
Derivative liability	1,227,500	—
Related party deferred revenue	2,600,000	2,600,000
Total current liabilities	5,288,099	3,634,622
<b>Related party deferred revenue</b>	6,596,374	9,085,099
<b>Related party convertible notes payable, net of \$1,129,000 unamortized discount</b>	2,371,000	—
Total liabilities	<u>14,561,473</u>	<u>12,719,721</u>
<b>Commitments and contingencies (Notes 2, 5 and 9)</b>	—	—
<b>Stockholders' deficit</b>		
Series A convertible preferred stock; \$.01 par value; 8,000,000 shares authorized and 7,965,000 shares issued and outstanding	7,965,000	7,965,000
Common stock, \$.01 par value; 70,000,000 shares authorized; 21,820,440 (2009) and 21,807,107 (2008) issued; 20,517,120 (2009) and 21,807,107 (2008) outstanding	218,205	218,071
Additional paid-in capital	25,631,208	25,490,092
Treasury stock, at cost, 1,303,320 shares (2009)	(1,679,234)	—
Notes receivable, stockholder	—	(573,620)
Accumulated deficit	(42,022,964)	(34,863,904)
Total stockholders' deficit	<u>(9,887,785)</u>	<u>(1,764,361)</u>
Total liabilities and stockholders' deficit	<u>\$ 4,673,688</u>	<u>\$ 10,955,360</u>

See notes to financial statements.

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**SURGIVISION, INC.**  
**Statements of Operations**

	Years Ended December 31,		
	2009	2008	2007
<b>Related party license revenue</b>	\$ 2,600,000	\$ 1,950,000	\$ —
<b>Operating costs and expenses:</b>			
Research and development costs	6,067,617	4,258,492	2,098,672
General and administrative expenses	3,595,917	2,920,311	1,413,369
<b>Total operating costs and expenses</b>	<u>9,663,534</u>	<u>7,178,803</u>	<u>3,512,041</u>
<b>Loss from operations</b>	<u>(7,063,534)</u>	<u>(5,228,803)</u>	<u>(3,512,041)</u>
<b>Other income (expense):</b>			
Interest income	106,197	193,756	209,641
Related party interest expense	(152,473)	(394,738)	(394,737)
	<u>(46,276)</u>	<u>(200,982)</u>	<u>(185,096)</u>
<b>Loss before income taxes</b>	<u>(7,109,810)</u>	<u>(5,429,785)</u>	<u>(3,697,137)</u>
<b>Income taxes</b>	49,250	—	—
<b>Net loss</b>	<u>\$ (7,159,060)</u>	<u>\$ (5,429,785)</u>	<u>\$ (3,697,137)</u>
<b>Net loss per share attributable to common stockholders:</b>			
Basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.26)</u>	<u>\$ (0.18)</u>
<b>Weighted average shares outstanding:</b>			
Basic	<u>21,346,533</u>	<u>20,980,324</u>	<u>20,098,058</u>

See notes to financial statements.

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## SURGIVISION, INC.

Statements of Stockholders' Equity (Deficit)  
Years Ended December 31, 2009, 2008, 2007

	Convertible Preferred Stock Series A		Common Stock		Additional Paid-in Capital	Treasury Stock	Stock Subscription Receivable	Notes Receivable Stockholders	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount						
Balances, January 1, 2007	7,965,000	\$7,965,000	19,877,885	\$198,780	\$23,023,823	\$ —	\$(100,000)	\$ (530,361)	\$(25,736,982)	\$ 4,820,260
Collection of stock subscription receivable	—	—	—	—	—	—	100,000	—	—	100,000
Accrued interest on note receivable	—	—	—	—	—	—	—	(21,600)	—	(21,600)
Common stock issued in connection with research and consulting agreement	—	—	255,384	2,553	53,631	—	—	—	—	56,184
Common stock issued in connection with consulting agreement	—	—	2,000	20	1,580	—	—	—	—	1,600
Warrants issued in connection with convertible note payable amendment	—	—	—	—	789,475	—	—	—	—	789,475
Employee share-based compensation	—	—	—	—	20,401	—	—	—	—	20,401
Net loss for the year	—	—	—	—	—	—	—	—	(3,697,137)	(3,697,137)
Balances, December 31, 2007	7,965,000	7,965,000	20,135,269	201,353	23,888,910	—	—	(551,961)	(29,434,119)	2,069,183
Employee share-based compensation	—	—	—	—	117,900	—	—	—	—	117,900
Accrued interest on note receivable	—	—	—	—	—	—	—	(21,659)	—	(21,659)
Conversion of convertible note payable	—	—	1,671,838	16,718	1,483,282	—	—	—	—	1,500,000
Net loss for the year	—	—	—	—	—	—	—	—	(5,429,785)	(5,429,785)
Balances, December 31, 2008	7,965,000	7,965,000	21,807,107	218,071	25,490,092	—	—	(573,620)	(34,863,904)	(1,764,361)
Employee share-based compensation	—	—	—	—	130,587	—	—	—	—	130,587
Accrued interest on notes receivable	—	—	—	—	—	—	—	(57,779)	—	(57,779)

Purchase of treasury stock for cash	—	—	—	—	—	(547,835)	—	—	—	(547,835)
Issuance of note receivable, stockholder	—	—	—	—	—	—	—	(500,000)	—	(500,000)
Options exercised for cash	—	—	13,333	134	10,529	—	—	—	—	10,663
Purchases of 519,849 shares of treasury stock through cancellation of note receivable and accrued interest	—	—	—	—	—	(1,131,399)	—	1,131,399	—	—
Net loss for the year	—	—	—	—	—	—	—	—	(7,159,060)	(7,159,060)
Balances, December 31, 2009	<u>7,965,000</u>	<u>\$7,965,000</u>	<u>21,820,440</u>	<u>\$218,205</u>	<u>\$25,631,208</u>	<u>\$(1,679,234)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$(42,022,964)</u>	<u>\$ (9,887,785)</u>

See notes to financial statements.

**SURGIVISION, INC.**  
**Statements of Cash Flows**

	Years Ended December 31,		
	2009	2008	2007
<b>Cash flows from operating activities:</b>			
Net loss	\$(7,159,060)	\$ (5,429,785)	\$(3,697,137)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Depreciation and amortization	168,710	84,484	16,728
Expenses paid through the issuance of common stock	—	—	57,784
Share-based compensation	130,587	117,900	20,401
Amortization of debt discount	98,500	394,738	394,737
Accrued interest on notes receivable, stockholder	(57,779)	(21,659)	(21,600)
Increase (decrease) in cash resulting from changes in:			
Due from related parties	8,113	(8,317)	1,864
Inventory	(569,350)	—	—
Prepaid expenses and other current assets	(33,383)	(21,440)	4,682
Deposits	4,775	(24,226)	(38,033)
Accounts payable and accrued expenses	731,977	603,975	141,154
Related party deferred revenue	(2,488,725)	11,560,099	125,000
<b>Net cash flows from operating activities</b>	<b>(9,165,635)</b>	<b>7,255,769</b>	<b>(2,994,420)</b>
<b>Cash flows from investing activities:</b>			
Purchases of furniture, software and equipment	(282,362)	(856,782)	(62,179)
Purchase of licenses	—	(90,000)	—
<b>Net cash flows from investing activities</b>	<b>(282,362)</b>	<b>(946,782)</b>	<b>(62,179)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from related party notes	—	—	500,000
Purchase of treasury stock for cash	(547,835)	—	—
Issuance of note receivable, stockholder	(500,000)	—	—
Deferred offering costs paid	(366,503)	—	—
Proceeds from related party convertible note	3,500,000	—	—
Proceeds from option exercises	10,663	—	—
Proceeds from Series A preferred stock offering	—	—	100,000
<b>Net cash flows from financing activities</b>	<b>2,096,325</b>	<b>—</b>	<b>600,000</b>
<b>Net change in cash</b>	<b>(7,351,672)</b>	<b>6,308,987</b>	<b>(2,456,599)</b>
<b>Cash, beginning of period</b>	<b>9,920,801</b>	<b>3,611,814</b>	<b>6,068,413</b>
<b>Cash, end of period</b>	<b><u>\$ 2,569,129</u></b>	<b><u>\$ 9,920,801</u></b>	<b><u>\$ 3,611,814</u></b>

See notes to financial statements.



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**SURGIVISION, INC.**  
**Statements of Cash Flows (Continued)**

**NON-CASH INVESTING AND FINANCING TRANSACTIONS**

- 2007—The Company issued warrants with a fair value of \$789,475 as part of the amendment to the convertible note payable
- 2008—The Company converted \$1,500,000 of convertible notes payable into 1,671,838 shares of common stock
- 2009—The Company cancelled related party notes receivable and accrued interest in the amount of \$1,131,399 in exchange for 783,471 shares of treasury stock

See notes to financial statements.

**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 1 – Formation and Nature of Business**

SurgiVision, Inc. (the “Company”), a Delaware corporation, was formed on March 12, 1998. The Company operates in a single segment. The Company is a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain and heart using direct, intra-procedural magnetic resonance imaging, or MRI, guidance while performing minimally invasive surgical procedures. Prior to 2008, the Company was a development stage entity.

The Company’s first product candidate is the ClearPoint system, which is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The Company’s second product candidate is the ClearTrace system, which is designed to allow catheter-based minimally invasive procedures in the heart to be performed in an MRI suite. The Company is also pursuing what it refers to as its SafeLead Development Program, the purpose of which is to incorporate the Company’s MRI-safety technologies into a third party’s implantable leads for cardiac and neurological applications.

**Note 2 – Significant Accounting Policies**

*Principles of Consolidation*—The financial statements include SurgiVision, Inc. and its approximate 93% owned subsidiary, Cardiac EP Sub, Inc., a Delaware corporation, which was formed on December 19, 2008. The minority interest associated with the investment in Cardiac EP Sub, Inc. is of nominal value as of December 31, 2009 and, consequently, has not been recognized in the financial statements. All significant intercompany balances and transactions are eliminated from the financial statements.

*Use of Estimates*—The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Concentration of Credit Risk*—The Company places its cash on deposit with financial institutions in the United States. In October and November 2008 the Federal Deposit Insurance Corporation (“FDIC”) temporarily increased coverage to \$250,000 for substantially all depository accounts and temporarily provides unlimited coverage for certain qualifying and participating non-interest bearing transaction accounts. The increased coverage is scheduled to expire on December 31, 2013, at which time it is anticipated amounts insured by the FDIC will return to \$100,000. From time to time, the Company may have amounts on deposit in excess of the insured limits. As of December 31, 2009, the Company had approximately \$94,000 of cash and cash equivalents which exceeded these insured amounts.

*Cash and Cash Equivalents*—Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less.

*Inventory*—Inventory is carried at the lower of cost (first-in, first-out (“FIFO”) method) or net realizable value. All items included in inventory relate to the Company’s ClearPoint system. As of December 31, 2009, the ClearPoint system has not received regulatory clearance from the Food and Drug Administration for commercial sale in the United States. If the Company is unable to obtain clearance, these amounts would be charged to expense to the extent that the inventory cannot be returned to the vendors for cash or sold for scrap. At each reporting period, the Company evaluates the net realizability of its inventory considering factors such as the likelihood of needed regulatory clearances or approvals, anticipated selling prices and relevant changes in market conditions.

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**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 2 – Significant Accounting Policies – (continued)**

Inventory consists of the following amounts related to the ClearPoint System as of December 31, 2009:

Software licenses (Note 9)	\$175,000
Hardware	268,447
Disposable Components—work in process	<u>125,903</u>
	<u>\$569,350</u>

*Furniture, Software and Equipment*—Furniture, software and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives, principally five to seven years. Leasehold improvements are depreciated on a straight line basis over the lesser of the estimated useful lives or the life of the related lease.

*Licenses*—Licenses are recorded at cost and are amortized using the straight-line method over their estimated useful life. The carrying value of licenses at December 31, 2009 and 2008 was \$63,000 and \$81,000, net of accumulated amortization of \$27,000 and \$9,000, respectively. Future amortization under licenses is expected to be approximately \$18,000 annually through June, 2013. One of the licenses contains a requirement to pay the licensor an additional \$40,000 upon the issuance of a certain patent, and a second license contains a requirement to pay the licensor an additional \$20,000 upon the issuance of another patent.

The license arrangements require certain minimum royalty payments to the licensor. The future minimum royalty payments are as follows:

Years ending December 31,	
2010	\$ 37,500
2011	50,000
2012	62,500
2013	75,000
2014	75,000
Thereafter	<u>1,087,500</u>
	<u>\$1,387,500</u>

Royalty payment amounts may be greater than the above amounts based on the negotiated royalty rate. If the Company sublicenses the intellectual property that is licensed from the licensor and the Company receives any payment under or with respect to such sublicense, the Company is obligated to pay the licensor an agreed upon percentage of such payment(s). The Company is required to reimburse the licensor for all costs associated with patent rights related to each respective license.

The Company may terminate these license agreements for any reason, upon giving the licensor either sixty or ninety days' written notice. Lastly, one of these licenses is cancelable by the licensor if, by the fourth anniversary of the effective date (June 30, 2012), there have been no commercial sales of a product subject to such license.

*Impairment of Long-Lived Assets*—The Company evaluates the recoverability of its long-lived assets (finite-lived intangible assets and furniture, software and equipment) whenever adverse events or changes in business

**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 2 – Significant Accounting Policies – (continued)**

climate indicate that the expected undiscounted future cash flows from the related assets may be less than previously anticipated. If the net book value of the related assets exceeds the undiscounted expected future cash flows of the assets, the carrying amount would be reduced to the present value of their expected future cash flows and an impairment loss would be recognized. There have been no impairment losses in the periods presented.

*Revenue Recognition*—The Company analyzes revenue recognition on an agreement by agreement basis as discussed herein.

- *Related Party Revenue Recognition under Boston Scientific Corporation “BSC” Neuro Agreement (Note 5)*—The Company analyzed whether the components of the arrangement represent separate units of accounting as defined by Accounting Principles Generally Accepted in the United States (“GAAP”). Application of these standards requires subjective determinations and requires management to make judgments about the value of the individual elements and whether delivered elements are separable from the other aspects of the contractual relationship. The Company determined it did not have clear and objective evidence of fair value of the various elements of the agreement and therefore, under GAAP regarding Multiple-Element Arrangements, has determined that the deliverables will be accounted for as one unit of accounting.

This agreement requires specified milestones in the development of an MRI-safe implantable lead to be achieved by December 31, 2012. If the milestones are not achieved by that date and this failure is not the result of BSC Neuro’s failure to reasonably cooperate with the Company in pursuing the milestones, the Company will be required to repay BSC Neuro certain amounts, including any development expenses and milestone payments previously made to the Company under this agreement and any patent prosecution costs incurred by BSC Neuro with respect to the intellectual property licensed under this agreement. The existence of this provision indicates the sales price is not fixed or determinable and all monies which have been or will be received prior to December 31, 2012 have and will be deferred until such time. If the repayment obligations are not triggered as of December 31, 2012, the related party deferred revenue related to this contract will be recognized over the estimated period of continuing involvement. If the repayment obligations are triggered as of December 31, 2012, the related party deferred revenue related to this contract will be repaid to BSC Neuro.

The agreement includes research and development services requirements. The Company has recognized deferred research and development services revenue along with the related costs (charged to expense) on a gross basis since the Company is obligated and bears all credit risk with respect to the cost of providing the services.

Future product royalty payments related to the agreement will be recognized as the related products are sold and payments are due to the Company.

- *Related Party Revenue Recognition under BSC Cardiac Agreement (Note 5)*—The Company analyzed whether the components of the arrangement represent separate units of accounting as defined by GAAP. Application of these standards requires subjective determinations and requires management to make judgments about the value of the individual elements and whether delivered elements are separable from the other aspects of the contractual relationship.

The Company defers recognition of non-refundable upfront license fees if there are continuing performance obligations without which the technology, know-how, rights, products or services

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**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 2 – Significant Accounting Policies – (continued)**

conveyed in conjunction with the non-refundable fees have no utility to the licensee that could be considered separate and independent of the Company's performance under other elements of the arrangement. Since the Company has continuing involvement through research and development services that is required because the Company's know-how and expertise related to the technology are proprietary to the Company, or can only be performed by the Company, such upfront fees are deferred and recognized over the estimated period of continuing involvement on the straight line basis.

Payments to be received related to substantive, performance-based milestones in research and development arrangements are deferred upon receipt and achievement of the milestones as specified in the underlying agreement and recognized over the period of continuing involvement.

Future product royalty payments related to the agreement will be recognized as the related products are sold and payments are due to the Company.

*Research and Development Costs*—Research and development costs consist of direct and indirect costs associated with the development of the Company's technology. These costs are expensed as incurred.

*Income Taxes*—Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that included the enactment date.

Valuation allowances are recorded for deferred tax assets when the recoverability of such assets is not deemed more likely than not.

Management has evaluated the effect of the guidance provided by GAAP regarding accounting for uncertainty in income taxes that became effective in 2009. In that regard, management has evaluated all tax positions that could have a significant effect on the financial statements and determined the Company has no uncertain tax positions at December 31, 2009. The Company's tax returns after 2005 remain open for examination.

*Net Loss Per Share*—Basic net loss per common share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. For all periods presented, diluted net loss per share is the same as basic net loss per share, as the inclusion of equivalent shares from outstanding common stock options, warrants, convertible debt and preferred stock would be anti-dilutive. The following table sets forth potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	Year ended December 31,		
	2009	2008	2007
Stock options	2,679,108	2,399,500	1,805,000
Warrants	1,642,167	3,314,005	3,314,005
Convertible preferred shares	7,965,000	7,965,000	7,965,000
Shares under convertible note agreements	1,750,000	—	1,671,838
	<u>14,036,275</u>	<u>13,678,505</u>	<u>14,755,843</u>

**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 2 – Significant Accounting Policies – (continued)**

*Share-Based Compensation*—The Company accounts for compensation for all arrangements under which employees and others receive shares of stock or equity instruments (including options and warrants) in accordance with FASB ASC Topic 718 “*Compensation – Stock Compensation*”, or ASC Topic 718. Under ASC Topic 718, the fair value of each award is separately estimated and amortized into compensation expense over the service period. The fair value of the Company’s share-based options and warrants is estimated on the grant date using the Black-Scholes valuation model. The Company’s determination of the fair value of the Company’s share-based awards on the grant date using valuation models requires the input of highly subjective assumptions, including the expected price volatility and option life. As the Company has been operating as a private company, it was unable to use actual price volatility and option life data as input assumptions within its Black-Scholes valuation model. Prior to October 2009, the Company used the expected volatilities based on the historical volatility of the industry sector in which the Company operates, in accordance with the guidance set forth in ASC Topic 718.

Beginning October 2009, for the calculation of expected volatility, because the Company lacks company-specific historical and implied volatility information, the Company based its estimate of expected volatility on the average of volatilities of publicly traded companies the Company deemed similar to the Company. The Company intends to consistently apply this process using this same methodology until a sufficient amount of historical information regarding the volatility of the Company’s own share price becomes available.

To estimate the expected term, the Company utilizes the “simplified” method for “plain vanilla” options as discussed within the Securities and Exchange Commission’s Staff Accounting Bulletin 107, or SAB 107. The Company believes that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method are true for the Company and for the Company’s share-based payment arrangements. The Company intends to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior becomes available.

The Company’s risk-free interest rates are based on a zero-coupon U.S. treasury instrument, the term of which is consistent with the expected term of the stock options. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock; therefore, the expected dividend yield is assumed to be zero.

*Fair Value Determination of Privately-Held Equity Securities*—The fair values of the common stock as well as the common stock underlying options and warrants granted as compensation, or issued in connection with the settlement of liabilities, were estimated by management, with input from an unrelated third-party valuation specialist.

Determining the fair value of stock requires making complex and subjective judgments. The Company has used the income approach, the market approach, and the probability weighted expected return method to estimate the value of the enterprise for the dates on which securities are issued/granted and outstanding. The income approach was based on estimated future cash flows that utilized the Company’s forecasts of revenue and costs. The assumptions underlying the revenue and cost estimates are consistent with the Company’s business plan. The market approach was based on recent sales of the Company’s common stock in privately negotiated transactions between stockholders. Once the Company began the process of preparing for its initial public offering of common stock, the Company began to utilize the probability weighted expected return method, which is based on identifying the most likely liquidity events for the Company, the probability of each occurring, and the equity values for each after applying different percentages to the likelihood of the different values assigned to each anticipated outcome of those events. The assumptions used in each of the different valuation methods take into account certain discounts such as selecting the appropriate discount rate and control and lack of marketability

**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 2 – Significant Accounting Policies – (continued)**

discounts. The discount rate used in each valuation was 35%. The discounts for lack of marketability ranged from 20% to 35% and the discount for lack of control ranged from 20% to 30%. If different discount rates or lack of marketability and control discounts had been used, the valuations would have been different. The enterprise value under each valuation method was allocated to preferred and common shares taking into account the enterprise value available to all stockholders and allocating that value among the various classes of stock based on the rights, privileges, and preferences of the respective classes in order to provide an estimate of the fair value of a share of our common stock. There is inherent uncertainty in these estimates.

*Fair Value Measurements*—Effective January 1, 2008, the Company adopted the provisions of a required new accounting standard related to fair value accounting for financial assets and liabilities, as well as for any other assets and liabilities that are carried at fair value on a recurring basis. As required, the Company adopted this standard for all non-financial assets and liabilities that are recognized or disclosed at fair value on a recurring basis, as of January 1, 2009. The adoption did not materially impact the Company’s consolidated financial position and results of operations.

Fair value in this standard is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The standard also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Three levels of inputs may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

The following table summarizes liabilities measured at fair value on a recurring basis:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
<b>Liabilities</b>				
Derivative liability, Note 6 (2009)	\$ —	\$ —	\$1,227,500	\$1,227,500

The financial instruments recorded in the balance sheets include cash and cash equivalents, accounts payable and related party convertible notes. Due to their short-term maturity, the carrying amounts of cash and cash equivalents and accounts payable approximate their fair value. At December 31, 2009, the fair value of the related party convertible notes payable is \$3,500,000.

*Derivative Financial Instruments.* The Company accounts for derivative instruments in accordance with FASB ASC Topic 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period as a gain or loss in the statement of operations unless the derivative qualifies for hedge accounting. At December 31, 2009 and 2008, the Company did not have any derivative instruments that were designated as hedges. (See Note 6)

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**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 3 – Liquidity and Management’s Plans – (continued)**

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. For the years ended December 31, 2009, 2008 and 2007, the Company has incurred net losses of approximately \$7,200,000, \$5,400,000, and \$3,700,000, respectively, and cumulative net loss since the Company’s inception through December 31, 2009 is approximately \$42,000,000. In view of these matters, the ability of the Company to continue as a going concern is dependent upon the Company’s ability to generate additional financing sufficient to support its research and development activities, clearance or approval of developed products for sale by applicable regulatory authorities, including the U.S. Food and Drug Administration, and ultimately to generate revenue sufficient to cover all costs. Since inception, the Company has financed its activities principally from the sale of equity securities, borrowings, and license arrangements. The Company intends on financing its future development activities and its working capital needs largely from the sale of equity securities until such time that funds provided by operations are sufficient to fund working capital requirements. There can be no assurance that the Company will 1) be successful at achieving its financing goals on reasonable commercial terms, if at all or 2) generate revenues sufficient to cover its costs.

**Note 4 – Furniture, Software and Equipment**

Furniture, software and equipment consist of the following:

	December 31,	
	2009	2008
Furniture and equipment	\$1,079,030	\$ 807,012
Software	19,232	8,888
Leasehold Improvements	157,236	157,236
	1,255,498	973,136
Less accumulated depreciation	(263,340)	(112,630)
	<u>\$ 992,158</u>	<u>\$ 860,506</u>

Depreciation expense was as follows:

	Years Ended December 31,		
	2009	2008	2007
	\$150,710	\$71,928	\$16,728

**Note 5 – Related Party License Agreements**

License and development agreements have been entered into with affiliates of Boston Scientific Corporation (“BSC”). Because BSC’s affiliate is a stockholder and has a representative on the Company’s board of directors, management has deemed all transactions with BSC and its affiliates to be of a related party nature.

*BSC Neuro Agreement*—Effective December 30, 2005, the Company entered into definitive license and development agreements (collectively, as amended, the “BSC Neuro Agreement”) with Advanced Bionics Corporation, an affiliate of BSC. Advanced Bionics Corporation subsequently changed its name to Boston Scientific Neuromodulation Corporation (“BSC Neuro”). Under the BSC Neuro Agreement, the Company granted BSC Neuro an exclusive commercial license with respect to certain of the Company’s owned and



**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 5 – Related Party License Agreements – (continued)**

licensed intellectual property, in the neuromodulation field, to make, use, import, lease and sell neuro-related leads, neuro-related lead extensions, and neuro-related lead-type devices, such as implantable pulse generators. The Company has continuing research and development obligations pursuant to the BSC Neuro Agreement with respect to the development of MRI-compatible and MRI-safe implantable neuromodulation leads.

Under the BSC Neuro Agreement, in addition to prospective royalty payments on net sales of licensed products, the Company could receive up to \$1.6 million in future milestone-based payments associated with successful development and regulatory approval of the leads. The Company did not receive any up-front license payments pursuant to this agreement. In addition, the Company could receive over \$500,000 in incentive payments for incremental development work BSC Neuro may request. This agreement requires specified milestones in the development of an MRI-safe implantable lead to be achieved by December 31, 2012. If the milestones are not achieved by that date and this failure is not the result of BSC Neuro's failure to reasonably cooperate with the Company in pursuing the milestones, the Company will be required to repay BSC Neuro certain amounts, including any development expenses and milestone payments previously made to the Company under this agreement and any patent prosecution costs incurred by BSC Neuro with respect to the intellectual property licensed under this agreement. As of December 31, 2009, the Company had received approximately \$750,000 of payments from BSC Neuro which would be subject to the repayment obligation described above. In addition, the Company would be responsible to reimburse BSC Neuro for out of pocket costs incurred by BSC Neuro in prosecuting the patents for the licensed technologies. As discussed in Note 2, Revenue Recognition, all amounts received have been recorded as deferred revenues.

*BSC Cardiac Pacemakers Agreement*—Effective March 19, 2008, the Company entered into definitive license and development agreements (collectively the "BSC Cardiac Agreement") with Cardiac Pacemakers, Inc. ("BSC Cardiac"), an affiliate of Boston Scientific Corporation. Under the BSC Cardiac Agreement, the Company granted BSC Cardiac an exclusive commercial license with respect to certain of the Company's owned and licensed intellectual property rights, in the field of implantable medical leads for cardiac applications, to make, have made, use, promote, market, import, distribute, lease, sell, offer for sale and commercialize products in the licensed field of use. The Company is required to continue to investigate the feasibility of its technology and, upon successful completion of feasibility studies, to work with BSC Cardiac to develop this technology for different types of MRI-compatible and MRI-safe implantable cardiac leads.

Pursuant to the BSC Cardiac Agreement, in addition to prospective royalty payments on net sales of licensed products, the Company received non-refundable licensing fees totaling \$13 million in 2008, and the Company could receive up to \$20 million in future milestone-based payments associated with the successful development and regulatory approval of the implantable cardiac leads, subject to certain patents being issued on patent applications licensed to BSC Cardiac. The Company initially recorded the payment as deferred revenue and is subsequently recognizing revenue over the five year estimated period of continuing involvement (see Note 2, Revenue Recognition). The Company determined the five year estimated period of continuing involvement based upon the Company's internal development plan and projected timeline for the different implantable cardiac leads.

Except as set forth below, the licensing provisions of the BSC Cardiac Agreement will terminate upon the expiration of the last issued patent that is licensed under the agreement, and the development provisions of the BSC Cardiac Agreement will expire upon FDA approval of a design for each of the different lead types described in the agreement. BSC Cardiac has the one-time option, within 60 days after successful completion of the first cardiac lead feasibility study, to cease further development work and to terminate the provisions of the BSC Cardiac Agreement. If BSC Cardiac elects to exercise its option under the BSC Cardiac Agreement to terminate

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**SURGIVISION, INC.**

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**Years Ended December 31, 2009, 2008 and 2007**

**Note 5 – Related Party License Agreements – (continued)**

further development efforts, the license the Company granted to BSC Cardiac will automatically become non-exclusive with respect to some intellectual property, other intellectual property will be removed from the scope of the license and revert to the Company, and BSC Cardiac will not be obligated to pay the Company any future royalties on net sales of products containing intellectual property that remains subject to the non-exclusive license. Likewise, any unachieved future milestone-based payments will not be paid or due the Company. However, upon any such termination, the Company will not be required to repay any portion of the upfront licensing fees paid and would recognize any unamortized deferred revenue.

Remaining related party deferred revenue is expected to be recognized as revenue as follows:

Years ending December 31,	
2010	\$2,600,000
2011	2,600,000
2012	2,600,000
2013	1,396,374
	<u>\$9,196,374</u>

**Note 6 – Related Party Notes Payable**

*Related Party Convertible Notes Payable (BSC)*—On October 16, 2009, the Company entered into a convertible note payable arrangement with BSC. The arrangement allowed for initial borrowings by the Company of \$2,000,000, which was received in October 2009, and additional borrowings at future dates totaling up to \$2,250,000. During November 2009 and December 2009, the Company borrowed an additional \$1,500,000 from BSC. All borrowings bear interest at 10% per annum and mature on the second anniversary of the date on which the funds were advanced (October through December 2011); however, the Company can prepay each loan at anytime prior to its respective maturity date. The principal and interest outstanding on each note is convertible, at the option of the holder, into one share of the Company's preferred stock at a conversion price equal to the lower of \$2.00 per share, or the price per share paid by investors in a future preferred stock financing conducted by the Company. The notes are secured by a first priority security interest in all of the Company's assets.

The Company analyzed the terms of the conversion feature under ASC Topic 815 and determined, based upon the conversion price reset provision, that the conversion feature represented a derivative required to be accounted for as a derivative liability (Note 2, Fair Value Measurements). Under this guidance the conversion feature was initially measured at fair value and will be adjusted to the current fair value at each reporting period with the changes in fair value recorded as income (expense) in the related statement of operations. The Company calculated the fair value of this derivative liability utilizing the Black-Scholes pricing model. The assumptions used in calculating the fair value of the derivative liability using this model as of the transaction dates were as follows:

Dividend yield	0%
Expected volatility	38.28%
Risk free interest rate	1.14%
Expected term	2 years

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**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 6 – Related Party Notes Payable – (continued)**

The proceeds from the transaction were allocated as follows:

<b>Financial Instrument</b>	
Convertible debt	\$2,272,500
Derivative liability	1,227,500
	<u>\$3,500,000</u>

There was no further adjustment of the derivative liability as of December 31, 2009 because the change in its fair value was insignificant.

The discount on the convertible debt has been and will be amortized through charges to interest expense based upon the effective interest method through the date of maturity.

*Related Party Convertible Notes Payable (BSC Neuro)*—During December 2005, BSC Neuro advanced the Company \$1,500,000 in the form of a convertible promissory note. The original maturity date of this note was December 31, 2007 or, if earlier, the expiration of a stipulated period of negotiations between BSC Neuro and the Company that followed the completion of certain product development work by the Company (the “Negotiation Period”).

The calculation of BSC Neuro’s conversion option under the note depended on whether BSC Neuro and the Company entered into a license agreement with respect to certain Company technology (the “Subsequent License”). If BSC Neuro and the Company did not enter into the Subsequent License, then the note was convertible into 10% of the Company’s fully diluted common shares (all outstanding common stock, all outstanding preferred stock convertible into shares of common stock, all warrants and options to acquire shares of common stock (vested and unvested) and all shares of common stock issuable under the Company’s equity compensation plans). If BSC Neuro and the Company did enter into the Subsequent License, then the note was convertible into 5% of the Company’s fully diluted common shares. There was no beneficial conversion feature associated with this transaction.

The note was amended on June 30, 2007, wherein the maturity date was extended to June 30, 2008 or, if earlier, the expiration of the Negotiation Period. The lender’s conversion option was then fixed at 5% of the Company’s fully diluted common shares. However, if at the time of conversion BSC Neuro and the Company had not entered into the Subsequent License, the Company was also required to issue BSC Neuro a warrant to purchase an additional 5% of the Company’s fully diluted common shares at an exercise price of \$0.01 per share. Such warrant would only be exercisable if BSC Neuro and the Company did not enter into the Subsequent License by the end of the Negotiation Period. The conversion option under the amended note is substantively the same as the conversion option under the original note.

The June 30, 2007 amendment was evaluated to determine if it qualified as a debt extinguishment accounting. Based on the analysis performed, there was no debt extinguishment recorded as the fair value of the pre-amendment and post-amendment cash flows related to the notes did not differ by more than 10%. The fair value of the aforementioned \$0.01 warrant of approximately \$790,000 was recorded as a debt discount on the date of amendment and amortized through interest expense through the extended maturity date (June 30, 2008).

On June 30, 2008, BSC Neuro exercised its conversion option and converted the note in full into 1,671,838 shares of common stock. Upon conversion, BSC Neuro and the Company had not entered into the Subsequent License. Therefore, the number of shares subject to the aforementioned warrant was fixed at 1,671,838. The

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**SURGIVISION, INC.**

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**Years Ended December 31, 2009, 2008 and 2007**

**Note 6 – Related Party Notes Payable – (continued)**

Negotiation Period expired during the year ended December 31, 2009, and BSC Neuro and the Company did not enter into the Subsequent License. However, BSC Neuro did not exercise the warrant and the warrant expired during the year ended December 31, 2009.

**Note 7 – Stockholders' Equity**

*Series A Preferred Stock*—In 2006, the Company issued 7,965,000 shares of Series A Convertible Preferred Stock for net proceeds of \$7,335,787 (\$7,965,000 net of \$629,213 in transaction expenses). Additionally, the placement agent received detachable warrants to acquire up to 566,000 shares of the Company's common stock at \$1.00 per share with a fair value of \$28,696 on the date of issuance. The warrants expire on December 31, 2011.

The holders of the Series A Convertible Preferred Stock have the following rights and privileges.

*Voting.* Each holder of Series A Convertible Preferred Stock is entitled to vote on all matters presented to holders of common stock, with each holder entitled to the number of votes equal to the number of shares of common stock into which his or her shares of Series A Convertible Preferred Stock could be converted.

*Dividend Rights.* There is no dividend rate on the Series A Convertible Preferred Stock; however, the Company will pay holders of Series A Convertible Preferred Stock any dividend it declares with respect to the common stock on an as converted basis.

*Conversion.* The holders of Series A Convertible Preferred Stock have the right to convert such shares, at any time, into shares of common stock. The initial conversion rate of Series A Convertible Preferred Stock is one-for-one, subject to adjustment for certain corporate events, including stock splits, stock dividends, and recapitalizations. The Series A Convertible Preferred Stock automatically convert into common stock at the then applicable conversion rate upon the closing of an initial public offering or the consent of holders of a majority of the outstanding shares of the Series A Convertible Preferred Stock.

*Liquidation.* In the event of the liquidation, dissolution or winding-up of the Company, the holders of Series A Convertible Preferred Stock would be entitled to receive \$1.00 per share before any liquidation distributions may be paid to the holders of the common stock.

*Redemption.* Shares of Series A Convertible Preferred Stock are not redeemable by the Company.

*Registration Rights Agreement*—The Company has an agreement with many of its current stockholders pursuant to which the Company has granted those stockholders certain registration rights. The stockholders who are parties to the agreement generally have two demand registration rights, which rights become effective as of the date that is six months after the Company's initial public offering (as such these registration rights are contingent upon the successful completion of an initial public offering). A requisite percentage of holders is required to exercise a demand registration right, and certain other restrictions apply. Stockholders also have the right to participate on a "piggyback basis" in certain registrations by the Company under the Securities Act of 1933, subject to certain restrictions, including underwriter holdbacks.

*Stock Incentive Plans*—The Company has two share-based compensation plans (the "2007 Plan" and the "1998 Plan", and collectively the "Plans"). The 1998 Plan provides for the granting of qualified incentive and

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**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 7 – Stockholders' Equity – (continued)**

non-qualified stock options to employees, directors, consultants and advisors. The 2007 Plan provides for the granting of qualified incentive and non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards to employees, directors, consultants and advisors. Awards may be subject to a vesting schedule as set forth in each individual award agreement. The Company terminated the 1998 Plan, effective June 24, 2008, with respect to future grants such that no new options may be awarded under the 1998 Plan on or after June 24, 2008. The maximum shares of common stock which can be issued under the 2007 Plan is 2,500,000.

Activity with respect to the stock options is summarized as follows:

	Options Outstanding	Options Exercisable	Range of Exercise Price	Weighted- average Exercise price per share	Intrinsic Value
Balance at January 1, 2007	1,215,000		\$0.22 - 6.00	\$ 0.43	\$ 320,000
Options exercisable at January 1, 2007		1,215,000	0.22 - 6.00	0.43	320,000
Options granted	590,000		0.80	0.80	
Balance at December 31, 2007	1,805,000		0.22 - 6.00	0.55	331,500
Options exercisable at December 31, 2007		1,445,000	0.22 - 6.00	0.49	331,500
Options granted	619,500		1.51 - 2.41	1.96	
Options cancelled or forfeited	(25,000)		1.50	1.50	
Outstanding at December 31, 2008	2,399,500		0.22 - 6.00	0.91	3,742,700
Options exercisable at December 31, 2008		1,728,333	0.22 - 6.00	0.67	3,133,667
Options granted	373,608 <sup>(1)</sup>		2.41	2.41	
Options exercised	(13,333)		0.80	0.80	
Options cancelled or forfeited	(80,667)		0.41 - 5.00	2.40	
Outstanding at December 31, 2009	2,679,108		0.22 - 6.00	1.07	3,694,400
Options exercisable at December 31, 2009		1,933,455	0.22 - 6.00	0.69	3,424,333

(1) All Options granted during the year ended December 31, 2009 were granted with an exercise price of \$2.41 per share, which was deemed to be the fair market value on the date of grant.

The following table summarizes information about stock options at December 31, 2009:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted - Average Remaining Contractual Life	Weighted - Average Exercise Price	Number Exercisable	Weighted - Average Exercise Price
\$ 0.22 - 0.80	1,710,000	\$ 5.30	\$ 0.34	1,656,667	\$ 0.40
1.51 - 2.41	939,108	7.30	2.12	246,788	2.04
6.00	30,000	1.00	6.00	30,000	6.00
	<u>2,679,108</u>	5.95	1.07	<u>1,933,455</u>	0.69

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**SURGIVISION, INC.**

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**Years Ended December 31, 2009, 2008 and 2007**

**Note 7 – Stockholders' Equity – (continued)**

The following table summarizes information about stock options at December 31, 2008:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted - Average Remaining Contractual Life	Weighted - Average Exercise Price	Number Exercisable	Weighted - Average Exercise Price
\$ 0.22 - 0.80	1,740,000	6.33	\$ 0.42	1,533,333	\$ 0.37
1.51 - 2.41	619,500	9.56	1.96	155,000	2.41
5.00 - 6.00	40,000	1.50	5.75	40,000	5.75
	<u>2,399,500</u>	7.09	0.91	<u>1,728,333</u>	0.67

The weighted-average grant-date fair value of options granted during the years ended December 31, 2009 and 2008 are \$0.71 and \$0.58, respectively. A summary of the status of the Company's nonvested stock options during the years ended December 31, 2009 and 2008, is presented below.

Nonvested Stock Options	Shares	Weighted - Average Grant Date Fair Value
Nonvested January 1, 2007	—	\$ —
Granted	360,000	0.10
Nonvested December 31, 2007	360,000	0.10
Granted	464,500	0.56
Vested	(153,333)	0.10
Nonvested December 31, 2008	671,167	0.42
Granted	373,608	0.71
Forfeited	(29,000)	0.71
Vested	(270,122)	0.28
Nonvested December 31, 2009	<u>745,653</u>	<u>\$ 0.60</u>

As of December 31, 2009 there was approximately \$397,000 of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of approximately 3 years.

The assumptions used in calculating the fair value of options using the Black-Scholes option-pricing model are set forth in the following table:

	Year Ended December 31,		
	2009	2008	2007
Dividend yield	0%	0%	0%
Expected Volatility	23.45% to 38.28%	24.45% to 26.44%	27.67% to 29.13%
Risk free Interest rates	1.48% to 2.43%	2.56% to 3.03%	4.50% to 5.06%
Expected lives	3.25 to 5.75 years	5 to 5.75 years	5 to 5.75 years

*Warrants*—Warrants have been issued for terms of up to five years.

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**SURGIVISION, INC.**

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**Years Ended December 31, 2009, 2008 and 2007**

**Note 7 – Stockholders' Equity – (continued)**

Common Stock warrants issued, expired, and outstanding during the years ended December 31, 2009, 2008 and 2007 are as follows:

	Number	Weighted Average Exercise Price per Share
Warrants outstanding at January 1, 2007	1,642,167	\$ 0.88
Warrants issued during the year ended December 31, 2007	1,671,838	0.01
Warrants outstanding at December 31, 2008 and 2007	3,314,005	0.44
Warrants expired during the year ended December 31, 2009	(1,671,838)	0.01
Warrants outstanding at December 31, 2009	<u>1,642,167</u>	<u>\$ 0.88</u>

The assumptions used in calculating the fair value of warrants utilizing the Black-Scholes pricing model in the year ended December 31, 2007 is as follows:

Dividend yield	0%
Expected volatility	20%
Risk free rates	4.91%
Expected term	1 year

**Stock Transactions with Related Parties –**

- During January 2009, the Company loaned \$500,000 under an 8% note receivable to a stockholder with an original maturity date in July 2010. The note was collateralized by 500,000 shares of the Company's common stock owned by the stockholder. In addition, during January 2009, the Company purchased 500,000 shares of the Company's common stock from that same stockholder for \$500,000 in cash (accounted for as a treasury stock purchase). During December 2009, the Company purchased 536,712 additional shares of the Company's common stock from this stockholder in exchange for cancellation of the aforementioned \$500,000 note receivable plus \$36,712 of accrued interest thereon.
- The Company had a note receivable from its Chief Executive Officer ("CEO") related to the sale of common stock. The note bears interest at 4.5%. Interest income related to this note was approximately \$21,100 for the year ended December 31, 2009 and approximately \$21,700 for each of the two years ended December 31, 2008 and 2007. On December 22, 2009, the Company purchased 266,608 shares of common stock from the CEO, for an aggregate purchase price of \$642,525. The Company paid a portion of the aggregate purchase price (\$594,687) by cancelling the aforementioned promissory note plus accrued interest, with the remainder paid in cash. Also, on December 22, 2009, the Company issued to the CEO options to purchase 266,608 shares of its common stock at an exercise price of \$2.41 per share.

**SURGIVISION, INC.**  
**Notes to Financial Statements**  
**Years Ended December 31, 2009, 2008 and 2007**

**Note 8 – Income Taxes**

The Company recorded income tax expense of \$49,250 for the year ended December 31, 2009 related to alternative minimum tax due which cannot be offset by net operating loss carryforwards. The Company had no income tax expense or benefit for the years ended 2008 and 2007. As the Company has incurred net operating losses, the Company has recognized valuation allowances for all deferred tax assets. The tax effect of temporary differences and net operating losses that give rise to components of deferred tax assets and liabilities consist of the following:

	December 31,		
	2009	2008	2007
Deferred tax assets (liabilities):			
Furniture, software and equipment	\$ (202,296)	\$ (144,776)	\$ (4,886)
Other	60,139	—	—
Deferred revenue	3,207,620	(8,139)	—
Accrued expenses	439,965	110,891	3,778
Net operating loss carryforward	<u>11,591,052</u>	<u>12,491,917</u>	<u>10,690,528</u>
	15,096,480	12,449,893	10,689,420
Less: valuation allowance	<u>(15,096,480)</u>	<u>(12,449,893)</u>	<u>(10,689,420)</u>
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

The Company has a cumulative federal net operating loss of approximately \$30,500,000 as of December 31, 2009. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a “loss corporation”, as defined, there are annual limitations on the amount of the net operating loss and other deductions which are available to the Company. The Company has not determined whether such ownership change has occurred. However, given the equity transactions in which the Company has engaged, the Company believes that the use of the net operating losses shown as deferred tax assets will be significantly limited.

**Note 9 – Commitments**

*Leases*—The Company leases office space in California, Maryland and Tennessee under non-cancellable operating leases. Leases expire in 2012, 2010 and 2014.

Future minimum lease payments under non-cancellable operating leases are as follows:

Years ending December 31,	
2010	\$167,809
2011	166,458
2012	124,018
2013	62,272
2014	58,399
Total minimum payments	<u>\$578,956</u>

*Co-Development Agreement*—The Company has entered into a co-development agreement whereby the Company is required to pay up to approximately \$2,476,000 in milestone-based payments for software development to be used in conjunction with products being developed by the Company. The software, upon completion, will be owned by the co-developer and sold through licenses. The co-developer will pay the



**SURGIVISION, INC.**

**Notes to Financial Statements**

**Years Ended December 31, 2009, 2008 and 2007**

**Note 9 – Commitments – (continued)**

Company a fixed amount per license sold by the co-developer until the Company recoups its investment in the software. The Company's remaining milestone-based payments under the co-development agreement at December 31, 2009 totaled approximately \$2,326,000, which is expected to be paid in installments through September 2011.

*Shared Research Agreements*—The Company has entered into research agreements with certain Universities whereby the Company has committed to pay certain research related expenses. As of December 31, 2009 the Company is committed to pay additional amounts aggregating approximately \$1,094,000, which will be payable at various dates through January 2011. In addition, the Company has agreed to provide in kind equipment and services over a two year period once the equipment is installed.

*Software License Agreement*—The Company is obligated under a master services and license agreement to purchase a minimum number of licenses for software code that is incorporated in the Company's ClearPoint system software. The minimum purchase obligation is \$175,000 for the contract year ending July 2009 (which purchase occurred and is included in Inventory in the accompanying 2009 balance sheet) and \$525,000 for each of the contract years ending July 2010, 2011 and 2012. The cost of each license will be charged to cost of sales as each ClearPoint system is sold, which sales are subject prior to FDA clearance.

**Note 10 – Subsequent Event**

In March 2010, the Company issued 10% senior unsecured convertible notes, or the bridge notes, in the aggregate principal amount of approximately \$4.1 million, or the bridge financing. The bridge notes automatically convert into shares of the Company's common stock upon the closing of the initial public offering of the Company's common stock at the lesser of \$2.00 per share or 80% of the offering price in the initial public offering, subject to a \$1.00 per share floor conversion price. In addition, subject to prior maturity, prepayment and/or certain adjustments, holders of the bridge notes may convert the outstanding principal amount of their bridge notes into shares of the Company's common stock at any time, based on a conversion price of \$2.00 per share. The bridge notes mature two years from the date of issuance, unless earlier converted, and accrue interest at the rate of 10% per annum. All accrued interest will be paid in cash and will not be converted into shares of the Company's common stock. In connection with the bridge financing, the Company engaged a placement agent, which received a cash fee of approximately \$285,000 and a warrant exercisable for 101,775 shares of the Company's common stock at a price equal to the lesser of \$2.00 per share or 80% of the offering price in the Company's initial public offering, subject to a \$1.00 per share floor conversion price.

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Shares

**SurgiVision, Inc.**

Common Stock

Prospectus

**Canaccord Adams**

**Rodman & Renshaw, LLC**

, 2010

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. *Other Expenses of Issuance and Distribution***

The following table sets forth the costs and expenses to be paid by us in connection with the sale of the shares of common stock being registered hereby. All amounts are estimates except for the SEC registration fee, the FINRA filing fee and the Nasdaq Capital Market listing fee.

	<u>Amount to be Paid</u>
SEC registration fee	\$ 2,139
FINRA filing fee	3,500
Nasdaq Capital Market listing fee	5,000
Printing and engraving expenses	200,000
Blue sky qualification fees and expenses	15,000
Accounting fees and expenses	*
Legal fees and expenses	*
Transfer agent and registrar fees	3,500
Miscellaneous expenses	*
Total	\$ *

\* To be provided by amendment.

**Item 14. *Indemnification of Directors and Officers***

Our certificate of incorporation, which will become effective upon the completion of this offering, contains provisions permitted under Delaware law relating to the liability of directors. These provisions eliminate a director's personal liability for monetary damages resulting from a breach of fiduciary duty, except in circumstances involving wrongful acts, such as:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of the law;
- any act related to unlawful stock repurchases, redemptions or other distribution or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These provisions do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of director's fiduciary duty. These provisions will not alter a director's liability under federal securities laws.

As permitted by Section 145 of the Delaware General Corporation Law, our bylaws, which will become effective upon the closing of this offering, require us to indemnify our directors and executive officers to the fullest extent not prohibited by the Delaware law. We may limit the extent of such indemnification by individual contracts with our directors and executive officers. Further, we may decline to indemnify any director or executive officer in connection with any proceeding initiated by such person or any proceeding by such person against us or our directors, officers, employees or other agents, unless such indemnification is expressly required to be made by law or the proceeding was authorized by our Board of Directors.

We have entered into indemnity agreements with each of our current directors and certain of our executive officers to give such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in our certificate of incorporation and bylaws and to provide additional procedural

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protections. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We have the power to indemnify our other officers, employees and other agents, as permitted by Delaware law, but we are not required to do so.

The Registrant maintains a directors' and officers' insurance and registrant reimbursement policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses the registrant for those losses for which the registrant has lawfully indemnified the directors and officers. The policy contains various exclusions, none of which apply to this offering.

Reference is made to the following documents filed as exhibits to this registration statement regarding relevant indemnification provisions described above and elsewhere herein:

<u>Exhibit Document</u>	<u>Number</u>
Form of Underwriting Agreement	1.1
Form of Amended and Restated Certificate of Incorporation	3.3
Form of Amended and Restated Bylaws	3.4
Third Amended and Restated Investor Rights' Agreement dated September 20, 2006	3.5
First Amended and Restated Stockholders' Agreement dated April 30, 2004	3.6
Form of Indemnification Agreement	10.8

#### **Item 15. *Recent Sales of Unregistered Securities***

The following sets forth information regarding all unregistered securities sold since December 31, 2006:

1. We have granted stock options to purchase an aggregate of 1,326,500 shares of common stock to employees, consultants and directors under our 2007 Stock Incentive Plan, which makes available an aggregate of 2,500,000 shares of common stock. Stock options to purchase 1,284,167 shares of our common stock remain outstanding. The issuance of these options was exempt from registration under Section 4(2) of the Securities Act, as a sale not involving a public offering, or pursuant to Rule 701 under the Securities Act.

2. On December 22, 2009, we issued to Mr. Jenkins an option to purchase 266,608 shares of our common stock at an exercise price of \$2.41 per share. The issuance of this option was exempt from registration under 4(2) of the Securities Act, as a sale not involving a public offering.

3. Between January 2006 and August 2007, Boston Scientific, one of our 5% common stockholders and the employer of one of our directors, loaned us \$1,500,000 in six equal quarterly installments pursuant to a convertible promissory note. This note became payable on June 30, 2008, at which time Boston Scientific converted the note into 1,671,838 shares of our common stock and a warrant for 1,671,838 shares of our common stock, which has since expired.

4. In November and December of 2006, we issued and sold an aggregate of 7,965,000 shares of our Series A Convertible Preferred Stock to 48 accredited investors at \$1.00 per share, for an aggregate offering price of \$7,965,000. Upon completion of this offering, these shares of preferred stock will automatically convert into shares of common stock. In connection with this Series A Preferred Stock offering, we engaged Gilford Securities Incorporated to serve as a placement agent. As placement agent, Gilford Securities Incorporated received a cash fee of approximately \$475,000 and a warrant exercisable for 566,000 shares of common stock at an exercise price of \$1.00 per share.

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5. During 2009, Boston Scientific loaned us \$3,500,000 pursuant to the terms of three convertible promissory notes. Interest on the loans accrues at 10% per annum and compounds annually. The Boston Scientific loans are secured by a first priority security interest in all of our assets. Each loan matures on the second anniversary of the date on which the funds were advanced; however, we can repay each loan at anytime prior to its respective maturity date. At the option of Boston Scientific, these loans are convertible into one share of our preferred stock for every \$2.00 of principal and interest outstanding at the time of conversion. To the extent that Boston Scientific has not exercised its conversion right prior to the completion of this offering, Boston Scientific will no longer have the right to convert the notes into shares of stock.

6. On December 21, 2007, we made a restricted stock award to one of our consultants for 2,000 shares of common stock. This award was made under our 2007 Stock Incentive Plan. This restricted stock award was exempt from registration under Section 4(2) of the Securities Act, as a sale not involving a public offering, or pursuant to Rule 701 under the Securities Act.

7. In March 2010, we issued 10% senior unsecured convertible notes, or the bridge notes, in the aggregate principal amount of approximately \$4.1 million to 50 accredited investors in a private placement, or the bridge financing. Upon consummation of this offering, the bridge notes will automatically convert into shares of our common stock upon the closing of this offering at the lesser of \$2.00 per share or 80% of the offering price in this offering, subject to a \$1.00 per share floor conversion price. In addition, subject to prior maturity, prepayment and/or certain adjustments, holders of the bridge notes may convert the outstanding principal amount of their bridge notes into shares of our common stock at any time, based on a conversion price of \$2.00 per share. The bridge notes mature two years from the date of issuance, unless earlier converted, and accrue interest at the rate of 10% per annum. All accrued interest will be paid in cash and will not be converted into shares of our common stock. In connection with the bridge financing, we engaged Gilford Securities Incorporated to serve as a placement agent. As placement agent, Gilford Securities Incorporated received a cash fee of approximately \$285,000 and a warrant exercisable for 101,775 shares of our common stock at a price equal to the lesser of \$2.00 per share or 80% of the offering price in our initial public offering subject to a \$1.00 per share floor conversion price.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (3) through (5) and (7) by virtue of Section 4(2) of the Securities Act and/or Rule 506 of Regulation D. Such sales and issuances did not involve any public offering, were made without general solicitation or advertising and each purchaser was a sophisticated investor with access to all relevant information necessary to evaluate the investment and represented to us that the shares were being acquired for investment.

#### **Item 16. Exhibits and Financial Statement Schedules**

##### (a) Exhibits

<u>Number</u>	<u>Description</u>
1.1*	Underwriting Agreement
3.1**	Amended and Restated Certificate of Incorporation of SurgiVision, Inc., as amended <sup>(1)</sup>
3.2**	Bylaws of SurgiVision, Inc., as amended <sup>(1)</sup>
3.3*	Form of Amended and Restated Certificate of Incorporation of SurgiVision, Inc. to be effective upon completion of this offering
3.4*	Form of Amended and Restated Bylaws of SurgiVision, Inc. to become effective upon completion of this offering
3.5**	Third Amended and Restated Investor Rights' Agreement dated September 20, 2006, as amended <sup>(1)</sup>
3.6**	First Amended and Restated Stockholders' Agreement dated April 30, 2004 <sup>(1)</sup>

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<u>Number</u>	<u>Description</u>
3.7**	Certificate of Designation, Preferences and Rights of Series A Convertible Preferred Stock of Surgi-Vision, Inc. filed with the State of Delaware on September 20, 2006 <sup>(3)</sup>
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4
4.2*	Specimen of Common Stock Certificate
5.1	Opinion of Baker, Donelson, Bearman, Caldwell & Berkowitz, PC
10.1**	Surgi-Vision, Inc. 1998 Stock Option Plan <sup>(1)</sup>
10.2**	Surgi-Vision, Inc. 2007 Stock Incentive Plan <sup>(1)</sup>
10.3*	Surgi-Vision, Inc. Key Personnel Incentive Program
10.4*	2010 Incentive Compensation Plan
10.5*	2010 Incentive Compensation Plan Form of Stock Option Agreement
10.6*	2010 Incentive Compensation Plan Form of Restricted Stock Agreement
10.7*	2010 Incentive Compensation Plan Form of Restricted Stock Unit Agreement
10.8*	Form of Indemnification Agreement
10.9**†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around June 20, 1998, as amended by that certain Amendment to License Agreement dated as of January 15, 2000, and as further amended by that certain Addendum to License Agreement entered into on or around December 7, 2004 <sup>(2)</sup>
10.10**†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around December 7, 2006 <sup>(2)</sup>
10.11**†	Technology License Agreement dated as of December 30, 2005 by and between SurgiVision, Inc. and Boston Scientific Neuromodulation Corporation (formerly known as Advanced Bionics Corporation), as amended by that certain Omnibus Amendment dated June 30, 2007, and as further amended by that certain Omnibus Amendment #2 dated March 19, 2008 <sup>(2)</sup>
10.12**†	System and Lead Development and Transfer Agreement dated as of December 30, 2005 by and between SurgiVision, Inc. and Boston Scientific Neuromodulation Corporation (formerly known as Advanced Bionics Corporation), as amended by that certain Amendment No. 1 dated May 31, 2006, as further amended by that certain Omnibus Amendment dated June 30, 2007, and as further amended by that certain Omnibus Amendment #2 dated March 19, 2008 <sup>(2)</sup>
10.13**†	Technology License Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc. <sup>(2)</sup>
10.14**†	Development Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc. <sup>(2)</sup>
10.15**†	Cooperation and Development Agreement, dated as of May 4, 2009, by and between SurgiVision, Inc. and Siemens Aktiengesellschaft, Healthcare Sector <sup>(2)</sup>
10.16	Consulting Agreement, effective as of May 1, 2009, by and between SurgiVision, Inc. and Dr. Paul Bottomley
10.17**	Stock Purchase Agreement, dated December 22, 2009, by and between SurgiVision, Inc. and Kimble L. Jenkins <sup>(3)</sup>
10.18**	Non-Qualified Stock Option Agreement, dated December 22, 2009, by and between SurgiVision, Inc. and Kimble L. Jenkins <sup>(3)</sup>

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<u>Number</u>	<u>Description</u>
10.19**†	Patent License Agreement – Nonexclusive entered into on or around April 27, 2009 by and between SurgiVision, Inc. and National Institutes of Health <sup>(2)</sup>
10.20**†	Master Services and Licensing Agreement dated as of July 20, 2007 by and between SurgiVision, Inc. and Cedara Software Corp. <sup>(2)</sup>
10.21**†	Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University <sup>(2)</sup>
10.22**†	Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University <sup>(2)</sup>
10.23**†	Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University <sup>(2)</sup>
10.24**†	Loan Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation <sup>(2)</sup>
10.25**†	Patent Security Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation <sup>(2)</sup>
10.26**†	Sponsored Research Agreement by and between SurgiVision, Inc. and the Regents of the University of California on behalf of its San Francisco campus entered into on or around August 24, 2007, as amended by that certain First Amendment to Sponsored Research Agreement dated December 1, 2008, as further amended by that certain Second Amendment to Sponsored Research Agreement dated May 1, 2009, as further amended by that certain Third Amendment to Sponsored Research Agreement dated November 2, 2009, as further amended by that certain Addendum to Sponsored Research Agreement dated February 4, 2010 <sup>(3)</sup>
10.27**†	Research Agreement by and between SurgiVision, Inc. and The University of Utah entered into on or around July 2, 2007, as amended by that certain First Amendment to the Research Agreement entered into on or around January 8, 2008, as further amended by that certain Second Amendment to the Research Agreement dated April 24, 2009, as further amended by that certain Third Amendment to the Research Agreement dated May 1, 2009, as further amended by that certain Fourth Amendment to the Research Agreement entered into on or around February 25, 2010 <sup>(3)</sup>
21**	List of Subsidiary <sup>(1)</sup>
23.1	Consent of Cherry, Bekaert & Holland, L.L.P.
23.2	Consent of Baker, Donelson, Bearman, Caldwell & Berkowitz, PC (included in Exhibit 5.1)
24.1**	Power of attorney. Reference is made to the signature page. <sup>(1)</sup>

\* To be filed by amendment.

\*\* Previously filed.

† Confidential treatment requested under 17 C.F.R. §§200.80(b)(4) and 230.406. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission pursuant to the confidential treatment request.

(1) Previously filed with the Securities and Exchange Commission on December 23, 2009 on the Registrant's Registration Statement on Form S-1 (SEC File No. 333-163957).

(2) Previously filed with the Securities and Exchange Commission on February 9, 2010 on the Registrant's Registration Statement on Form S-1/A (SEC File No. 333-163957).

(3) Previously filed with the Securities and Exchange Commission on February 26, 2010 on the Registrant's Registration Statement on Form S-1/A (SEC File No. 333-163957).

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**Item 17. Undertakings**

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, if the Registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the Registration Statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the Registration Statement or made in a document incorporated or deemed incorporated by referenced into the Registration Statement or prospectus that is part of the Registration Statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the Registration Statement or prospectus that was part of the Registration Statement or made in any such document immediately prior to such date of first use.

That, for the purpose of determining liability of the Registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned Registrant undertakes that in a primary offering of securities of the undersigned Registrant pursuant to this Registration Statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned Registrant or used or referred to by the undersigned Registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned Registrant or its securities provided by or on behalf of the undersigned Registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned Registrant to the purchaser.





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**EXHIBIT INDEX**

<u>Number</u>	<u>Description</u>
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† Confidential treatment requested under 17 C.F.R. §§200.80(b)(4) and 230.406. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission pursuant to the confidential treatment request.

- (1) Previously filed with the Securities and Exchange Commission on December 23, 2009 on the Registrant's Registration Statement on Form S-1 (SEC File No. 333-163957).
- (2) Previously filed with the Securities and Exchange Commission on February 9, 2010 on the Registrant's Registration Statement on Form S-1/A (SEC File No. 333-163957).
- (3) Previously filed with the Securities and Exchange Commission on February 26, 2010 on the Registrant's Registration Statement on Form S-1/A (SEC File No. 333-163957).

[LETTERHEAD OF BAKER, DONELSON, BEARMAN, CALDWELL &amp; BERKOWITZ, PC]

[ , 2010]

SurgiVision, Inc.  
One Commerce Square, Suite 2550  
Memphis, TN 38103

Re: Registration Statement on Form S-1  
(SEC File Number 333-163957)

Ladies and Gentlemen:

We have acted as counsel to SurgiVision, Inc., a Delaware corporation (the "Company"), in connection with a Registration Statement on Form S-1, as amended (the "Registration Statement"), relating to the proposed issuance and sale by the Company of up to shares of the Company's common stock, par value \$0.01 per share (including shares to be subject to the Underwriters' warrants and over-allotment option) (the "Shares").

In connection with this opinion, we have (i) examined and relied upon (a) the Registration Statement and related prospectus, (b) the Company's Amended and Restated Certificate of Incorporation, filed as Exhibit 3.1 to the Registration Statement, and Bylaws, filed as Exhibit 3.2 to the Registration Statement, (c) the Company's Amended and Restated Certificate of Incorporation, filed as Exhibit 3.3 to the Registration Statement, and the Company's Amended and Restated Bylaws, filed as Exhibit 3.4 to the Registration Statement, each of which shall be in effect upon the closing of the offering contemplated by the Registration Statement, and (d) the originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below, and (ii) assumed that the Shares to be sold to the underwriters by the Company will be sold at a price established by the Board of Directors of the Company or the pricing committee thereof in accordance with Section 153 of the Delaware General Corporation Law, and we have undertaken no independent verification with respect thereto. We have assumed the genuineness and authenticity of all documents submitted to us as originals, and the conformity to originals of all documents where due execution and delivery are a prerequisite to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of officers of the Company and have not sought to independently verify such matters.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares, when sold and issued in accordance with the Registration Statement and related prospectus, as amended and supplemented through the date of issuance, will be validly issued, fully paid and non-assessable.

This opinion is given as of the date hereof, and we assume no obligation to advise you after the date hereof of facts or circumstances that come to our attention or changes in law that occur which could affect the opinions contained herein. This opinion is being rendered for the benefit of the Company in connection with the matters addressed herein.

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Our opinions expressed above are limited to the Delaware General Corporation Law, and we express no opinion with respect to the applicability of any other laws. As used herein, the term “Delaware General Corporation Law” includes the statutory provisions contained therein, all applicable provisions of the Delaware Constitution and reported judicial decisions interpreting these laws.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement, and to the reference to our firm under the heading “Legal Matters” in the Prospectus constituting part of the Registration Statement.

Very truly yours,  
BAKER, DONELSON, BEARMAN, CALDWELL  
& BERKOWITZ, PC

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Robert J. DelPriore, Authorized Representative

## CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (this "Agreement") is made effective as of May 1, 2009, by and between SurgiVision, Inc., a Delaware corporation (the "Company"), and Dr. Paul Bottomley ("Consultant").

The Company and Consultant hereby agree that Consultant will advise the Company on matters relating to the field of internal MRI coils including advances in MRI hardware and software, in vivo and/or implantable MRI/RF safe probes, leads, electrodes, coils, catheters, and implantable interventional or diagnostic medical devices, such as implantable pulse generators, implantable leads, neuromodulation and/or deep brain stimulation devices and related operational MRI compatible software and hardware (the "Field"), under the following terms and conditions:

1. Consulting Services. Consultant's responsibilities shall include the following activities (collectively referred to as the "Services"):

- a) informing the Company of new developments in the Field, subject to the provisions set forth in Section 2 below regarding non-disclosure under this Agreement;
- b) advising the Company on the Company's research and development projects relating to the Field;
- c) advising the Company regarding development of prototype devices;
- d) assisting with technical evaluation of the Company's methods, processes, devices, products and prototypes;
- e) participating in scientific advisory committee meetings in relation to the Field, as the Company may request,
- f) timely disclosing to the Company patentable ideas, conceptions, and/or inventions resulting from services rendered under this Agreement ("Inventions"), whether conceived or reduced to practice by Consultant alone or with employees or other advisors or consultants to Company, and cooperating with the Company to prepare, file and prosecute patent applications for Inventions as are deemed necessary by the Company to publish or protect Inventions, by patent or otherwise, and to vest title to Inventions in the Company or its nominees, their successors or assigns; and
- g) cooperating with the Company to provide expert technical advice based on Consultant's know-how for commercializing products in the Field, upon reasonable request from Company.

The Services shall be performed via telephone and correspondence and/or onsite at the Company's facilities, and they may include meetings with personnel and other consultants at times and locations to be mutually agreed upon. In each instance, Consultant shall perform the Services only upon Company's request and after the scope of the Services has been approved by Company.

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2. Consultant's Obligations to JHU. The parties acknowledge that the Johns Hopkins University, its Schools and Divisions, and the Johns Hopkins Hospital and Health System and its affiliated hospitals ("JHU") is not a party to this Agreement, which is a private contract between Consultant and the Company. Therefore, JHU shall have no liability under this Agreement. The office address of Consultant may be identified in this Agreement for the purpose of convenient communication between the Company and Consultant. Consultant shall not use the facilities, equipment, materials, funds, or resources owned or administered by JHU or located on any of the premises of JHU, excluding those such materials, resources, or space that the Company is granted use of by JHU via formal institutional transactions, including rent of incubator space, hourly charges to the Company by JHU for services, and the like. Consultant shall not engage or employ students, trainees, post-doctoral fellows or other employees of JHU to provide services under this Agreement. JHU policies and Consultant's obligations to JHU shall govern and be afforded primacy in the event a conflict arises between such obligations and policies in this Agreement. Consultant shall not disclose under this Agreement: (a) any invention, improvement, or other information that is proprietary to JHU and not generally available to the public without permission from the Johns Hopkins Technology Transfer Office, other than through formal institutional transactions; or (b) unpublished results of, or unpublished data from, research or clinical activity conducted at, by, or on behalf of JHU, except where said unpublished results or data are posted or made openly available to the scientific community, for example via electronic means, web-sites, on-line methods, on-line courses, and the like or except with the permission of Johns Hopkins Technology Transfer Office. Nothing in this Agreement shall in any way inhibit Consultant's ability to conduct research and other academic activities at, through, or on behalf of JHU, or to lecture upon, submit for publication, publish, or otherwise disclose the results of such activities, regardless of the sponsor or field of such activities, during or at any time after the term of this Agreement.

3. Confidentiality. "Confidential Information" means all oral, written, graphic, or physical information, disclosed to Consultant under this Agreement, not generally available to the public, including without limitation, information related to Company's products, processes, techniques, technology, formulae, research data, manufacturing methods, know-how, and trade secrets. All Confidential Information is and will be the exclusive property of Company and its affiliates. Consultant agrees not to use Confidential Information for any purposes other than the performance of the Services. Nothing in this Agreement shall limit or be construed to limit Consultant's right to use, disseminate, or publish any information that: (a) is or becomes available to the public through no breach of this Agreement by Consultant; (b) was or is obtained by Consultant from a third party who had the legal right to disclose the information to Consultant; (c) is already in the possession of Consultant at the time it is communicated to Consultant under this Agreement (or any predecessor agreement hereto); (d) was developed by Consultant independently of and without reference to any information communicated to Consultant under this Agreement (or any predecessor agreement hereto); or (e) is required to be disclosed by law, government regulation, or court order.

4. Speaking, Non-Endorsement, and Publications. Consultant and Company agree that Company will not use Consultant's name or likeness for the purpose of endorsement,



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promotion or marketing of the Company or its products. Consultant shall not under this Agreement speak with or to any third parties in any context or manner that could reasonably constitute endorsement, promotion, or marketing of any product or technology. In speaking with or to any third parties or if citing Consultant in any context, format, or document, the following disclaimer must be presented: “Participation by Dr. Bottomley *[in the development of this product or as an advisor, consultant, speaker, or member of the Scientific Advisory Board]* does not constitute or imply endorsement by the Johns Hopkins University or the Johns Hopkins Hospital and Health System.” Consultant shall not publish, nor submit for publication, any work resulting from the Services provided hereunder without prior written approval from Company. If Consultant is listed as an author on any publication resulting from performance of Services under this Agreement, the following form of acknowledgement must be added to the body of the publication:

a) If Consultant’s contributions to the work result wholly from the Services performed under this Agreement, Consultant’s position, address, and contact information will be listed as at the Company, and JHU will not be mentioned in this reference (with the exception that, in the event that JHU’s name is included in the official mailing address of a biotechnology park and the Company’s premises are located therein, then JHU’s name may be included as a legitimate mailing address); or

b) If Consultant’s contributions to the work include materials arising out of both the Services performed under this Agreement and work done at JHU: “Dr. Bottomley is a paid consultant to SurgiVision, Inc. This arrangement has been approved by Johns Hopkins University in accordance with its conflict of interest policies.”

5. No Conduct of Clinical Research. Consultant shall be engaged by the Company to provide consulting services only as set forth in Section 1 above, and shall not direct or conduct clinical trials for or on behalf of the Company under this Agreement. Data provided to Consultant under this Agreement will not include any identifying information regarding patients or human subjects and Consultant will not have access to this information, either directly or indirectly through coding systems that link de-identified data to individual persons.

6. Ownership of Intellectual Property. All discoveries, inventions, improvements, or processes (whether patentable or not) conceived or first reduced to practice by Consultant, whether alone or in collaboration with employees of or other consultants or advisors to the Company, resulting from the Services rendered under this Agreement will be owned exclusively by the Company. Consultant shall assign to the Company all rights, title, and interest thereto and agrees to execute any documents attesting to the ownership thereof as requested by the Company. Consultant shall reasonably assist the Company in obtaining or perfecting the Company’s rights, title, and interest, including, without limitation, the filing and prosecution of any patent applications. The Company shall have no rights under this Agreement to any publication, invention, discovery, improvement, or other intellectual property whatsoever, whether or not publishable, patentable, or copyrightable, which is developed as a result of a program of research a) financed in whole or in part by funds provided by or under the control of JHU, or b) using the facilities, resources, or employees of JHU (which for this purpose does not include any materials, resources, or space that the Company is granted use of by JHU via formal institutional transactions, including rent of incubator space, hourly charges to the Company by JHU for services, and the like).

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7. Compensation. In consideration for Consultant's Services hereunder, the Company shall pay Consultant as follows:

a) \$60,000 per year, payable in equal monthly installments; and

b) Reasonable out-of-pocket expenses (upon presentation of appropriate receipts) incurred by Consultant, including all travel, food and lodging in connection with the Services provided hereunder.

Payment shall be made within forty-five (45) days of receipt of an invoice of itemized services and submission of appropriate vouchers and receipts as may be reasonably necessary to substantiate Consultant's out-of-pocket expenses.

Consultant shall not be paid vacation, holiday, or sick time during the term of the Agreement. In the event of premature termination of this Agreement, the Company shall pay Consultant for the Services performed and expenses incurred through the date of termination. In the event of any overpayment by the Company, Consultant shall, upon submission by the Company of documents evidencing such overpayment, remit the same to the Company within thirty (30) days after termination. Consultant shall also cooperate with Company in producing documents as evidence of overpayment of either party.

8. Term and Termination. This Agreement shall be effective for a period of twenty-four (24) months, beginning May 1, 2009 and ending April 30, 2011.

This Agreement may be extended by written agreement signed by both parties. Either party may terminate this Agreement with or without cause upon giving thirty (30) days prior written notice to the other party. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto or in connection therewith. Any written agreements altering the term and/or conditions of this agreement may be subject to advance review and approval by the Johns Hopkins University School of Medicine's Office of Policy Coordination.

9. Compliance. In the performance of the Services hereunder, Consultant shall comply with all applicable federal, state, and local laws, regulations, and guidelines. Consultant shall also comply with the Company's policies while on the Company premises.

10. Independent Contractor. Consultant's status under this Agreement is that of an independent contractor. Consultant shall not be deemed an employee, agent, partner, or joint venturer of the Company for any purpose whatsoever, and Consultant shall have no authority to bind or act on behalf of the Company. This Agreement shall not entitle Consultant to participate in any benefit plan or program of Company. Consultant shall be responsible for, and agrees to comply with, obligations under federal and state tax laws for payment of income and, if applicable, self-employment tax.

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11. Assignment. Consultant may not assign this Agreement or any interest herein, or delegate any of his duties hereunder, to any third party without the Company's prior written consent, which consent is within the Company's sole discretion to grant or withhold. Any attempted assignment or delegation by Consultant without such consent shall be null and void.

12. Debarment. Consultant warrants and represents that Consultant has never been, is not currently, and during the term of this Agreement, will not become:

a) an individual who has been debarred by the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. 335a (a) or (b) ("Debarred Individual") from providing services in any capacity to a person that has an approved or pending drug product application, or an employer, employee or partner of a Debarred Individual; or

b) a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. 335a (a) or (b) ("Debarred Entity") from submitting or assisting in the submission of any abbreviated drug application, or an employee, partner, shareholder, member, subsidiary or affiliate of a Debarred Entity.

Consultant further warrants and represents that no Debarred Individual or Debarred Entity has performed or rendered, or will perform or render, any services or assistance relating to activities taken pursuant to this Agreement. Consultant further warrants and represents that Consultant has no knowledge of any circumstances which may affect the accuracy of the foregoing warranties and representations, including, but not limited to, FDA investigation of, or debarment proceedings against Consultant or any person or entity performing services or rendering assistance relating to activities taken pursuant to this Agreement, and Consultant will immediately notify the Company if Consultant becomes aware of any such circumstances during the term of this Agreement.

13. Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the matters herein contained and supersedes all previous agreements and undertakings with respect thereto. This agreement may be modified only by written agreement signed by the parties.

This Agreement shall be governed by and construed in accordance with the laws of the State of Maryland without regard to its conflicts of laws rules.

[The next page is the signature page]

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IN WITNESS WHEREOF, the parties have executed this Consulting Agreement as of the date(s) set forth below, but with an effective date as of May 1, 2009.

COMPANY:

SurgiVision, Inc.



By: \_\_\_\_\_

Name: OSCAR THOMAS

Title: Vice President, Business Affairs

Date: October 13, 2009

Address:

One Commerce Square

Suite 2550

Memphis, TN 38103

CONSULTANT:



\_\_\_\_\_  
Dr. Paul Bottomley

Date: Tuesday, October 13, 2009

Address:

\_\_\_\_\_  
6308 Velvet Path

\_\_\_\_\_  
Columbia, MD 21044

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference of our firm under the caption “Experts” in the registration statement (**Form S-1/A No. 333-163957**) and related prospectus dated April 6, 2010 and inclusion of our report in such registration statement and related prospectus, dated April 6, 2010, with respect to the financial statements of SurgiVision, Inc.

/s/ Cherry, Bekaert & Holland, L.L.P.

Tampa, Florida

April 6, 2010