SECURITIES AND EXCHANGE COMMISSION

FORM S-1/A

General form of registration statement for all companies including face-amount certificate companies [amend]

Filing Date: **2006-11-22**
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FILER

ST FRANCIS MEDICAL TECHNOLOGIES INC

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SIC: **3841** Surgical & medical instruments & apparatus

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As filed with the Securities and Exchange Commission on November 22, 2006

Registration No. 333-137507

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1
TO

FORM S-1

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**3841**	**94-3366462**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

1201 Marina Village Parkway, Suite 200
Alameda, CA 94501
(510) 337-2600
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Kevin K. Sidow
President and Chief Executive Officer
1201 Marina Village Parkway, Suite 200
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(510) 337-2600
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of the proposed sale to the public: From time to time 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, 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(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. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price(1)(2)	Amount of registration fee

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Common Stock, $0.001 par value per share	$86,250,000	$9,228.75(3)

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.

(3) Previously paid.

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

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The information contained in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated November 22, 2006

Shares

ST. FRANCIS MEDICAL TECHNOLOGIES, INC

Common Stock

This is the initial public offering of shares of common stock by St. Francis Medical Technologies, Inc. We are offering shares of our common stock. We anticipate the initial public offering price will be between $ and $ per share.

We expect our common stock to be quoted on The NASDAQ Global Market under the symbol "SFMT."

This investment involves risk. See "Risk Factors" beginning on page 9.

	Per Share	Total
Initial Public Offering Price	$	$
Underwriting Discount	$	$
Proceeds, Before Expenses, to St. Francis Medical Technologies, Inc.	$	$

The underwriters have a 30-day option to purchase up to additional shares of common stock from us and certain selling stockholders to cover over-allotments, if any.

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

Citigroup **JPMorgan**

Piper Jaffray **Thomas Weisel Partners LLC**

The date of this prospectus is , 2006

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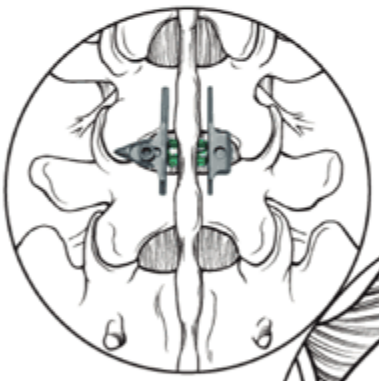
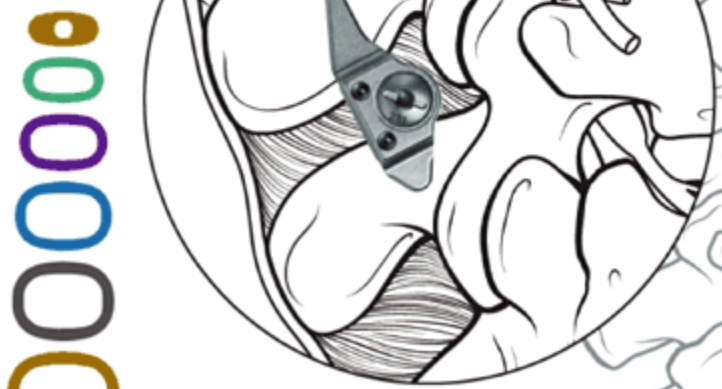
ST. FRANCIS MEDICAL TECHNOLOGIES, INC

X·STOP®

THE X•STOP® IPD® SOLUTION





The X•STOP is implanted between the spinous processes of the symptomatic levels

Limits extension and prevents compression of the nerves

Preserves anatomical structures and mobility

The X•STOP IPD System features spacers in six sizes to match the patient's anatomy

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any person to provide you with different information. This prospectus is not an offer to sell, nor is it an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover, but the information may have changed since that date.

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SUMMARY

The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider. Therefore, you should also read the more detailed information set out in this prospectus, including the consolidated financial statements and related notes appearing elsewhere in this prospectus, before investing in our common stock. References in this prospectus to "we," "us" and "our" refer to St. Francis Medical Technologies, Inc., a Delaware corporation, and its subsidiary, unless the context requires otherwise.

Our Business

We are a medical device company focused on the design, development and marketing of motion-preserving technologies and procedures for orthopedic and neurological spine surgery. Our first product, the X STOP Interspinous Process Decompression System, or the X STOP, is a less invasive implant designed to treat lumbar spinal stenosis, or LSS, a condition resulting from the narrowing or constriction of neural pathways that often leads to debilitating pain in the lower back and legs. We believe that the X STOP fills a significant gap in the continuum of care for LSS sufferers that, until now, left patients whose condition did not respond to conservative, non-operative therapies, such as oral pain medications and corticosteroid injections, with no viable alternative other than laminectomy, an invasive surgical procedure. We believe that the X STOP will become the standard of care for patients with moderate forms of LSS.

We received premarket approval from the U.S. Food and Drug Administration, or FDA, in November 2005 for the X STOP for LSS and commercially introduced the product in the United States in January 2006. As a condition to our premarket approval, the FDA has required us to conduct a post-approval clinical study to determine, among other things, whether the patient selection criteria on our current labelling are adequate and whether the results of our pivotal clinical study can be replicated with a larger number of patients. In addition, in order to expand the indications for the X STOP, we would be required to conduct additional clinical studies and seek additional regulatory approvals. We received CE mark clearance in June 2002 and commenced European commercial sales in December 2002.

We market the X STOP through independent distributors and sales agents with over 350 sales representatives worldwide, as well as through five direct sales personnel in the United States. Since inception, we have sold over 15,000 units of the X STOP worldwide. In the first nine months of 2006, we trained over 1,000 surgeons in the United States. Our revenues were $10.7 million for the year ended December 31, 2005, nearly all of which was derived from sales of the X STOP outside the United States. Our revenues for the three months ended September 30, 2006 were $16.8 million, 80.3% of which was generated from sales of the X STOP in the United States. Our net loss for the year ended December 31, 2005 was $3.5 million and for the nine months ended September 30, 2006, we had net income of $11.2 million. As of September 30, 2006, we had an accumulated deficit of $12.5 million.

Reimbursement claims for our X STOP procedure are typically submitted by the hospital and the physician to Medicare or other third-party payors. In August 2006, the U.S. Centers for Medicare and Medicaid Services, which administers the Medicare program, approved a special add-on payment for hospitals for X STOP procedures, which became effective on October 1, 2006. We believe this add-on payment will further enhance patients' access to the X STOP.

Inserted through a small incision, the X STOP is placed in the space between the bones of the symptomatic vertebrae in the lumbar spine, or lower back. The X STOP is designed to limit extension of the lumbar spine, and keep open the neural pathways that carry nerves to the legs, thereby relieving symptoms. The device can be surgically implanted in a less invasive procedure that may be performed with local anesthesia, typically in less than an hour. The X STOP is not fixed to any bony structures. Rather, the X STOP is secured in position using an adjustable wing that is designed to keep the X STOP implant in place and minimize the risk of unintended movement of the X STOP. The procedure also does not require the permanent removal of bone and connective tissue. As a result of this design, the X

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STOP procedure is reversible, and therefore does not compromise future therapeutic alternatives, including laminectomy.

LSS Market and Conventional Treatments

Lumbar Spinal Stenosis

LSS is a narrowing or constriction of the spinal canal, which causes impingement on the spinal cord and nerve roots that extend from the spine to the legs. LSS is most often caused by degenerative or arthritic conditions that lead to changes in the intervertebral discs, ligaments and facet joints surrounding the spinal canal. LSS most commonly occurs in the lower three levels of the lumbar spine. The impinged nerves commonly cause pain, weakness and numbness in the lower back or buttocks that further radiates to the thighs and lower legs. Patients suffering from LSS typically live with significant lifestyle constraints that limit daily activities and quality of life.

According to Verispan, there are currently approximately 1.4 million individuals in the United States with a primary or secondary diagnosis of LSS. Approximately 500,000 of these patients are treated with conservative, non-operative therapies. Approximately 140,000 additional patients in the United States undergo spinal surgery for LSS annually. In addition, many LSS sufferers do not seek treatment. Our initial target market for the X STOP procedure consists of LSS sufferers with moderate symptoms whose condition is not responding to conservative, non-operative therapies or who would otherwise receive a laminectomy. We estimate this initial target market consists of over 200,000 procedures annually in the United States. The aging of the U.S. population as well as increases in the prevalence of obesity are expected to contribute to growth in the incidence of LSS.

Conventional LSS Treatment Alternatives and Their Limitations

Treatment for patients diagnosed with LSS depends on the severity of the disease. Physicians typically treat patients with milder forms of LSS through conservative, non-operative therapies. If symptoms do not improve, physicians may recommend surgical procedures.

Conservative, Non-Operative Therapies. Conservative, non-operative therapies include lifestyle changes, physical therapy, non-steroidal anti-inflammatory drugs, or NSAIDs, and other oral pain medications, and corticosteroid injections to suppress inflammation. Lifestyle changes and physical therapy can slow the progression of the disease but rarely provide long term symptom relief. NSAIDs, such as aspirin or ibuprofen, can provide pain relief. However, NSAIDs typically have a “ceiling” effect in that there is a maximum limit to the amount of pain relief they can provide. Once these limits are reached, additional dosage strength will not provide increased relief. Prolonged use of NSAIDs can have side effects. Epidural injections of corticosteroids represent a more aggressive form of drug therapy that is often used to treat LSS. However, corticosteroids can have significant side effects and the number of corticosteroid injections a patient can receive in a given time frame is typically limited. Furthermore, each successive corticosteroid injection will typically provide symptom relief that is of shorter duration than that provided by the previous injection. These therapies may provide temporary relief for some patients and may stabilize or slow the worsening of LSS symptoms, particularly for patients with less severe forms of LSS. However, these therapies do not address the underlying cause of the disease and symptoms often worsen to a point where the patient becomes a candidate for a surgical procedure.

Surgical Procedures. In a surgical procedure known as a decompressive laminectomy, the surgeon removes bone, known as the lamina, from the back part of the symptomatic vertebrae over the spinal canal to create more space for, and relieve pressure on, the impinged spinal cord and nerve roots. The removal of bone, ligaments, and muscle required to access and remove the lamina can weaken the structure of the spine and result in the spine becoming unstable in the area in which the laminectomy was performed. This instability is often a reason why many laminectomy patients also undergo a simultaneous fusion procedure, where two vertebrae are fused together, eliminating the pain by preventing motion at the affected segment. A laminectomy procedure cannot be performed using local anesthesia and typically takes two hours to complete, with patients often remaining in the hospital for up to three days. A laminectomy with simultaneous fusion can take several hours to complete and

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patients can remain in the hospital for longer than three days. Recovery time after a laminectomy can be substantial, ranging from several weeks to months. In addition, patients may require long-term physical therapy. Laminectomy also involves significant risks including spinal cord or other neural damage. A meta analysis of 74 published journal articles found that, in those articles reporting surgical complications, the mean percentage of patients experiencing a surgical complication was 12.6%.

Gap in Continuum of Care for LSS

We believe that the traditional treatment paradigm for LSS leaves a substantial portion of the patient population faced with a choice of therapeutic alternatives, each of which has significant drawbacks. Conservative, non-operative therapies generally provide only temporary symptom relief, have diminishing efficacy, may result in side effects, and typically are viewed as only a short-term solution. On the other end of the continuum of care, laminectomy is an invasive, open surgical procedure performed under general anesthesia with inherent safety risks. The surgery involves prolonged hospital stays, extended recovery periods and, occasionally, long-term physical therapy and is not advisable for seriously ill patients or patients who have co-morbidities. Accordingly, we believe that a significant market opportunity exists for a less invasive procedure that is designed to address the underlying causes of LSS rather than merely manage or temporarily alleviate the symptoms. We also believe that the availability of such a procedure could cause many LSS sufferers to seek treatment or reconsider their therapeutic options.

Our Solution − The X STOP Interspinous Process Decompression System

Our X STOP solution represents a new motion-preserving approach to the treatment of LSS that provides physicians and patients with a safe and effective treatment alternative that fills the current gap in the continuum of care between conservative, non-operative therapies and laminectomy. Unlike conservative, non-operative therapies, the X STOP addresses the underlying cause of LSS by reducing the narrowing or constriction of the neural pathways and the neural foramina, the tunnels through which the nerves traverse. The X STOP is implanted in a less invasive procedure that may be performed under local anesthesia and does not require the permanent removal of bone and connective tissue. The procedure, therefore, does not compromise any potential future therapeutic options.

We believe that the principal benefits of our X STOP solution are:

Efficacious, Motion-Preserving Therapy. In our pivotal clinical study, at 24-month follow up, patients treated with the X STOP device reported significant symptom improvement including reduction in back, buttock and leg pain as well as overall satisfaction with the procedure. The X STOP has been found to significantly increase the dimensions of the spinal canal and the neural foramina while preserving the patient' s range of motion. In a study published in 2003, treatment outcomes for patients treated with the X STOP in our pivotal study were compared to outcomes from a study published in 1997 involving a group of laminectomy patients. Although this comparative data analysis should not be viewed as a substitute for a study directly comparing the X STOP procedure with laminectomy, the X STOP patients in our pivotal study reported symptom relief and overall satisfaction with the X STOP procedure that were similar to those reported by the laminectomy patients in the study.

Less Invasive, Same Day, Cost-Effective Procedure. The X STOP has been designed to be implanted under local or general anesthesia in a less invasive procedure that involves a relatively small incision. Patients implanted with the X STOP can return home from the procedure the same day. We believe the less invasive nature of the procedure, coupled with the short post-procedure recovery time, makes the X STOP a cost-effective alternative for the patients it can effectively treat.

Rapid Symptom Relief. The X STOP implant relieves the pinching of the nerves causing the pain associated with LSS by limiting extension of the spine. As a result, symptom relief is often experienced shortly after the procedure.

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Preserves Treatment Options. Because the X STOP procedure does not result in the removal of, or permanent attachment to, bones and does not compromise connective tissue, the procedure is reversible without permanently damaging bone or soft tissue. As a result, the procedure does not limit a patient' s future treatment options.

May Enable Patients to Resume More Active Lifestyle. The symptom relief provided by the X STOP may enable patients to resume normal daily activities and, in many cases, return to a more active lifestyle including recreational activities. Inactive, sedentary lifestyles have been linked to obesity, depression and general physical deterioration.

Ease of Use. Surgeons implant the X STOP posterior to the spinal cord using a straight-forward surgical technique, making the procedure less surgically complex than many other spine surgeries. The procedure typically takes less than an hour to perform.

Favorable Safety Profile. The X STOP is separated from the spinal cord by bone, which substantially reduces the risk of intraoperative injury to nerves or the spinal cord. During our pivotal clinical trial, there were no reports of neural injury associated with the X STOP procedure. The X STOP procedure generally results in only minor trauma to the spinal anatomy and can be performed under local anesthesia.

Available to Broad Patient Population. The X STOP enables physicians to treat elderly patients or seriously ill patients who may have other co-morbidities that make more invasive surgery inadvisable or impossible.

Our Strategy

Our goal is to be a leading provider of motion-preserving medical devices for the treatment of LSS and other spinal degenerative diseases. The key elements of our strategy include:

establish the X STOP as the standard of care for the treatment of moderate LSS;

increase awareness of LSS among physicians and patients;

expand our sales and marketing infrastructure;

expand indications for the X STOP into new markets; and

establish a motion-preserving franchise.

Risks Associated With Our Business

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors." We may be unable, for many reasons, including those that are beyond our control, to implement our current business strategy. We are dependent on the success of the X STOP and cannot be certain that it will achieve the broad acceptance necessary to develop a sustainable, profitable business. We expect that domestic and international sales of the X STOP will continue to account for a substantial portion of our revenue for the foreseeable future. It is difficult to predict the future growth rate or size of the market for the X STOP. Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory approvals, product recalls, termination of distribution, or sales and relationships, product seizures or civil penalties. From inception through March 30, 2006, we incurred losses, and, as of September 30, 2006, we had an accumulated deficit of $12.5 million. There can be no assurance that we will maintain our recent profitability, and our failure to do so would negatively impact our business.

Corporate Information

We were formed in Nevada in July 1996 as St. Francis Medical Technologies, LLC, and subsequently incorporated in Nevada in January 1999 as St. Francis Medical Technologies, Inc. In January 2001, we reincorporated in Delaware. Our principal executive offices are located at 1201 Marina Village Parkway,

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Suite 200, Alameda, California 94501. Our telephone number is (510) 337-2600. Our website is located at *www.sfmt.com*. The information found on, or accessible through, our website is not a part of this prospectus.

We currently have registered trademarks for X STOP®, X-STOP®, IPD®, X STOP®, SFMT®, St. Francis Medical Technologies and our logo. All other trademarks, tradenames and service marks appearing in this prospectus are the property of their respective owners.

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The Offering

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares
Estimated initial public offering price per share	$ to $
Use of Proceeds	We intend to use the net proceeds from this offering for sales and marketing initiatives, research and development activities and general corporate purposes. We may also use a portion of the proceeds from this offering to acquire products, technologies or businesses that are complementary to our own. See "Use of Proceeds."
Proposed NASDAQ Global Market symbol	SFMT

The number of shares of common stock that will be outstanding after this offering is based on 8,890,088 shares outstanding as of September 30, 2006, and excludes:

- 1,251,200 shares of common stock issuable upon the exercise of all options outstanding under our Stock Incentive Plan and our 2006 Stock Plan with a weighted-average exercise price of $1.08 per share; and
- 1,800,000 shares of common stock reserved for future issuance under our 2006 Stock Plan and our 2006 Employee Stock Purchase Plan.

Unless otherwise indicated, all information in this prospectus assumes:

- the conversion of all our outstanding shares of preferred stock into 14,492,520 shares of our common stock immediately prior to the closing of this offering;
- the underwriters do not exercise their over-allotment option; and
- the adoption of our amended and restated certificate of incorporation and bylaws.

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Summary Consolidated Financial Data

We derived the summary consolidated statements of operations data for the years ended December 31, 2003, 2004 and 2005 and the summary consolidated balance sheet data as of December 31, 2004 and 2005 from our audited consolidated financial statements included elsewhere in this prospectus. We derived the summary consolidated statements of operations data for the nine months ended September 30, 2005 and 2006, and the summary consolidated balance sheet data as of September 30, 2006 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. We prepared this unaudited information on the same basis as our audited financial statements and have included all adjustments, consisting only of normal recurring adjustments that we consider necessary to state fairly the results of operations for the nine months ended September 30, 2005 and 2006 and our financial position as of September 30, 2006. Our historical results are not necessarily indicative of the results to be expected for any future periods and you should not consider the results for the nine months ended September 30, 2006 as indicative of results expected for the full fiscal year.

You should read this data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the information under "Selected Consolidated Financial Data" and "Management' s Discussion and Analysis of Financial Condition and Results of Operations."

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
	(in thousands, except per share data)				
Consolidated Statements of Operations Data(1):					
Revenues	$ 1,017	$ 3,816	$ 10,712	$ 7,093	$ 36,525
Cost of revenues	139	573	1,664	974	3,487
Gross profit	878	3,243	9,048	6,119	33,038
Operating expenses:					
Research and development	2,161	2,827	2,531	1,893	2,958
Sales and marketing	1,641	2,830	5,589	3,558	15,461
General and administrative	1,726	2,878	4,652	3,475	3,799
Total operating expenses	5,528	8,535	12,772	8,926	22,218
Income (loss) from operations	(4,650)	(5,292)	(3,724)	(2,807)	10,820
Interest income	133	129	79	59	90
Other income (expense), net	(28)	193	105	71	268
Net income (loss)	(4,545)	(4,970)	(3,540)	(2,677)	11,178
Less: net income (loss) allocable to preferred stockholders	–	–	–	–	(7,565)
Net income (loss) allocable to common stockholders	$ (4,545)	$ (4,970)	$ (3,540)	$ (2,677)	$ 3,613
Net income (loss) per share allocable to common stockholders − basic	$ (0.73)	$ (0.77)	$ (0.52)	$ (0.41)	$ 0.47
Net income (loss) per share allocable to common stockholders − diluted	$ (0.73)	$ (0.77)	$ (0.52)	$ (0.41)	$ 0.40
Weighted-average shares outstanding used in calculating net income (loss) per share − basic	6,189	6,424	6,791	6,592	7,751
Weighted-average shares outstanding used in calculating net income (loss) per share − diluted	6,189	6,424	6,791	6,592	9,145
Pro forma net income (loss) per share					
Basic (unaudited)			$ (0.17)		$ 0.16
Diluted (unaudited)			$ (0.17)		$ 0.15
Pro forma weighted-average shares outstanding used in calculating net income (loss) per share					
Basic (unaudited)			21,283		22,243
Diluted (unaudited)			21,283		23,637

(1) See Note 2 of the notes to our consolidated financial statements for a description of the method used to compute pro forma basic and diluted net income (loss) per common share and weighted-average number of shares used in pro forma per common share data.

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The following table presents a summary of our balance sheet as of September 30, 2006:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all our outstanding preferred stock into 14,492,520 shares of our common stock upon the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of shares of common stock by us in this offering at an assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses.

	As of September 30, 2006		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 5,530	$ 5,530	$
Working capital	19,657	19,657	
Total assets	26,533	26,533	
Convertible preferred stock	27,759	–	
Total stockholders' equity (deficit)	(7,012)	20,747	

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RISK FACTORS

An investment in our common stock offered by this prospectus involves a substantial risk of loss. You should carefully consider these risk factors, together with all of the other information included in this prospectus, before you decide to purchase shares of our common stock. We believe the risks and uncertainties described below are the most significant we face. The occurrence of any of the following risks could harm our business. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations.

Risks Related to Our Business

Our success is dependent on our only product, the X STOP, and we cannot be certain that it will achieve the broad acceptance necessary to develop a sustainable, profitable business.

Our revenues are derived entirely from sales of the X STOP Interspinous Process Decompression System, or X STOP, and related surgical instruments. We expect that sales of the X STOP will continue to account for substantially all of our revenues for the foreseeable future. It is difficult to predict the market acceptance and future growth rate or size of the market for the X STOP. The expansion of the X STOP market depends on a number of factors, such as:

- physician and patient preference for the X STOP over current therapies or procedures;
- physician and patient experience with the X STOP including ease of implantation, safety profile, degree of symptom relief and procedure recovery time;
- short and long-term safety and efficacy outcomes of the X STOP;
- effectiveness of sales and marketing efforts to increase physician and patient awareness of the X STOP; and
- availability of adequate coverage and reimbursement for hospitals and surgeons.

If the X STOP fails to achieve market acceptance, our business and results of operations would be harmed, and our stock price would likely decline.

We have a limited operating history, have incurred significant operating losses since inception and cannot assure you that we will continue to maintain our recent profitability.

Until 2004, we were a development stage company. We have only recently achieved profitability and have yet to demonstrate that we have sufficient revenues to become a sustainable, profitable business. Even if we do achieve sufficient revenues, we expect our operating expenses will increase as we expand our business to meet anticipated growing demand for our products, we devote resources to our sales and marketing efforts, and pursue new research and development opportunities. In addition, we expect a significant increase in our expenses associated with becoming a public company. We incurred net losses of approximately $4.5 million in 2003, $5.0 million in 2004 and $3.5 million in 2005. As of September 30, 2006, we had an accumulated deficit of approximately $12.5 million. While we recently achieved profitability, we may not be able to maintain it. Our failure to maintain profitability would negatively impact the market price of our common stock, may require us to curtail our operations or seek additional capital which may be highly dilutive to current stockholders.

To market and sell our products, we depend on third-party sales agents and distributors, and they may not be successful in selling our products.

We currently depend on third-party sales agents and distributors to carry out most of the sales efforts with respect to the X STOP both in the United States and in Europe. If these entities are not successful in selling our products, we may be unable to increase or maintain our level of domestic or international revenues. Over the long term, we intend to grow our business, and to do so we will need to attract

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additional sales agents and distributors to expand sales in the territories in which we do not directly sell our products. These third parties may not commit the necessary resources to market and sell our products. In addition, some sales agents and distributors provide services to competitors, and those competitors may have the ability to influence the products that our distributors and sales agents choose to market and sell. Our competitors may be able, by offering higher commission payments or otherwise, to convince our distributors and sales agents to terminate their relationships with us, or reduce their sales and marketing efforts for our products. If current or future sales agents and distributors do not perform adequately, or if we are unable to locate new, or maintain relationships with existing, sales agents and distributors in particular geographic areas, we may not increase or sustain our sales. In addition, in the event of inadequate performance of current or future sales agents and distributors, we may need to obtain the services of new sales agents or distributors or carry out such marketing and sales activities ourselves. No one market in which we use sales agents or distributors represents a significant portion of our revenues but, in the aggregate, problems with these distribution arrangements could negatively affect our sales strategy, negatively impact our revenues and results of operations and the market price of our common stock could suffer.

As a condition of FDA premarket approval of the X STOP for treatment of LSS, we are required to design and conduct an additional clinical study, and if the results of this study are not satisfactory, the FDA could take action to limit our ability to market and sell the X STOP.

As a condition of receipt of premarket approval from the U.S. Food and Drug Administration, or FDA, for the X STOP, we are required by the FDA to conduct a single-arm study involving 240 patients, all of whom will undergo an X STOP procedure. This condition of approval study is being required by the FDA to, among other things, determine whether patient selection criteria based on our approved labeling are adequate, and to evaluate whether the results from our pivotal study can be replicated with a larger number of patients. In addition to the condition of the approval study, we have been required to follow patients in our pivotal study for five years. In the event that the results of this condition of approval study indicate that the X STOP is less efficacious in treating patients with moderate LSS symptoms than suggested by the results of our pivotal study, or in the event unforeseen issues or concerns related to safety arise, the FDA could require us to modify the labeling of the X STOP which could have the effect of reducing the size of the indicated patient population for the procedure. In addition to reducing the portion of the LSS patient population that would be candidates for the X STOP, any such action would also likely adversely affect our plans for expanding the indications for the X STOP. Any FDA action to limit the indicated patient population for the X STOP based on the results of our condition of approval study would harm our business and results of operations, and would likely cause our stock price to decline.

We are dependent on single source suppliers and manufacturers for the X STOP, and the loss of any of these suppliers or manufacturers, or their inability to supply us with an adequate supply of materials could harm our business.

We rely exclusively on contract manufacturers to produce our X STOP device and the surgical instruments we market for use with the X STOP procedure. In order for us to be successful, our contract manufacturers must be able to provide us with products and components in substantial quantities, in compliance with strictly enforced regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. The failure of our contract manufacturers to comply with strictly enforced regulatory requirements could expose us to regulatory enforcement. Our anticipated growth could strain the ability of our contract manufacturers to deliver an increasingly larger supply of products, materials and components. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we are unable to obtain sufficient quantities of our products and surgical instruments to meet customer demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

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RMS Company is our exclusive manufacturer for the X STOP. Our dependence on a single manufacturer involves several risks, including limited control over availability, quality and delivery schedules. Additionally, Invibio, Inc. is the only known supplier of biocompatible polyetheretherketone, or PEEK, which is a material used in a version of the X STOP that is currently marketed in Europe. We have a supply agreement with Invibio, pursuant to which we have agreed to purchase our entire supply of PEEK from Invibio.

Our reliance on our sole source manufacturer and sole source supplier subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- interruption of supply resulting from modifications to, or discontinuation of, a supplier' s operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier' s variation in a component;
- uncorrected quality and reliability defects that impact performance, efficacy and safety of products from replacement suppliers;
- price fluctuations for key components;
- difficulty and/or product delays related to identifying and qualifying alternative suppliers for components in a timely manner; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

Any significant delay or interruption in the supply of the X STOP or the materials it is made of, or our inability to obtain alternate sources at acceptable prices and in a timely manner could impair our ability to meet the demand of our customers and harm our business. Identifying and obtaining regulatory approval for additional or replacement manufacturers or suppliers may not be accomplished quickly or at all and could involve significant additional costs. Any supply interruption or failure to obtain additional suppliers would limit our ability to sell our products and could therefore harm our business and results of operations and cause our stock price to decline.

The use, misuse or off-label use of our products may harm our image in the marketplace or result in injuries that lead to product liability suits, which could be costly to our business or result in FDA sanctions if we are deemed to have engaged in such promotion.

Our currently marketed products have been cleared and approved by the FDA for use under specific circumstances for the treatment of moderate LSS. There may be increased risk of injury if physicians attempt to use our products in procedures outside of those indications cleared for use, known as off-label use. We train our salesforce not to promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared for use. However, we cannot prevent a physician from using our products for off-label applications. Furthermore, the use of the X STOP procedure for indications other than LSS may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Physicians may also misuse our product if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management' s attention from our core business, be expensive to defend and result in sizable damage awards against us that may not be covered by insurance. If we are deemed by the FDA to have engaged in the promotion of off-label use of our products, we could be subject to FDA prohibitions on the sale of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry. Any of these events could harm our business and results of operations and cause our stock price to decline.

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If our customers are unable to obtain coverage of or sufficient reimbursement for procedures performed with our products, it is unlikely that our products will be widely used.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medical devices for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. Adequate coverage and reimbursement from governmental, such as Medicare and Medicaid, and commercial payors is central to new product acceptance. Customers are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products and related procedures.

Because a large percentage of the population for which the X STOP is intended includes elderly individuals who are Medicare beneficiaries, Medicare' s coverage and payment policies are particularly significant to our business. Medicare coverage for procedures using our technology currently exists in the hospital setting inpatient and outpatient departments. The Medicare program also has approved add-on payments for the X STOP device when implanted during hospital inpatient and outpatient departments, effective October 1, 2006 and January 1, 2007, respectively. These add-on payments are subject to annual reviews and may remain in effect for two to three years.

In addition, Medicare makes separate payments to physicians for their professional services. Medicare payments for both the physician fees and for procedures performed in hospital outpatient settings are currently in large part under unspecified spine surgery codes. Effective January 1, 2007, the following two new Category III CPT codes have been developed: CPT codes 0171T entitled "Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level" and 0172T entitled "Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level." Category III codes are temporary codes for emerging technology and services, and it is unclear whether the level of reimbursement would be impacted by the change. Further, in the future, new, Category I CPT codes, for which national payment levels are established, could be implemented with respect to the X STOP. In the event such new codes are implemented, it is possible that reimbursement under such codes could be at lower levels than what physicians and hospitals are currently receiving under general, unspecified codes or will receive under Category III CPT codes. However, the availability of national payment levels may simplify the process of submitting claims for payment. As of now, it is not possible to assess the full impact of procedure-specific X STOP CPT codes on our business or results of operations. If such new procedure specific codes were adopted, and the levels of reimbursement for physicians and hospitals were to decline significantly below current levels, our business and results of operations would be harmed and our stock price would likely decline.

All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs. These cost-control methods include prospective payment systems, capitated rates, group purchasing, redesign of benefits, requiring pre-authorizations or second opinions prior to major surgery, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare. These cost-control methods also potentially limit the amount which healthcare providers may be willing to pay for medical devices. In addition, in the United States, no uniform policy of coverage and reimbursement for medical technology exists among all these payors. Therefore, coverage of and reimbursement for medical technology can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, limiting our ability to sell our products on a profitable basis.

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Reimbursement in international markets may require us to undertake country-specific reimbursement activities, including additional clinical studies, which could be time consuming, expensive and may not yield acceptable reimbursement rates.

In international markets, market acceptance of our products will likely depend in large part on the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and by region in some countries, and include both government-sponsored healthcare and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. In addition, even if we do obtain international reimbursement approvals, the level of reimbursement may not be enough to commercially justify expansion of our business into the approving jurisdiction. For example, even though we have obtained clearance to market the X STOP in Japan, we do not plan to market the X STOP there until we receive approval for adequate levels of reimbursement from Japanese regulatory authorities. We may be required to conduct clinical studies of the X STOP in Japan in order to obtain such approvals, and we cannot assure that the outcomes of any such studies will be successful or that we will obtain approval for increased X STOP reimbursement in the Japanese healthcare system. In addition, we have applied for formal reimbursement approval in the German healthcare system. Our application is currently pending, and we cannot assure that it will be approved or that, if approved, the levels of reimbursement will be adequate. To the extent we or our customers are unable to obtain reimbursement for X STOP procedures in major international markets in which we seek to market and sell the X STOP, our international revenue growth would be harmed, and our business and results of operations would be adversely affected.

Our future growth depends on increasing physician awareness of the X STOP.

We target our sales and education efforts to orthopedic spine surgeons or neurosurgeons, whom we collectively refer to as spine surgeons. However, the initial point of contact for many patients may be primary care physicians who commonly treat patients experiencing complications resulting from lumbar spinal stenosis, or LSS. We believe that we must educate physicians to change their screening and referral practices. If we do not educate referring physicians about LSS in general, and the existence of the X STOP in particular, they may not refer patients who are candidates for the X STOP procedure to spine surgeons, and those patients may go untreated or receive conservative, non-operative therapies, such as aspirin or ibuprofen. If we are not successful in educating physicians about screening for LSS or about referral opportunities, our ability to increase our revenue may be impaired.

If the clinical studies that we intend to conduct are unsuccessful, we may not be able to develop or increase our market acceptance and our business prospects may suffer.

We plan to sponsor additional clinical studies to demonstrate the benefits of our products in both current markets where we are trying to increase use of our products and in new markets. Initiating and completing a study is time consuming and expensive, and the outcome is uncertain. The initiation and completion of any of these studies may be prevented, delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;
- patients do not enroll in, or enroll at the expected rate, or complete a clinical study;
- patients do not comply with study protocols;
- patients do not return for post-treatment follow-up at the expected rate;
- patients experience serious or unexpected adverse side effects, including for a variety of reasons that may not be related to our products including the advanced stage of co-morbidities that may exist at the time of treatment, causing a clinical study to be put on hold;

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sites participating in an ongoing clinical study may withdraw, requiring us to engage new sites;

difficulties or delays in bringing additional clinical sites on-line;

third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule or consistent with the investigator agreement, clinical study protocol, good clinical practices, and other FDA requirements;

third-party organizations do not perform data collection and analysis in a timely or accurate manner;

regulatory inspections of our clinical studies require us to undertake corrective action or suspend or terminate our clinical studies;

changes in governmental regulations or policies;

interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy; or

the study design is inadequate to demonstrate safety and efficacy.

If we fail to maintain regulatory approvals and clearances, or experience significant delays in obtaining regulatory approvals or clearances for product enhancements, our ability to commercially distribute and market our products could suffer.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. For example, our X STOP product has received approval under the more rigorous premarket approval application process. Our failure to comply with such regulations could lead to the imposition of untitled letters, warning letters, injunctions, suspensions or loss of regulatory clearances or approvals, product recalls, product seizures or civil or criminal penalties. The process of obtaining regulatory authorizations to market a medical device, particularly from the FDA, is costly and time consuming, and there can be no assurance that any future authorizations will be granted on a timely basis, if at all.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent, and to the extent we continue to market and sell our products in foreign countries, we will be subject to rigorous regulation in the future. In such circumstances, we would rely significantly on our distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

Our ability to market the X STOP in the United States is limited to treatment of moderate LSS and expansion of our marketing claims will require us to file for additional approvals and conduct further clinical trials.

We have FDA approval in the United States for treatment of patients aged 50 or older suffering from neurogenic claudication secondary to a confirmed diagnosis of LSS, who have moderately impaired physical function, with or without back pain, are experiencing relief from their symptoms in flexion and who have undergone a regimen of at least six months of conservative, non-operative therapies. This approval restricts our ability to market or advertise the X STOP for other indications, such as lower back pain, a spine condition known as adjacent level disease or other conditions where the X STOP may be used. If we are unable to broaden the clinical indications for which we may market the X STOP, our future growth and our business and results of operations would be adversely affected.

Competition from companies that have longer operating histories and greater resources than us may harm our X STOP business.

The medical device industry is highly competitive, subject to rapid technological change and significantly affected by new product introductions and market activities of other participants. Demand for the

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X STOP could be diminished by equivalent or superior products and technologies offered by competitors. In addition, as the markets for medical devices, including the X STOP, develop, additional competitors could enter the market. For example, the DIAM Spinal Stabilization System from Medtronic, Inc., the Wallis system from the Abbott Spine division of Abbott Laboratories, and the coflex from Paradigm Spine have each received FDA approval to enter pivotal clinical trials. To compete effectively, we will need to continue to effectively demonstrate that our products are attractive alternatives to those new and existing devices and treatments. We believe that the principal competitive factors in our market include:

- efficacy in the treatment of LSS;
- acceptance by spine surgeons;
- ease of use and reliability;
- pricing and qualification for coverage and reimbursement;
- technical leadership and superiority;
- effective marketing and distribution; and
- speed to market.

We compete against several well established competitors and other potential competitors are substantially larger than we are and may enjoy competitive advantages, including:

- more established distribution networks;
- entrenched relationships with physicians, sales representatives or distributors;
- products and procedures that are less expensive, which could result in pricing pressures on the X STOP;
- greater experience in launching, marketing, distributing and selling products;
- greater experience in obtaining and maintaining FDA and other regulatory clearances and approvals;
- greater experience and resources for facilitating coverage and reimbursement for physician and hospital customers;
- established relationships with healthcare providers and payors; and
- greater financial and other resources for product development, sales and marketing, acquisitions of products and companies, and intellectual property protection.

For these reasons, we may not be able to compete successfully against our current or potential future competitors, and sales of the X STOP may decline.

If we are unable to recruit, hire and retain skilled and experienced personnel, our ability to effectively manage and expand our business will be harmed.

Our success largely depends on the skills, experience and efforts of our officers and other key employees who may terminate their employment at any time. The loss of any of our senior management team, in particular our President and Chief Executive Officer, Kevin K. Sidow, could harm our business. The announcement of the loss of one of our key employees could negatively affect our stock price. Our ability to retain our skilled workforce and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. Similar to other medical device companies, we face challenges in hiring, training, managing and retaining employees in certain areas including sales and marketing, clinical and regulatory and research and development. Our failure to hire and retain qualified personnel could delay new product development and commercialization, hinder our marketing and sales efforts or disrupt our administrative activities, which would adversely impact our competitiveness and financial results.

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If we fail to properly manage our anticipated growth, our business could suffer.

Rapid growth of our business is likely to place a significant strain on our managerial, operational and financial resources and systems. To execute our anticipated growth successfully, we must attract and retain qualified personnel and manage and train them effectively. In addition, we anticipate hiring additional personnel to assist in the commercialization of our current products and in the development of future products. We will be dependent on our personnel and third parties to effectively market and sell our products to an increasing number of customers. We will also depend on our personnel to develop and manufacture new products and product enhancements. Further, our anticipated growth will place additional strain on our suppliers and manufacturers resulting in increased need for us to carefully monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

If we choose to acquire new businesses, products or technologies, we may experience difficulty in the identification or integration of any such acquisition, and our business may suffer.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We have no current commitments with respect to any acquisition or investment. We do not know if we will be able to identify or complete any acquisitions, or whether we will be able to successfully integrate any acquired business, product or technology or retain key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, In addition, these integration efforts could disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will suffer. In addition, any amortization or charges resulting from acquisitions could harm our operating results.

We may require significant additional capital to pursue our growth strategy, and we may be unsuccessful in raising any needed capital.

We believe that our existing cash and cash equivalents together with the net proceeds from this offering will be sufficient to meet our anticipated cash needs for at least the next 12 months. We intend to spend substantial amounts on sales and marketing initiatives to support the ongoing commercialization of our products and on research and development activities, including support of product development, regulatory compliance and clinical study initiatives. We may require more advanced information systems to support our expected growth. We may need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to act on opportunities to acquire complementary businesses, products or technologies. The timing and amount of our working capital and capital expenditure requirements may vary significantly depending on numerous factors, including:

- market acceptance of our products;
- the revenues generated by our products;
- the need to adapt to changing technologies and technical requirements, and the costs related thereto;
- the costs associated with expanding our manufacturing, marketing, sales and distribution efforts; and
- the existence and timing of opportunities for expansion, including acquisitions and strategic transactions.

If our capital resources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or to obtain debt financing. The sale of additional equity or debt

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securities, or the use of our stock in an acquisition or strategic transaction, could result in additional dilution to our stockholders. Additional debt would result in increased expenses and could result in covenants that would restrict our operations. We have not made arrangements to obtain additional financing, and there is no assurance that financing, if required, will be available in amounts or on terms acceptable to us, if at all.

Modifications to our products may require new regulatory approvals or clearances or may require us to recall or cease marketing our modified products until approvals or clearances are obtained.

Modifications to our products may require new premarket approval, or PMA, applications or 510(k) clearances. The FDA requires device manufacturers to initially make a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification does not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new PMA or 510(k) is necessary. However, the FDA can review a manufacturer' s decision and may disagree. The FDA may also determine that a new approval or clearance is required, and in this event could require the manufacturer to recall or cease marketing the modified devices until the necessary approvals or clearances are obtained. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional approval or clearances. If the FDA disagrees and requires new approvals or clearances for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If we determine that a modification to an FDA-cleared or approved device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then we must submit and obtain a new PMA approval or 510(k) clearance. Where we determine that modifications to our products require a new PMA approval or 510(k) clearance, we may not be able to obtain those additional approvals or clearances for the modifications or additional indications in a timely manner, or at all. For those products sold in Europe, we must notify KEMA, our EU Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Delays in obtaining required future approvals or clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

If we or our suppliers fail to comply with the FDA' s Quality System Regulation or ISO Quality Management Systems, manufacturing of our products could be negatively impacted and sales of our products could suffer.

Our manufacturing processes and those of our suppliers are required to comply with the FDA' s Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. We are also subject to similar foreign requirements and licenses, known as ISO Quality Management Systems, or QMS. In addition, we and our manufacturing partners must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic inspections by governmental agencies, including the FDA, state authorities and comparable foreign agencies. If we or our suppliers fail to comply with the QSR or QMS, our operations could be disrupted and our manufacturing interrupted.

We are currently undergoing an FDA Quality System inspection, which is our first post-approval inspection by the FDA. We cannot assure you that this inspection will not reveal material compliance matters or that we will be deemed to be in compliance with QSR. Failure to take adequate and timely corrective action in response to an adverse Quality System inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our devices, operating restrictions, civil fines, criminal prosecutions, warning letters and adverse publicity, any of which would cause our business to suffer.

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Furthermore, our key component suppliers may not comply with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

We and our third-party contract manufacturers underwent successful inspections by the FDA during 2004 and 2006, respectively. However, there can be no assurances that the FDA will not find objections during the course of any future inspections of us and our third-party manufacturers.

Inspections by the EU Notified Body are conducted biannually and the EU Notified Body also has the right to make unannounced visits to our manufacturing facility. Our most recent inspection in November 2005 resulted in no major non-conformities and three minor non-conformities. The Notified Body granted us ISO 13485:2003 certification, which enables us to design, develop, manufacture, and distribute our products.

The FDA and the Notified Body may impose additional inspections or audits at any time and may conclude that our quality system is improperly validated or not otherwise in compliance with applicable regulations. Such findings potentially could disrupt our business, harm our reputation and adversely affect out sales.

We may be subject to product liability or other claims that exceed our insurance coverage, which may have an adverse effect on our financial position and results of operations.

Product liability insurance is increasingly costly to obtain and the scope of coverage is reduced. As a consequence, we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to cover the amounts in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our insurance coverage, we may incur significant costs associated with loss or damage that could have an adverse effect on our financial position and results of operations. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all. We do not have the financial resources to self-insure, and it is unlikely that we will have these financial resources in the foreseeable future.

We have product liability insurance that covers our products and business operations, but we may need to increase and expand this coverage commensurate with our expanding business. Any product liability claims brought against us, with or without merit, could result in:

- substantial costs of related litigation or regulatory action;
- substantial monetary penalties or awards;
- decreased demand for our products;
- reduced revenue or market penetration;
- injury to our reputation;
- withdrawal of clinical study participants;
- an inability to establish strategic relationships;
- increased product liability insurance rates; and
- prevention of securing continuing coverage.

In addition, medical malpractice carriers are withdrawing coverage in certain regions or substantially increasing premiums. In the event we become a defendant in a product liability suit in which the treating surgeon or hospital does not have adequate malpractice insurance, the likelihood of liability being imposed on us could increase.

Product liability claims against us, particularly to the extent not covered by insurance, could harm our business, financial conditions and results of operations and cause our stock price to decline.

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The risks inherent in our international operations may adversely impact our revenues, results of operations and financial condition.

We derive, and anticipate we will continue to derive, a significant portion of our revenues from operations in Europe. As we expand internationally, we will need to hire, train and retain qualified personnel for our direct sales efforts and retain representatives and distributors and train their personnel in countries where language, cultural or regulatory impediments may exist. We cannot be sure that representatives, distributors, physicians, regulators or other government agencies will accept our products, services and business practices. Compliance with such regulations is costly. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Failure to comply with applicable legal and regulatory obligations could result in the disruption of our sales activities.

Our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions, including:

operating under government-run healthcare systems and changes in third-party reimbursement policies;

changes in duties and tariffs, taxes, trade restrictions, license obligations and other non-tariff barriers to trade;

burdens of complying with a wide variety of foreign laws and regulations related to healthcare products;

costs of localizing product and service offerings for foreign markets;

business practices favoring local companies;

longer payment cycles and difficulties collecting receivables through foreign legal systems;

fluctuations in currency exchange rates;

difficulties in enforcing or defending agreements and intellectual property rights; and

changes in foreign political or economic conditions.

We cannot ensure that one or more of these factors will not harm our business. Any material decrease in our international revenues or inability to expand our international operations would adversely impact our revenues, results of operations and financial condition.

Our products may in the future be subject to product recalls that could harm our reputation, business 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 product labeling. 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, manufacture or product labeling. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. For example, in June 2006, we discovered that four units of the X STOP were mislabeled, and conducted a voluntary recall from our distributors to repackage and resterilize the mislabeled units. Recalls of any of our products would divert managerial and financial resources, and may have an adverse effect on our financial condition and results of operations. A recall announcement would harm our reputation with customers, impact our revenues, potentially expose us to product liability claims and negatively affect our stock price.

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We are required to report to the FDA if our products malfunction or cause or contribute to a death or serious injury.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA device-related deaths, serious injuries and any malfunction which could result in death or serious injury if it were to reoccur. All manufacturers placing medical devices in the market in the EU are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the national body, known as a Competent Authority, that oversees the implementation of the EU Medical Device Directive within the jurisdiction in which the incident occurred. Were this to happen to us, the relevant Competent Authority would file an initial report, and there would then be a further inspection or assessment if there are particular issues.

Malfunction of our products could result in future voluntary corrective actions, such as recalls, customer notifications, regulatory inspection or enforcement action. We have reported a number of Medical Device Reports, or MDRs, since the introduction of the X STOP. MDRs to date were primarily due to the need for subsequent surgical intervention. We cannot guarantee that such malfunctions will not occur in the future. If they do occur, we may elect to take voluntary corrective action, and we may be subject to involuntary corrective action such as notification, fines, seizures or recalls. If someone is harmed by a malfunction, we may be subject to product liability claims. 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.

Failure to obtain regulatory approval in additional foreign jurisdictions will prevent us from expanding the commercialization of our products abroad.

We intend to market the X STOP in a number of additional international markets. Although the X STOP has been approved for commercialization in certain international regulatory jurisdictions, in order to market our products in other foreign jurisdictions, we will need to obtain separate regulatory approvals. The approval procedure varies among jurisdictions and can involve substantial additional testing. Approval by the FDA does not ensure approval by regulatory authorities in other jurisdictions, and approval by one foreign regulatory authority does not ensure 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 approval in addition to other risks. In addition, the time required to obtain foreign approval may differ from that required to obtain FDA approval, and we may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market other than in Europe and Japan.

We are subject to healthcare fraud and abuse laws and regulations, and a failure to comply with such laws and regulations could have a material adverse effect on our business.

Our industry is subject to various broad state and federal healthcare fraud and abuse laws including the federal Anti-Kickback Statute, which prohibits any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of, or the furnishing or arranging for, an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs.

If our past or present operations, including our arrangements with third-party sales agents and distributors and our financial arrangements with physicians who use our products, are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation. The scope and enforcement of these laws and regulations are uncertain and subject to rapid change. Because of the far-reaching and uncertain nature of these laws, we are required to monitor our practices to remain in compliance with these laws. If we were to violate one or more of these laws, our business, financial condition and results of operations could be materially adversely

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affected. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change some of our existing business practices, which could have a material adverse effect on our business, financial condition and results of operations.

Several surgeons, including three investigators in our pivotal study, are stockholders of ours. Drs. James Zucherman and Ken Hsu, who are co-founders of our company and co-inventors of the X STOP, each own 1,201,000 shares of our common stock. Dr. Charles Hartjen owns 10,000 shares of our common stock. Other surgeons, who were not investigators in our pivotal study, own an aggregate of 20,000 shares of our common stock and options to purchase 52,500 shares of our common stock as of September 30, 2006. Additionally, some of these surgeons are paid consulting fees or reimbursed for expenses by us.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. In the United States in recent years, new legislation and regulations at the federal and state levels have effected major changes in the healthcare system. For example, on December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which, among other things, established a new prescription drug benefit and changed reimbursement methodologies for drugs and devices used in hospitals. In addition, the Centers for Medicare and Medicaid Services, or CMS, recently revised the methodology for calculating relative values used to determine hospital inpatient payment rates under the Medicare program. Future legislative initiative directed at increasing the accessibility of healthcare and reducing costs could be introduced at either the federal or state level. The potential for adoption of these proposals affects or may affect our ability to market our products. Any adoption of healthcare reform proposals on a state-by-state basis could require us to develop state-specific marketing and sales approaches. In addition, we may experience pricing pressures in connection with the sale of our products due to additional legislative proposals or healthcare reform initiatives. Future legislation and regulations may adversely affect the growth of the X STOP market, the demand for the X STOP or our products currently under development. Our results of operations and our business could therefore be adversely affected by future healthcare reforms.

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our success depends significantly on our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, as well as a combination of trade secret, trademark and copyright laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our pending U.S. and foreign patent applications may not issue as patents or may not issue in a form that will be advantageous to us. Any patents we have obtained or do obtain may be challenged by re-examination, opposition or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid. In addition, competitors may be able to design alternative methods or devices that avoid infringement of our patents. To the extent our intellectual property protection offers inadequate protection, or is found to be invalid, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition to pursuing patents on our technology, we have taken steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual

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property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such 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, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate.

In the event a competitor infringes upon our patent or other intellectual property rights, litigation to enforce our intellectual property rights or to defend our patents against challenge, even if successful, could be expensive and time consuming and could require significant time and attention from our management. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against challenges from others.

The medical device industry is characterized by patent litigation, and we could become subject to litigation that could be costly, result in the diversion of our management' s time and efforts, require us to pay damages or prevent us from selling our products.

The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether or not a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that they own U.S. or foreign patents containing claims that cover our products, their components or the methods we employ in the manufacture or use of our products. In addition, we may become a party to an interference proceeding declared by the U.S. Patent and Trademark Office to determine the priority of invention. Because patent applications can take many years to issue and in many instances at least 18 months to publish, there may be applications now pending of which we are unaware, which may later result in issued patents that contain claims that cover our products. There could also be existing patents, of which we are unaware, that contain claims that cover one or more components of our products. As the number of participants in our industry increases, the possibility of patent infringement claims against us also increases.

Any interference proceeding, litigation or other assertion of claims against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of our management from our core business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to be infringing, we could be required to pay substantial damages and/or royalties and could be prevented from selling our products unless we could obtain a license or were able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may be unable to make, use, sell or otherwise commercialize one or more of our products. In addition, if we are found to willfully infringe, we could be required to pay treble damages, among other penalties.

Risks Related to this Offering

Our common stock has never been publicly traded, and we expect that the price of our common stock will fluctuate substantially.

Before this initial public offering, there has been no public market for our common stock. An active public trading market may not develop after completion of this offering or, if developed, may not be sustained. The public trading price for our common stock after this offering will be affected by a number of factors, including:

- changes in earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earning estimates;
- quarterly variations in our or our competitors' results of operations;
- changes in governmental regulations or in the status of our regulatory approvals or clearances;

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changes in availability of third-party reimbursement in the United States or other countries;

the announcement of new products or product enhancements by us or our competitors;

announcements related to patents issued to us or our competitors and to litigation;

sales of large blocks of our common stock, including sales by our executive officers and directors; and

general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

These factors may materially and adversely affect the market price of our common stock.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market after the completion of this offering, the market price of our common stock could decline. There will be approximately 8,890,088 shares of common stock, including shares issuable upon the exercise of options outstanding as of September 30, 2006, eligible for sale beginning 180 days after the date of this prospectus, subject to an extension of no more than 34 additional days. In addition, six months after the completion of this offering, the holders of 14,492,520 shares of common stock issued upon the conversion of our preferred stock may require us, subject to certain conditions, to file a registration statement covering those shares. We also intend to file a registration statement on Form S-8 to facilitate the resale of the shares of common stock reserved for issuance under our Stock Incentive Plan and 2006 Stock Plan. If any of these stockholders cause a large number of securities to be sold in the public market, the sales could reduce our stock price. In addition, sales of these shares could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

As a result of being a public company, we will incur increased costs that may place a strain on our resources or divert our management' s attention from other business concerns.

As a public company, we will incur additional legal, accounting and other expenses that we do not incur as a private company. We will need to comply with the Sarbanes-Oxley Act of 2002, or SOX, and the related rules and regulations adopted by the Securities and Exchange Commission and The NASDAQ Global Market, including expanded disclosures, accelerated reporting requirements and more complex accounting rules. In particular, under current Securities and Exchange Commission regulations we will be subject to the requirements of Section 404 of SOX in 2007, and be required to engage in additional management assessments of our internal control structures and procedures for financial reporting, and will undergo additional procedures by our independent registered public accounting firm, which will be required to attest to, and report on, management' s assessments. These efforts we expect to undertake in connection with SOX Section 404 will be costly and time consuming, and will divert management' s attention and resources. Many of these laws, regulations and standards have been relatively recently adopted by regulatory authorities and are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

The Securities Exchange Act of 1934, as amended, or the Exchange Act, will require us to file annual, quarterly and current reports with respect to our business and financial condition, which will require us to incur legal, accounting and other expenses. SOX will require us to maintain effective disclosure controls and procedures and internal control for financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight will be required. We expect that the corporate governance rules and regulations of the SEC and The NASDAQ Global Market will make some of our activities more time consuming and costly. These laws and regulations could make it more difficult or

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more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These requirements may place a strain on our resources and divert our management' s attention from other business concerns, which could have an adverse effect on our business, financial condition and results of operations. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. In addition, while we plan to hire additional staff with public company experience and technical accounting knowledge, there can be no assurance that we will be able to do so. If we are successful, such hiring will increase our operating expenses in the future.

If we are unable to complete the required assessment as to the adequacy of our internal control over financial reporting as required by SOX Section 404 or if we fail to maintain adequate disclosure controls and procedures and internal control over financial reporting, our ability to produce timely, accurate and reliable periodic financial statements could be impaired. We have revised previously reported financial information for the period ended June 30, 2006 to reflect an error in the calculation of net income allocable to common stockholders and the calculation of basic and diluted net income per share available to common stockholders as further described in Note 1 to the financial statements included herein. If we do not maintain adequate disclosure controls and procedures or internal control over financial reporting, investors could lose confidence in the accuracy of our periodic reports filed under the Exchange Act. Additionally, our ability to obtain additional financing could be impaired.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

After the completion of this offering, our directors, officers and principal stockholders each holding more than 5% of our common stock collectively will control approximately % of our outstanding common stock, assuming the exercise of all options held by such persons. As a result, these stockholders, if they act together, would be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws and Delaware law could discourage a takeover.

Our amended and restated certificate of incorporation and bylaws to be effective upon completion of this offering and Delaware law contain provisions that might enable our management to resist a takeover. These provisions include:

- a classified board of directors;
- advance notice requirements to stockholders for matters to be brought at stockholder meetings;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws; and
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer.

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law that, in general, prohibit any business combination or merger with a beneficial owner of 15% or more of our common stock unless the holder' s acquisition of our stock was approved in advance by our board of directors. These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. See "Description of Capital Stock−Anti-Takeover Effect of Provisions of the Amended and Restated Certificate of Incorporation and Bylaws" included elsewhere in this prospectus.

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We have broad discretion in the use of the proceeds which could result in our utilizing the proceeds in ways that may not yield a return to stockholders.

Our management will have broad discretion over the use and investment of the proceeds from this offering, and accordingly, investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds. Our management may utilize a portion or all of the proceeds from this offering in ways that our stockholders may not agree with or that may not yield a favorable return. The failure of our management to apply the proceeds from this offering effectively could harm our business, financial condition and results of operations.

We may become involved in securities class action litigation that could divert management' s attention and harm our business.

The stock market in general, The NASDAQ Global Market and the market for medical device companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performances of those companies. Further, the market prices of securities of medical device companies have been particularly volatile. These broad market and industry factors may materially harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a particular company' s securities, securities class action litigation has often been brought against that company. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management' s attention and resources, which could materially harm our financial condition and results of operations.

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. Although our common stock has been approved for quotation on The NASDAQ Global Market, 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. 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 completion of this offering. Investors may not be able to sell their common stock at or above the initial public offering price.

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 our current and future debt agreements, and other factors our board of directors may deem relevant. We are subject to several covenants under our debt arrangements that place restrictions on our ability to pay dividends. If we do not pay dividends, a return on your investment will only occur if our stock price appreciates.

New investors in our common stock will experience immediate and substantial dilution as a result of this offering and future equity issuances, and as a result, our stock price could decline.

Our initial public offering price is substantially higher than the book value per share, or the per share value attributed from our tangible assets less our total liabilities, of our common stock. If you purchase common stock in this offering, you will incur immediate dilution of $ in net tangible book value per share of common stock, based on an assumed initial public offering price of $ per share. See "Dilution" contained elsewhere in this prospectus.

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This dilution is due in large part to earlier investors having paid substantially less than the initial public offering price when they purchased their shares. Investors purchasing shares of common stock in this offering will contribute approximately % of the total amount we have raised since our inception, but will own only approximately % of our total common stock immediately following the completion of this offering.

We believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to meet our projected operating requirements for at least the next 12 months. Because we may need to raise additional capital to continue to expand our business and develop new products, among other things, we may conduct substantial additional equity offerings. These future equity issuances, together with the exercise of outstanding options and warrants and any additional shares issued in connection with acquisitions, will result in further dilution to investors.

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management are forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

- the implementation of our business model and strategic plans for our business, product and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our X STOP device;
- our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing;
- the timing or likelihood of regulatory filings and approvals;
- our use of proceeds from this offering;
- our financial performance; and
- competitive companies and technologies and our industry.

The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the section entitled “Risk Factors,” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of shares of our common stock that we are selling in this offering will be approximately $ million, based on an assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses. If the underwriters' over-allotment option is exercised in full, we estimate that we will receive net proceeds of approximately $ million. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds to us from this offering by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses.

Of the net proceeds that we will receive from this offering, we expect to use approximately:

- $30.0 million for sales and marketing initiatives to support the ongoing commercialization of the X STOP;
- $12.0 million for research and development activities; and
- $10.0 million for clinical and regulatory activities, including $4.0 million for our condition of approval study.

We intend to use the remainder of our net proceeds for general corporate purposes. We may also use a portion of the proceeds from this offering to acquire products, technologies or businesses that are complementary to our own; however, we currently have no agreements or commitments to complete any such transaction. Pending these uses, we intend to invest our net proceeds from this offering primarily in debt instruments of the U.S. government, its agencies and high-quality corporate issuers.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. The amount and timing of our expenditures will depend on several factors, including cash flows from our operations and the anticipated growth of our business. Accordingly, our management will have broad discretion in the application of the net proceeds and investors will be relying on the judgment of our management regarding the application of the proceeds from this offering. We reserve the right to change the use of these proceeds as a result of certain contingencies such as the results of our commercialization efforts, competitive developments, opportunities to acquire products, technologies or businesses and other factors.

DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, we 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 payment of dividends present in our current and future debt agreements, and other factors that our board of directors may deem relevant. We are subject to several covenants under our debt arrangements that place restrictions on our ability to pay dividends.

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CAPITALIZATION

The following table summarizes our cash and cash equivalents and capitalization as of September 30, 2006:

The following table presents a summary of our balance sheet as of September 30, 2006:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all our outstanding preferred stock into 14,492,520 shares of our common stock upon the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of shares of common stock by us in this offering at an assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses.

This table should be read in conjunction with "Management' s Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of September 30, 2006		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Convertible preferred stock, par value of $0.001, 15,000,000 shares authorized, 14,492,520 shares issued and outstanding, actual; no shares authorized, no shares issued and outstanding, pro forma as adjusted	27,759	–	–
Stockholders' equity (deficit):			
Preferred stock, par value of $0.001, no shares authorized, actual; 10,000,000 shares authorized, pro forma and pro forma as adjusted	–	–	–
Common stock, par value of $0.001, 30,000,000 shares authorized, 8,890,088 shares issued and outstanding, actual; 75,000,000 shares authorized, 23,382,608 shares issued and outstanding, pro forma, and shares issued and outstanding, pro forma as adjusted	9	23	
Additional paid-in capital(1)	9,163	36,908	
Deferred stock-based compensation	(3,533)	(3,533)	
Accumulated other comprehensive loss	(153)	(153)	
Accumulated deficit	(12,498)	(12,498)	
Total stockholders' equity (deficit)(1)	(7,012)	20,747	
Total capitalization(1)	$20,747	$20,747	$

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) each of additional paid-in capital, total stockholders' equity (deficit) and total capitalization by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses.

The number of shares shown as issued and outstanding in the table above excludes:

- 1,251,200 shares of common stock issuable upon the exercise of all options outstanding under our Stock Incentive Plan and our 2006 Stock Plan with a weighted-average exercise price of $1.08 per share; and
- 1,800,000 shares of common stock reserved for future issuance under our 2006 Stock Plan and our 2006 Employee Stock Purchase Plan.

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DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the assumed initial public offering price of $ per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. Our historical net tangible book value deficit as of September 30, 2006 was $7.0 million. Our pro forma net tangible book value per share set forth below represents our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding on September 30, 2006, and assumes the automatic conversion of all of our preferred stock into shares of our common stock immediately prior to the closing of this offering.

Dilution per share to new investors represents the difference between the amount per share paid by new investors who purchase shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after the completion of this offering. Giving effect to the sale of shares of our common stock offered by us at the assumed initial public offering price of $ per share, and after deducting underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value as of December 31, 2005 would have been approximately $ million. This amount represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders, and an immediate dilution in pro forma net tangible book value of $ per share to new investors purchasing shares of our common stock in this offering. The following table illustrates this dilution:

Assumed initial public offering price per share		$
Historical net tangible book value deficit per share as of September 30, 2006	$(0.79)	
Increase per share due to assumed conversion of all shares of preferred stock	1.68	
Pro forma net tangible book value per share as of September 30, 2006	0.89	
Increase per share to existing investors		
Pro forma as adjusted net tangible book value per share after the offering		
Dilution per share to new investors		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) our pro forma as adjusted net tangible book value by $ million, the pro forma as adjusted net tangible book value per share by $ per share and the dilution in the pro forma net tangible book value to new investors in this offering by $ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses.

The following table sets forth as of September 30, 2006, on a pro forma as adjusted basis, the differences between the number of shares of common stock purchased from us, the total consideration paid, and the average price per share paid by existing stockholders and new investors purchasing shares of our common stock in this offering, before deducting underwriting discounts and commissions and estimated offering expenses at an assumed initial public offering price of $ per share.

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Weighted-Average Price Per Share
Existing stockholders		%	$	%	$
New investors					
Total		. %	$	. %	

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) total consideration paid by new investors, total consideration paid by all stockholders and the average price per share paid by all stockholders by $, $ and $, respectively, assuming the

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number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses.

Assuming the exercise in full of all options outstanding as of September 30, 2006, that, by their terms, are not subject to automatic exercise upon the closing of this offering the number of shares purchased by existing stockholders would be increased by shares to shares, representing % of shares purchased, total consideration paid by them would be increased by approximately $ to $, representing % of total consideration, and the weighted-average price per share paid by them would be decreased by $ per share to $ per share.

If the underwriters exercise their over-allotment option in full, the percentage of shares of common stock held by existing stockholders will decrease to approximately % of the total number of shares of our common stock outstanding after the completion of this offering, and the number of shares held by new investors will be increased to , or approximately % of the total number of shares of our common stock outstanding after the completion of this offering.

The tables above exclude as of September 30, 2006:

- 1,251,200 shares of common stock issuable upon the exercise of all options outstanding under our Stock Incentive Plan and our 2006 Stock Plan with a weighted-average exercise price of $1.08 per share; and
- 1,800,000 shares of common stock reserved for future issuance under our 2006 Stock Plan and 2006 Employee Stock Purchase Plan.

The exercise of options, all of which have an exercise price less than the assumed initial public offering price, would increase the dilution to new investors an additional $ per share, to $ per share.

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SELECTED CONSOLIDATED FINANCIAL DATA

We derived the selected consolidated statements of operations data for the years ended December 31, 2003, 2004 and 2005 and the selected consolidated balance sheet data as of December 31, 2004 and 2005 from our audited consolidated financial statements included elsewhere in this prospectus. We derived the consolidated statements of operation data for the years ended December 21, 2001 and 2002 and the consolidated balance sheet data as of December 31, 2001, 2002 and 2003 from our audited consolidated financial statements not included in this prospectus. We derived the selected consolidated statements of operations data for the nine months ended September 30, 2005 and 2006 and the selected consolidated balance sheet data as of September 30, 2006 from our unaudited consolidated financial statements included elsewhere in this prospectus. We have prepared this unaudited information on the same basis as our audited financial statements and have included all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair statement of our financial position and operating results for such period. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under "Management' s Discussion and Analysis of Financial Condition and Results of Operations."

	Years Ended December 31,					Nine Months Ended September 30,	
	2001	2002	2003	2004	2005	2005	2006
						(unaudited)	
	(In thousands, except per share data)						
Consolidated Statements of Operations Data(1):							
Revenues	$150	$35	$1,017	$3,816	$10,712	$7,093	$36,525
Cost of revenues	43	15	139	573	1,664	974	3,487
Gross profit	107	20	878	3,243	9,048	6,119	33,038
Operating expenses:							
Research and development	2,128	1,517	2,161	2,827	2,531	1,893	2,958
Sales and marketing	566	1,194	1,641	2,830	5,589	3,558	15,461
General and administrative	1,028	1,056	1,726	2,878	4,652	3,475	3,799
Total operating expenses	3,722	3,767	5,528	8,535	12,772	8,926	22,218
Income (loss) from operations	(3,615)	(3,747)	(4,650)	(5,292)	(3,724)	(2,807)	10,820
Interest income	395	102	133	129	79	59	90
Other income (expense), net	–	28	(28)	193	105	71	268
Net income (loss)	(3,220)	(3,617)	(4,545)	(4,970)	(3,540)	(2,677)	$11,178
Less: net income (loss) allocable to preferred stockholders	–	–	–	–	–	–	(7,565)
Net income (loss) allocable to common stockholders	$(3,220)	$(3,617)	$(4,545)	$(4,970)	$(3,540)	$(2,677)	$3,613
Net income (loss) per share allocable to common stockholders – basic	$(0.52)	$(0.58)	$(0.73)	$(0.77)	$(0.52)	$(0.41)	$0.47
Net income (loss) per share allocable to common stockholders – diluted	$(0.52)	$(0.58)	$(0.73)	$(0.77)	$(0.52)	$(0.41)	$0.40
Weighted-average shares outstanding used in calculating net income (loss) per share – basic	6,186	6,192	6,189	6,424	6,791	6,592	7,751
Weighted-average shares outstanding used in calculating net income (loss) per share – diluted	6,186	6,192	6,189	6,424	6,791	6,592	9,145
Pro forma net income (loss) per share							
Basic (unaudited)					$(0.17)		$0.16
Diluted (unaudited)					$(0.17)		$0.15
Pro forma weighted-average shares outstanding used in calculating net income (loss) per share							
Basic (unaudited)					21,283		22,243
Diluted (unaudited)					21,283		23,637

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	As of December 31,					As of September 30,
	2001	2002	2003	2004	2005	2006
						(unaudited)
Consolidated Balance Sheet Data:						
Cash, cash equivalents and available-for-sale securities	$ 5,610	$ 1,753	$ 7,854	$ 5,215	$ 1,958	$ 6,710
Working capital	5,696	2,024	8,651	7,124	5,943	19,657
Total assets	6,215	2,528	13,399	8,865	9,968	26,533
Convertible preferred stock	12,775	12,775	27,759	27,759	27,759	27,759
Total stockholders' deficit	(7,005)	(10,621)	(15,166)	(19,789)	(21,437)	(7,012)

(1) See Note 2 of the notes to our consolidated financial statements for a description of the method used to compute pro forma basic and diluted net income (loss) per common share and weighted-average number of shares used in pro forma per common share calculations.

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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 in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this prospectus.

Overview

We are a medical device company focused on the design, development and marketing of motion-preserving technologies and procedures for orthopedic and neurological spine surgery. Our first product, the X STOP, is designed to treat moderate lumbar spinal stenosis, or LSS, a condition resulting from the narrowing or constriction of neural pathways that often leads to debilitating pain in the lower back and legs. We believe that the X STOP fills a significant gap in the continuum of care for LSS sufferers.

We were a development stage company from our inception in 1997 until 2004, during which time our operations consisted primarily of start up activities, including developing the X STOP, recruiting personnel and raising capital.

United States Operations

We commenced enrollment for our U.S. pivotal trial of the X STOP in June 2000, and completed enrollment in July 2001. We received premarket approval from the FDA for the X STOP for the treatment of LSS in November 2005. In late 2005, we began to build our U.S. distribution and sales management organization. In January 2006, we initiated our training and education programs for spine surgeons on the X STOP procedure, and we commenced full commercial introduction of the X STOP in the United States.

We market and sell the X STOP in the United States to spine surgeons through a network of 24 specialty sales agent firms with approximately 275 total sales representatives and five direct sales representatives covering specific geographic territories. We primarily target high volume practitioners among the approximate 5,000 spine surgeons. In the nine months ended September 30, 2006, we trained approximately 1,000 spine surgeons in the use of our implant and surgical instruments. We currently sell the X STOP to over 400 hospital customers in the United States. No single customer in the United States accounted for more than five percent of our revenues in the nine months ended September 30, 2006.

We are expanding our sales and marketing and reimbursement support personnel in the United States to further penetrate the LSS market. We increased our headcount in these areas from seven employees as of January 1, 2006 to 30 employees as of September 30, 2006, and we expect to continue to grow in these areas.

Reimbursement claims for the X STOP procedure are typically submitted by the hospital and physician to Medicare or other third party payors using billing codes for spinal surgical procedures. The current U.S. list price for the X STOP device is $5,500. In August 2006, the Centers for Medicare and Medicaid Services, or CMS, announced its approval of a per-procedure, new technology add-on payment to hospitals for inpatient procedures using the X STOP. This add-on payment became effective on October 1, 2006 and can increase payment amounts to hospitals performing the X STOP procedure. The add-on payment is reviewed on an annual basis and may be available for two to three years. In addition, we received notification in August 2006 that CMS will establish a new device category for transitional pass-through payment for the X STOP for services performed in the hospital outpatient departments, effective January 1, 2007. Hospitals performing outpatient X STOP procedures will be able to receive an additional pass-through payment for the cost of each device implanted. The pass-through

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payment is reviewed on an annual basis and may be available up to two to three years. We believe that both the add-on and pass-through payments will enhance patients' access to the procedure in the United States.

Our X STOP and surgical instruments are manufactured by sole source, third-party contract manufacturers and we use a third-party sterilization vendor. We currently offer five different titanium X STOP sizes in the United States (6, 8, 10, 12 and 14 mm). We received FDA approval for polyether-etherketone, or PEEK, version of the X STOP in August 2006 and intend to launch this device in the United States in mid to late 2007.

International Operations

We received CE mark clearance to market the X STOP for the treatment of LSS in June 2002 and commenced European commercial sales in December 2002. Our European subsidiary, SFMT Europe B.V., currently manages our sales activities outside of the United States, where we use a mix of distributors, sales agents and direct sales personnel. We received regulatory clearance to market the X STOP in Japan in June 2001. However, we do not currently market the X STOP in Japan and do not plan to do so until reimbursement for our procedure increases. To date, the majority of our international sales have been in Europe but we expect European sales to continue to decline as a percentage of our overall revenues as we expand our sales and marketing efforts in the United States. In markets outside of the United States, we offer six different X STOP sizes (6, 8, 10, 12, 14 and 16 mm) in titanium and PEEK versions.

Financial Operations Overview

The following is a description of the components of our revenue and expenses.

Revenues. Revenues are derived almost exclusively from sales of the X STOP. During fiscal years 2003, 2004 and 2005, substantially all of our revenues were derived from international sales of the X STOP, primarily in Europe. Following U.S. commercial introduction of the X STOP in January 2006, the percentage of our revenues derived from the United States has increased substantially in the nine months ended September 30, 2006. Although we intend to continue to expand our international sales and marketing efforts, we expect that a substantial majority of our revenues will be derived from U.S. sales in future periods.

Cost of revenues. Cost of revenues consists primarily of material, labor and overhead costs related to our X STOP device and surgical instruments. Cost of revenues also includes facilities-related costs, depreciation, distribution, freight and packaging costs, the amortization of surgical instrument sets provided to distributors and stock-based compensation expense. We expect that cost of revenues as a percentage of revenues will remain relatively stable.

Research and development. Research and development expenses consist primarily of personnel costs within our product development, regulatory and clinical functions and the costs of clinical studies and product development projects. Research and development expense also includes stock-based compensation expense and facilities-related costs. In future periods, we expect research and development expenses to continue to grow in absolute terms as we continue to conduct further development to pursue expanded indications of the X STOP and develop technologies for other spine applications, but we expect these expenses to remain relatively stable or decrease slightly as a percentage of revenues.

Sales and marketing. Sales and marketing expenses consist primarily of sales commissions paid to our sales agents and sales representatives, personnel costs within our sales, marketing, reimbursement support and training functions, and costs associated with participation in medical conferences, physician symposia, surgeon training and promotional activities. Sales and marketing expenses also consist of stock-based compensation expense. We expect sales and marketing expenses to increase in absolute terms as we expand our sales and marketing efforts and incur additional sales commission expense related to sales growth. We expect these expenses to decrease as a percentage of revenues.

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General and administrative. General and administrative expenses consist primarily of salaries, stock-based compensation and other related costs for personnel serving the executive, finance, information technology and human resource functions, as well as, legal fees, accounting fees, insurance costs and facilities-related costs. We expect general and administrative costs to increase in absolute terms as we increase personnel and become subject to reporting requirements as a publicly held company. We expect these expenses to remain relatively stable or decrease slightly as a percentage of revenues.

Interest income. Interest income is primarily comprised of interest earned on our cash, cash equivalents and available-for-sale securities.

Other income (expense), net. We realize currency gains or losses upon the settlement of certain transactions denominated in foreign currencies. We also have intercompany balances denominated in foreign currencies that must be remeasured to current exchange rates on a monthly basis. In 2006, we initiated a hedging program whereby the intercompany receivable balance is hedged using foreign currency option or forward contracts to minimize the income statement impact of the gains or losses resulting from such remeasurement transactions. We amortize the premium cost of foreign currency option contracts over the period of the related contracts.

Results of Operations

Nine Months Ended September 30, 2005 and 2006 (unaudited)

Revenues. Revenues increased from $7.1 million in the nine months ended September 30, 2005 to $36.5 million in the nine months ended September 30, 2006. The increase in revenues was attributable to the full commercial launch of the X STOP in the United States in January 2006, the significant expansion of our sales network, and the ongoing acceptance of the product in Europe. The number of X STOP units sold increased from almost 3,000 in the nine months ended September 30, 2005 to more than 9,600 in the nine months ended September 30, 2006. The increase in X STOP units sold was driven by an increase in the number of surgeon users and hospital customers in the United States. During the nine months ended September 30, 2006, U.S. sales represented 71.9% of our revenues. There were no U.S. sales in the nine months ended September 30, 2005. The shift in revenue mix toward U.S. sales in the nine months ended September 30, 2006 resulted in an increase in average selling prices from approximately $2,400 in the nine months ended September 30, 2005 to approximately $3,800 in the nine months ended September 30, 2006 due to the higher average selling prices generated by U.S. sales. We expect U.S. sales to continue to account for a substantial majority of our revenues in future periods.

Cost of revenues. Cost of revenues increased from $974,000 in the nine months ended September 30, 2005 to $3.5 million in the nine months ended September 30, 2006. The increase was primarily attributable to the increase in the number of X STOP units sold. The increase was also attributable to costs of $246,000 related to the cost of surgical instruments provided to certain distributors during the nine months ended September 30, 2006. As a percentage of revenues, cost of revenues decreased from 13.7% in the nine months ended September 30, 2005 to 9.5% in the nine months ended September 30, 2006 primarily due to a revenue mix shift to U.S.-based sales which have higher average selling prices than in international markets.

Research and development. Research and development expenses increased from $1.9 million in the nine months ended September 30, 2005 to $3.0 million in the nine months ended September 30, 2006. The increase was primarily attributable to a $452,000 increase in stock-based compensation, a $27,000 increase in personnel costs and a $337,000 increase in European clinical trial spending. As a percentage of revenues, research and development expenses were 26.7% in the nine months ended September 30, 2005 and 8.1% in the nine months ended September 30, 2006.

Sales and marketing. Sales and marketing expenses increased from $3.6 million in the nine months ended September 30, 2005 to $15.5 million in the nine months ended September 30, 2006. The increase was primarily attributable to costs associated with the U.S. commercial introduction of the

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X STOP, including a $5.3 million increase in sales commissions, a $1.6 million increase in stock-based compensation, a $1.1 million increase in costs related to surgeon training, a $1.8 million increase in personnel costs primarily related to new sales, marketing and reimbursement support personnel, a $638,000 increase in costs related to marketing communication and tradeshow materials, a $531,000 increase in travel costs and a $389,000 increase in European sales and marketing expenses. As a percentage of revenues, sales and marketing expenses in the nine months ended September 30, 2005 and September 30, 2006 were 50.2% and 42.3%, respectively.

General and administrative. General and administrative expenses increased from $3.5 million in the nine months ended September 30, 2005 to $3.8 million in the nine months ended September 30, 2006 primarily attributable to a $555,000 increase in audit and legal fees, a $173,000 increase in general insurance costs, a $121,000 increase in travel, and a $105,000 increase in personnel costs, offset by the decline in stock-based compensation of $817,000 due to the recognition of certain stock-based compensation in 2005. As a percentage of revenues, general and administrative expenses in the nine months ended September 30, 2005 and September 30, 2006 were 49.0% and 10.4%, respectively.

Interest income. Interest income increased from $59,000 in the nine months ended September 30, 2005 to $90,000 in the nine months ended September 30, 2006. The increase in interest income is primarily attributable to higher cash, cash equivalents and short-term investment balances that increased as a result of cash provided by operations.

Other income (expense), net. Other income (expense), net in the period ended September 30, 2006, primarily consisted of foreign exchange gains of $576,000, offset by $258,000 of premium cost of currency options.

Years Ended December 31, 2003, 2004 and 2005

Revenues. Revenues increased from $1.0 million in 2003 to $3.8 million in 2004 and to $10.7 million in 2005. We commenced sales to European distributors in the first quarter of 2003 following receipt of CE Mark clearance for the X STOP in June 2002. Our primary sales activity in 2003 was in Germany and to a lesser extent The Netherlands and the United Kingdom. The increase from 2003 to 2004 was attributable primarily to continued penetration in those countries, and expanded distribution into Greece, Spain and Turkey. The increase from 2004 to 2005 was attributable to continued penetration in those markets and the addition of distribution in Italy, South Africa, Israel and Australia.

Cost of revenues. Cost of revenues increased from $139,000 in 2003 to $573,000 in 2004 and to $1.7 million in 2005. The increase was primarily attributable to increased sales of the X STOP. As a percentage of revenues, cost of revenues was 14% in 2003, 15% in 2004 and 16% in 2005. Primary factors that contributed to the changes in the cost of revenues as a percentage of revenues were due to change in mix from higher priced agent-based sales to lower margin distributor-based sales.

Research and development. Research and development expenses increased from $2.2 million in 2003 to $2.8 million in 2004 and decreased to $2.5 million in 2005. The increase from 2003 to 2004 was primarily attributable to a $457,000 increase in personnel-related costs and higher facilities related costs. The decrease from 2004 to 2005 was primarily attributable to a $274,000 decrease in U.S. clinical trial expenses, a $221,000 decrease in personnel-related costs in the development organization, and a $145,000 decrease in regulatory consulting fees, partially offset by a $268,000 increase in our European clinical and regulatory personnel and related clinical studies and a $42,000 increase in stock-based compensation.

Sales and marketing. Sales and marketing expenses increased from $1.6 million in 2003 to $2.8 million in 2004 and to $5.6 million in 2005. The increase from 2003 to 2004 was primarily attributable to a $795,000 million increase in commissions and personnel costs related to our European business, $116,000 increase in U.S. personnel costs and $81,000 of additional consulting costs. The increase from 2004 to 2005 was primarily attributable to $1.3 million increased commissions and personnel costs related to our European business, $832,000 of U.S. launch related promotional materials, a $278,000 increase in stock-based compensation, a $114,000 increase in surgeon training

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costs, and a $71,000 increase in personnel costs primarily related to additional hiring of U.S. sales and marketing personnel.

General and administrative. General and administrative expenses increased from $1.7 million in 2003, to $2.9 million in 2004 and to $4.7 million in 2005. The increase from 2003 to 2004 was primarily attributable to a $609,000 increase in our European operations costs, a $216,000 increase in our U.S. personnel costs, a $73,000 increase in facilities related costs, and a $47,000 increase in accounting services. The increase from 2004 to 2005 was primarily attributable to a $1.4 million increase in stock-based compensation, a $545,000 increase in personnel costs and an $89,000 increase in recruiting and relocation expenses.

Interest income. Interest income decreased slightly from $133,000 in 2003 to $129,000 in 2004 and decreased to $79,000 in 2005. The decrease in interest income is principally attributable to lower cash, cash equivalents and available-for-sale securities balances that decreased as a result of cash used to support operations.

Other income (expense), net. In 2003, we had foreign currency transaction losses of $28,000, and foreign currency transaction gains and other income of $193,000 and $105,000 in 2004 and 2005, respectively.

Quarterly Results of Operations

The following table sets forth our unaudited operating results for each of the six quarters preceding September 30, 2006. We have prepared this unaudited information on the same basis as the audited financial statements and have included all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of our financial position and operating results for such period. The amount and timing of our operating expenses may fluctuate significantly in the future as a result of a variety of factors. Our historic results are not necessarily indicative of the results that may be expected in the future.

	Quarters Ended					
	June 30, 2005	Sept. 30, 2005	Dec. 31, 2005	March 31, 2006	June 30, 2006	Sept. 30, 2006
	(unaudited, in thousands)					
Revenues	$2,449	$2,689	$3,618	$6,501	$13,246	$16,778
Cost of revenues	334	439	689	1,033	1,046	1,408
Gross profit	2,115	2,250	2,929	5,468	12,200	15,370
Operating expenses:						
Research and development	687	503	637	883	842	1,233
Sales and marketing	1,451	955	2,033	3,801	5,089	6,571
General and administrative	885	673	1,176	900	1,021	1,878
Total operating expenses	3,023	2,131	3,846	5,584	6,952	9,682
Income (loss) from operations	(908)	119	(917)	(116)	5,248	5,688
Interest income	20	18	20	15	18	57
Other income (expense), net	(168)	30	33	90	296	(118)
Net income (loss)	$(1,056)	$167	$(864)	$(11)	$5,562	$5,627

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Stock-Based Compensation

For the years ended December 31, 2003, 2004 and 2005 and the nine-month periods ended September 30, 2005 and 2006, employee and non-employee stock-based compensation expense, under APB No. 25, SFAS 123R and EITF 96-18, has been allocated as follows:

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
			(in thousands)		
Cost of revenues	$–	$–	$3	$–	$29
Research and development	26	15	57	–	452
Sales and marketing	–	–	278	102	1,678
General and administrative	–	–	1,360	1,258	441
Total	$26	$15	$1,698	$1,360	$2,600

At December 31, 2005, we had deferred stock-based compensation under APB No. 25 as shown in the statement of stockholders' deficit of approximately $4.7 million. As of December 31, 2005, deferred stock-based compensation of $1.4 million is expected to be amortized in 2006, $1.3 million in 2007, $1.2 million in 2008 and $0.8 million in 2009.

We recorded employee stock-based compensation expense of $2.3 million (unaudited) in the nine months ended September 30, 2006. For the nine months ended September 30, 2006, the total compensation cost related to stock-based awards granted or modified under SFAS 123R to employees and directors but not yet recognized was approximately $7.2 million (unaudited), net of estimated forfeitures. We will amortize this cost on a straight-line basis over a weighted average period of approximately four years.

Stock-based compensation expense related to stock options granted to non-employees is recognized on a straight-line basis. The options generally vest ratably over four years. The values attributable to these options are amortized over the service period and the unvested portion of these options are remeasured as the services are provided and the options are earned. The stock-based compensation expense will fluctuate as the deemed fair value of the common stock fluctuates. In connection with the grant of stock options to non-employees, we recorded stock-based compensation expense of $26,000, $15,000, and $133,000 for the years ended December 31, 2003, 2004 and 2005 and $74,000 and $295,000 for the nine month periods ended September 30, 2005 and 2006, respectively (unaudited).

Income Taxes

In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatment of items, such as depreciation, for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. We must then assess whether it is "more likely than not" that our deferred tax assets will be recovered from future taxable income and to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the statement of operations. Our management reviews its assumptions regarding the realization of deferred tax assets on an ongoing basis. Continued profitability and future changes in our management' s assumptions may result in a partial or full release of the deferred tax valuation allowance.

During the year ended December 31, 2005 and the nine month period ended September 30, 2006, we have decided to not release our deferred tax valuation allowance since the weight of evidence does not exceed the threshold of "more likely than not" as required by SFAS No. 109 that we would be able to realize our deferred tax asset. Due to uncertainty surrounding the realization of deferred tax assets

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through future taxable income, we have provided a full valuation allowance and no benefit has been recognized for the net operating loss and other deferred tax assets. Accordingly, deferred tax asset valuation allowances have been established as of December 31, 2003, 2004 and 2005 and September 30, 2006 to reflect these uncertainties.

As of December 31, 2005, we had net operating loss carryforwards of approximately $18.9 million and $10.5 million available to reduce future taxable income, if any, for federal and California state income taxes, respectively. The net operating loss carryforwards begin to expire by 2019 and 2008 for federal and California income taxes, respectively. We also had federal and state research and development credit carryforwards of approximately $417,000 and $462,000, respectively, at December 31, 2005. The federal credits will expire starting in 2019 if not utilized. Utilization of the net operating loss carryforward may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions.

Liquidity and Capital Resources

As of September 30, 2006, our accumulated deficit was $12.5 million (unaudited). We currently invest our cash and cash equivalents in institutional money market funds, consisting of debt instruments of the U.S. government, its agencies and high-quality corporate issuers. We place our short-term investments primarily in U.S. government bonds and commercial paper. Since inception, we have financed our operations primarily through private sales of convertible preferred stock resulting in aggregate net proceeds of $27.8 million.

As of September 30, 2006, we had cash, cash equivalents and available-for-sale securities of $6.7 million and working capital of $19.7 million (unaudited). In April 2006, we entered into a one-year line of credit with a bank that provides for borrowings of up to $2.0 million. The line of credit is collateralized by substantially all of our assets and is subject to an adequate borrowing base and compliance with certain financial covenants. To date, no amount has been drawn on the line of credit.

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2005, excluding the convertible preferred stock to be converted into common stock upon completion of this offering:

	Payments Due by Period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**
			(in thousands)	
Operating leases − facilities	$944	$286	$658	$ −

In July 2006, the Company entered into a new lease agreement with a five year term with its landlord to lease a larger facility within the same business park as its current facility and concurrently was released from the earlier lease that was due to expire in February 2009. Future minimum lease payments under the new lease are $4.0 million.

Net cash provided by (used in) operating activities. Net cash provided by operating activities was $3.9 million (unaudited) in the first nine months of 2006. Operating cash flows improved following the commercial introduction of our product in the United States. During the first nine months of 2006, net cash provided by operations primarily resulted from our positive operating cash flows resulting from increased unit sales and increased average selling prices associated with U.S. commercial introduction of the X STOP. Accounts receivable increased by $9.1 million as a result of increased revenues and inventory increased by $1.9 million as a result of forecasted demand of the Company' s product. Net cash used in operating activities was $5.1 million, $6.0 million and $3.4 million for 2003, 2004 and 2005, respectively. For each of these annual periods, net cash used in operating activities was attributable primarily to operating spending exceeding cash flow from customer sales and collections.

Net cash provided by (used in) investing activities. Net cash used in investing activities was $1.5 million (unaudited) for the first nine months of 2006. Net cash provided by (used in) investing activities was $(9.6) million, $5.7 million and $3.3 million for 2003, 2004 and 2005, respectively. For

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each of these periods, net cash provided by (used in) investing activities reflected purchases of property and equipment, primarily for research and development, information technology, manufacturing operations and capital improvements to our facilities and purchases or sales and maturities of short-term investments.

Net cash provided by financing activities. Net cash provided by financing activities was $1.1 million (unaudited) for the first nine months of 2006. Net cash provided by financing activities was $15.0 million, $93,000 and $371,000 for 2003, 2004 and 2005, respectively. These amounts primarily reflect the sale of convertible preferred stock during 2003 and the proceeds from the exercise of stock options.

We believe that our existing cash and cash equivalents together with the net proceeds from this offering will be sufficient to meet our anticipated cash needs for at least the next 12 months. We intend to spend substantial amounts on sales and marketing initiatives to support the ongoing commercialization of our products and on research and development activities, including support of product development, regulatory compliance and clinical study initiatives. We may need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to act on opportunities to acquire complementary businesses, products or technologies.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and disclosures of contingent assets and liabilities at the date of the financial statements. On a periodic basis, we evaluate our estimates, including those related to accounts receivable, inventories, income taxes and stock-based compensation. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue recognition. We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, *"Revenue Recognition."* SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) title has transferred; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. We generally use customer purchase orders to determine the existence of an arrangement. We use documents from our sales agents to verify that product has been delivered and title has transferred. We assess whether the fee is fixed or determinable based on the terms of the agreement associated with the transaction. In order to determine whether collection is reasonably assured we assess a number of factors, including past transaction history with the customer and the creditworthiness of the customer. If we determine that collection is not reasonably assured, we would defer the recognition of revenue until collection becomes reasonably assured, which is generally upon receipt of payment.

Accounts receivable. We extend limited credit to first time customers and adjust credit limits based upon payment history. We monitor collections and payments from our customers and maintain an allowance for doubtful accounts based upon our historical experience and any specific customer collection issues that we have identified. While our credit losses have historically been within our expectations and the allowance established, we may not continue to experience the same credit loss rates that we have in the past.

Inventory. We state our inventories at the lower of cost or market, computed on a standard cost basis, which approximates actual cost on a first-in, first-out basis and market being determined as the lower of replacement cost or net realizable value. Standard costs are monitored on an annual basis and updated as necessary to reflect changes in supplier costs and the rate of our overhead absorption is adjusted based on projections of our manufacturing department costs and production plan. Inventory

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reserves are established when conditions indicate that the selling price could be less than cost due to obsolescence, or we deem we hold excessive levels of inventory based on market demand.

Stock-based compensation. Prior to January 1, 2006, we accounted for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, or APB No. 25, and its interpretations and complied with the disclosure provisions of SFAS No. 123, Accounting for Stock-Based Compensation. Under APB No. 25, compensation expense is based on the difference, if any, on the date of the grant, between the deemed fair value of our stock and the exercise price. Employee stock-based compensation is amortized on a straight-line basis over the vesting period of the underlying options. SFAS No. 123 defines a "fair value" based method of accounting for an employee stock option or similar equity investment.

Stock-based compensation expense under APB No. 25, which is a non-cash charge, results from stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the estimated fair value of the underlying common stock on the date of grant. During the year ended December 31, 2005 and the nine months ended September 30, 2006, we granted options to employees to purchase a total of 1,688,900 shares of common stock at exercise prices ranging from $0.65 to $14.63 per share. In determining the fair market value of our common stock as of the date of each option grant, we relied on our board of directors, the members of which have extensive experience in the life science industry and all but one of whom are non-employee directors, to determine a reasonable estimate of the then current value of our common stock. Given the absence of an active market for our common stock, our board of directors determined the deemed fair value of our common stock on each grant date based on several factors, including progress achieved in our business and sales of the X STOP, and the senior liquidation preferences and other rights associated with our preferred stock. In addition, during this period we obtained three valuations of our common stock from an independent valuation consultant.

In connection with the preparation of our financial statements necessary for this offering, we have used hindsight and retroactively assessed the estimated fair value of our common stock after considering the expected valuation that we would obtain in an initial public offering. For this and other reasons, the reassessed fair value used to compute the stock-based compensation expense may not be reflective of the fair market value that would result from the application of other valuation methods, including accepted valuation methods for tax purposes. Stock-based compensation expense per share equals the difference between the reassessed fair value per share of our common stock on the date of grant and the exercise price per share and is amortized over the vesting period of the underlying option, generally four years.

In performing this reassessment, we considered several factors, including increased sales of our X STOP product in the U.S. and European markets, hiring of key managerial personnel, additions to our sales and marketing infrastructure, CMS reimbursements for extra procedures, progress made in the FDA approval process and the expected valuation that we would obtain in an initial public offering. We have reviewed these material factors and events between the period from January 1, 2005 through September 30, 2006 and have recorded stock-based compensation expense based upon a reassessed fair value of our common stock using a progression from $0.65 at January 1, 2005 to $16.20 at September 30, 2006. Based upon this reassessment, the aggregate intrinsic value of our outstanding options vested and expected to vest at September 30, 2006 was $17.8 million (unaudited).

Effective January 1, 2006, we adopted the fair value provisions of Statement of Financial Accounting Standards No. 123R, Share-Based Payment, or SFAS No. 123R, which supersedes previous accounting under APB No. 25. SFAS No. 123R requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. SFAS No. 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. We adopted SFAS No. 123R using the prospective transition method, which requires that for nonpublic entities that used the minimum value method for either pro forma or financial statement recognition purposes, SFAS No. 123R shall be applied to option awards granted, modified, repurchased or cancelled after the required effective date. For options granted prior to the

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SFAS No. 123R effective date, which the requisite service period has not been performed as of January 1, 2006, we will continue to recognize compensation expense on the remaining unvested awards under the intrinsic-value method of APB No. 25. All option grants valued after January 1, 2006 will be expensed on a straight-line basis.

Under SFAS No. 123R, we calculated the fair value of the stock option grants using the Black-Scholes option-pricing model. For the nine months ended September 30, 2006, the fair value was based on the following weighted average assumptions: the expected term of 4 years; the expected volatility of 60%, the risk free interest rate of 4.68% and 0.0% for the dividend yield. Estimated volatility for the nine months ended September 30, 2006 reflects the application of SAB No. 107 *Share Based Payment* interpretive guidance and, accordingly, due to a lack of historical information regarding the volatility of our stock price, incorporates historical volatility of similar public entities in similar markets. The expected term has been computed based upon the vesting term, cancellation history, historical exercises and contractual term of the options. Future expense amounts for any particular quarterly or annual period could be affected by changes in our assumptions or changes in market conditions.

We account for equity instruments issued to non-employees in accordance with the provisions of Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period, on a straight-line basis.

In 2005, we issued a full recourse note receivable to our Chief Executive Officer totaling $827,475 in connection with the early exercise of stock options. This note bore interest at a rate of 3.76% per annum which we consider to be below the market rate on the issuance dates. In accordance with FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25, the options are accounted under variable accounting from date of grant to date of exercise. We recognized the expense from the date of grant to the date of exercise in accordance with FASB Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans, an Interpretation of APB Opinions No. 15 and 25. The unamortized deferred stock-based compensation expense of $520,000 as of September 30, 2006 will be amortized on a straight line basis over the remainder of the vesting period. This note was repaid in September 2006.

Accounting for income taxes. In preparing our consolidated financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatment of items such as deferred revenue, for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. We must then assess whether it is "more likely than not" that our deferred tax assets will be recovered from future taxable income and to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the statement of operations. Management reviews its assumptions regarding the realization of deferred tax assets on an ongoing basis. Continued profitability and future changes in management' s assumptions may result in a partial or full release of the deferred tax valuation allowance. A release of the valuation allowance would have a favorable impact on the tax provision within the statement of operations.

During the year ended December 31, 2005 and the nine month period ended September 30, 2006, we decided to not release its deferred tax valuation allowance since the weight of evidence does not exceed the threshold of "more likely than not" as required by SFAS No. 109 that we would be able to realize its deferred tax asset.

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Off-Balance Sheet Liabilities Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements. In addition, we do not engage in trading activities involving non-exchange traded securities.

Quantitative and Qualitative Disclosures About Market Risk

During 2006, we began using foreign currency options and forward contracts to protect against losses due to the effect of currency movements between the U.S. dollar and the Euro on our intercompany balances. These foreign currency option contracts or forwards are not designated as hedges under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. The fair value of changes of these contracts, net of premium amortization, is reported in earnings as foreign exchange gain on loss, which is included in other income (expense), net in our statements of operations. Premiums on the foreign currency options are amortized over the term of the related contracts. Assuming a hypothetical adverse change of 10% in foreign exchange rates in relation to the Euro and U.S. dollar as of September 30, 2006, the impact of the adverse change would not be material to our consolidated financial statements.

We invest our excess cash primarily in institutional money market funds, U.S. government securities, corporate bonds and commercial paper. We do not utilize any other derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions in any material fashion. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

The majority of our sales and purchases outside of the United States are denominated in the local currency, future fluctuations in the value of the U.S. dollar will affect our operating results.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*, or SFAS No. 151. SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, to clarify the accounting for abnormal amounts of idle facility expense, handling costs and wasted material. Among other provisions, the new rule requires that such items be recognized as current-period charges, regardless of whether they meet the criterion of "so abnormal" as stated in ARB No. 43. We adopted SFAS No. 151 as of January 1, 2006, which did not have a material effect on our financial statements.

In June 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections: a Replacement of Accounting Principles Board Opinion No. 20 and FASB Statement No. 3*, or SFAS No. 154. SFAS No. 154 requires retrospective application for voluntary changes in accounting principle unless it is impracticable to do so. Retrospective application refers to the application of a different accounting principle to previously issued financial statements as if that principle had always been used. SFAS No. 154' s retrospective application requirement replaces APB No 20' s requirement to recognize most voluntary changes in accounting principle by including in net income (loss) of the period of the change the cumulative effect of changing to the new accounting principle. SFAS No. 154 defines retrospective application as the application of a different accounting principle to prior accounting periods as if that principle had always been used or as the adjustment of previously issued financial statements to reflect a change in the reporting entity. SFAS No. 154 also redefines "restatement" as the revising of previously issued financial statements to reflect the correction of an error. The requirements of SFAS No. 154 are effective for accounting changes made in fiscal years beginning after December 15, 2005 and will only impact the financial statements in periods in which a change in accounting principle is made. We do not expect that the adoption of this standard will have an impact on our financial statements.

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In November 2005, the FASB issued FASB Staff Position, or FSP, Nos. FAS 115-1 and FAS 124-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, which provide guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and the measurement of an impairment loss. These FSPs include accounting considerations subsequent to the recognition of an other-than-temporary impairment and require certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. These FSPs are required to be applied to reporting periods beginning after December 15, 2005. The adoption of these standards did not have a material impact on our financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for the Uncertainty in Income Taxes − an Interpretation of FASB Statement No. 109*, or FIN 48, which clarifies the accounting uncertainty in tax positions. This interpretation requires that we recognize in our financial statements the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on our financial statements.

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements,* or SAB No. 108. SAB No. 108 states that registrants should use both a balance sheet approach and an income statement approach when quantifying and evaluating the materiality of a misstatement. The interpretations in SAB No. 108 contain guidance on correcting errors under the dual approach as well as provide transition guidance for correcting errors. This interpretation does not change the requirements within SFAS No. 154 for the correction of an error on financial statements. SAB No. 108 is effective for annual financial statements covering the first fiscal year ending after November 15, 2006. We will be required to adopt this interpretation by December 31, 2006. We are currently evaluating the requirements of SAB No. 108 and the impact this interpretation may have on our financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements,* or SFAS No. 157. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We will be required to adopt SFAS No. 157 in the first quarter of fiscal year 2008. We are currently evaluating the requirements of SFAS No. 157 and the impact this standard may have on our financial statements.

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BUSINESS

Overview

We are a medical device company focused on the design, development and marketing of motion-preserving technologies and procedures for orthopedic and neurological spine surgery. Our first product, the X STOP Interspinous Process Decompression System, is a less invasive implant designed to treat lumbar spinal stenosis, or LSS, a condition resulting from the narrowing or constriction of neural pathways that often leads to debilitating pain in the lower back and legs. According to Verispan, there are currently approximately 1.4 million individuals in the United States who suffer from LSS. We believe that the X STOP fills a significant gap in the continuum of care for LSS sufferers that, until now, left patients whose condition does not respond to conservative, non-operative therapies, such as oral pain medications and corticosteroid injections, with no viable alternative other than laminectomy, an invasive surgical procedure. We believe that the X STOP will become the standard of care for patients with moderate forms of LSS.

We received premarket approval from the FDA in November 2005 for the X STOP for LSS and commercially introduced the product in the United States in January 2006. We received CE mark clearance in June 2002 and commenced European commercial sales in December 2002. We currently sell the X STOP through independent distributors and sales agents with over 350 sales representatives worldwide, as well as through five direct sales personnel in the United States. Since inception, we have sold over 15,000 units of the X STOP worldwide. In the first nine months of 2006, we trained over 1,000 spine surgeons in the United States. Our revenues were $10.7 million for 2005, nearly all of which was derived from outside the United States. Our revenues for the three months ended September 30, 2006 were $16.8 million, 80.3% of which was generated from the United States. In August 2006, CMS approved a special add-on payment for hospitals for X STOP procedures, which became effective on October 1, 2006, and CMS also granted a pass-through payment for reimbursement in the hospital outpatient setting which becomes effective January 1, 2007. We believe these payments will enhance patients' access to the procedure.

Inserted through a small incision, the X STOP is placed between the bones of the symptomatic vertebrae in the lumbar spine, or lower back. The X STOP is designed to limit extension of the lumbar spine, and keep open the neural pathways that carry nerves to the legs, thereby relieving symptoms. The device can be surgically implanted in a less invasive procedure that may be performed with local anesthesia, typically in less than an hour. The X STOP is not fixed to any bony structures. Rather, the X STOP is secured in position using an adjustable wing that is designed to keep the X STOP in place and minimize the risk of unintended movement of the X STOP. The procedure also does not require the permanent removal of bone or connective tissue. As a result, the X STOP procedure is reversible and therefore the procedure does not compromise future therapeutic alternatives, including laminectomy.

Industry Background

Spinal Anatomy

The spine is the core of the human skeleton, and provides both structural support and flexibility. The spine consists of 29 separate bones called vertebrae that are joined by connective tissue to permit a normal range of motion. The vertebrae are divided into five sections: the cervical vertebrae in the neck area, the thoracic vertebrae at the back wall of the chest, the lumbar vertebrae at the inward curve of the lower back, the sacrum which are fused vertebrae between the hip bones and the coccyx, or tail bone, which are fused vertebrae at the bottom end of the spine. Predominantly, degenerative diseases of the spine afflict the lumbar spine as these vertebrae bear much of the body' s weight and biomechanical stress during ordinary daily activities, such as standing and walking, and other forms of physical activity.

Vertebrae are paired into what are called motion segments that move by means of three joints: two facet joints and an intervertebral disc which separates the vertebrae. The intervertebral discs help keep the spine flexible and act as shock absorbers to cushion the vertebrae during motion. Spinal ligaments

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and other connective tissue in the spinal column connect the vertebrae to permit a normal range of motion and provide stability to the spine. The spinal canal contains and protects the spinal cord.

Lumbar Spinal Stenosis

LSS is a narrowing or constriction of the spinal canal, which causes impingement on the spinal cord and nerve roots that extend from the spine to the legs. LSS is most often caused by degenerative or arthritic conditions that lead to changes in the intervertebral discs, ligaments and facet joints surrounding the spinal canal. LSS most commonly occurs in the lower three levels of the lumbar spine.

The impinged nerves commonly cause pain, weakness and numbness in the lower back or buttocks that further radiates to the thighs and lower legs. When seated or bending forward, patients experience symptom relief as the spine is in flexion, resulting in a widening of the lumbar spinal canal. Physical symptoms tend to worsen while the patient is walking or standing upright, when the spine is in extension, decreasing the space available for the nerve roots. As a result, patients suffering from LSS typically live with significant lifestyle constraints that limit daily activities and quality of life.

Physicians can often quickly assess if a patient is likely suffering from LSS if the patient feels pain while their spine is extended and relief when the spine is in flexion. Subsequent to this initial symptomatic assessment, physicians can confirm a diagnosis of LSS using a combination of tools, including medical history, physical examination and a range of imaging modalities, including X-rays, MRIs, or CT scans.

According to Verispan, a market research organization, there are currently approximately 1.4 million individuals in the United States with a primary or secondary diagnosis of LSS. Approximately 500,000 of these patients are treated with conservative, non-operative therapies. Approximately 140,000 additional patients in the United States undergo spinal surgery for LSS annually. In addition, many LSS sufferers do not seek treatment. These individuals may view their LSS symptoms simply as common back pain that is an inevitable consequence of aging and not as a disease state for which treatment alternatives exist. The aging of the U.S. population as well as increases in the prevalence of obesity are expected to contribute to growth in the incidence of LSS.

Conventional LSS Treatment Alternatives and Their Limitations

Treatment for patients diagnosed with LSS depends on the severity of the disease. Physicians typically treat patients with milder forms of LSS through conservative, non-operative therapies. If symptoms do not improve or worsen, physicians may recommend surgical procedures.

Conservative, Non-Operative Therapies. Conservative, non-operative therapies include:

- lifestyle changes such as increased rest and reduced physical activity;
- physical therapy;
- non-steroidal anti-inflammatory drugs, or NSAIDs, and other oral pain medications; and
- epidural corticosteroid injections into the spinal area.

Lifestyle changes and physical therapy can slow the progression of the disease but rarely provide long term symptom relief. In addition, patients usually alter their lifestyle by reducing their level of physical activity, which may lead to obesity, depression and general physical deterioration and acceleration of the degenerative processes associated with aging. Those patients who continue to experience considerable pain over time often have to resort to more aggressive forms of therapy to seek relief.

NSAIDs such as aspirin or ibuprofen, can provide pain relief. However, NSAIDs typically have a “ceiling” effect in that there is a maximum limit to the amount of pain relief they can provide. Once these limits are reached, additional dosage strength will not provide increased relief. Prolonged use of NSAIDs can have side effects. Analgesics, such as acetaminophen, may also provide pain relief although they do not reduce inflammation. However, chronic use of analgesics can cause kidney and liver damage.

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Epidural corticosteroid injections represent a more aggressive form of drug therapy that is often used to treat LSS. Patients receiving this therapy are given injections of corticosteroids into the area in the spinal canal surrounding the spinal cord and nerve roots, which is known as the epidural space. Corticosteroids suppress inflammation and, as a result, may provide relief from LSS symptoms. However, corticosteroids can have significant side effects including stomach irritation, dizziness and decreased or blurred vision. As a result of these side effects and the potent nature of corticosteroids, the number of corticosteroid injections a patient can receive in a given time frame is typically limited. Furthermore, each successive corticosteroid injection will typically provide a given patient with symptom relief that is of a shorter duration than that provided by the previous injection. Accordingly, while steroid injections may provide some patients with temporary relief from LSS symptoms, they do not represent a viable long-term therapeutic alternative for many LSS patients.

These conservative, non-operative therapies may provide temporary relief for some patients and may stabilize or slow the worsening of LSS symptoms, particularly for patients with less severe forms of LSS. However, these therapies do not address the underlying cause of the disease and symptoms often worsen to a point where the patient becomes a candidate for a surgical procedure.

Surgical Procedures. Decompressive laminectomy is the most commonly performed surgical procedure to treat LSS. In a decompressive laminectomy, the surgeon removes bone, known as the lamina, from the back part of the symptomatic vertebrae over the spinal canal to create more space for, and relieve pressure on, the impinged spinal cord and nerve roots. The neural foramina, the tunnels through which the nerve roots traverse, may also be surgically enlarged.

To access the lamina, the surgeon must create an incision in the middle of the back and dissect the muscles covering the lamina. Once the lamina is removed, the facet joints, which are directly over the nerve roots, may be trimmed to give the nerve roots more space. In addition, ligaments in the spine may also be removed or compromised during the procedure. The removal of bone, ligaments, and muscle can weaken the structure of the spine and result in the spine becoming unstable in the area in which the laminectomy was performed. This instability is often a reason why many laminectomy patients also undergo a simultaneous fusion procedure, a highly invasive surgical procedure used to treat the instability, degeneration and deformities resulting from various diseases or injuries. Consequently, a fusion procedure compromises the ability of the spine to move. Although a fusion procedure may eliminate the pain by preventing motion at a segment, it may increase loads and stress at adjacent vertebral levels and facet joints. Over time, this increased load and stress may lead to degeneration and the patient may have to undergo another surgery to extend fusion to the adjacent levels.

A laminectomy is an open surgical procedure performed under general anesthesia and typically takes two hours to complete with patients often remaining in the hospital for up to three days following the procedure. A laminectomy with simultaneous fusion can take several hours to complete and patients can remain in the hospital for longer than three days. Recovery time after a laminectomy can be substantial, ranging from several weeks to months. For patients who have undergone a simultaneous fusion procedure, recovery time can be longer. Patients may also require long-term physical therapy. Laminectomy also involves significant risks including:

- spinal cord or other neural damage during the procedure;
- infections;
- tears in the dural membrane surrounding the spinal cord which can lead to painful and potentially serious leakage of cerebro-spinal fluid;
- blood clots in leg veins (deep vein thrombosis); and
- decreased intestinal function and neurological deterioration.

A meta analysis of 74 published journal articles found that, of those articles reporting surgical complications, the mean percentage of patients experiencing a surgical complication was 12.6%. In addition, for elderly patients or patients with co-morbidities, laminectomy is often not appropriate due

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to the risks associated with general anesthesia and open surgery in addition to the risks of the procedure itself.

Industry sources estimate that approximately 300,000 laminectomies were performed in the United States in 2005, of which approximately one-half were for the treatment of LSS.

Gap in Continuum of Care for LSS

We believe that the traditional treatment paradigm for LSS leaves a substantial portion of the patient population faced with a choice of therapeutic alternatives, each of which has significant drawbacks.

Conservative, non-operative therapies, such as oral pain medications or epidural corticosteroid injections, generally provide only temporary symptom relief, have diminishing efficacy, may result in side effects, and typically are viewed as only a short-term solution. Other conservative, non-operative therapies such as increased rest, reduced physical activity or regular physical therapy have significant lifestyle repercussions. Although, conservative, non-operative therapies may be adequate for patients experiencing milder LSS symptoms, patients whose symptoms worsen notwithstanding these therapies are faced with the unattractive choice of living with their symptoms or undergoing a decompressive laminectomy. A meta-analysis of 74 published journal articles determined that patients typically waited over four years after symptom onset before electing to undergo a laminectomy.

On the other end of the continuum of care, laminectomy is an invasive surgical procedure performed under general anesthesia with inherent safety risks. The surgery involves prolonged hospital stays, extended recovery periods and, occasionally, long-term physical therapy and is not advisable for seriously ill patients or patients who may have co-morbidities.

Accordingly, we believe that a significant market opportunity exists for a less invasive procedure that is designed to address the underlying causes of LSS rather than merely manage or temporarily alleviate the symptoms. We also believe that the availability of such a procedure could cause many LSS sufferers to seek treatment or reconsider their therapeutic options.

Our Solution − The X STOP Interspinous Process Decompression System

Our X STOP solution represents a new motion-preserving approach to the treatment of LSS that provides physicians and patients with a safe and effective treatment alternative that fills the current gap in the continuum of care between conservative, non-operative therapy and laminectomy. Unlike conservative, non-operative therapy, the X STOP addresses the underlying cause of LSS by reducing the narrowing or constriction of the neural pathways and the neural foramina. The X STOP is implanted in a less invasive procedure that may be performed under local anesthesia and does not require the permanent removal of bone and connective tissue. The procedure, therefore does not compromise any potential future therapeutic options. The initial target market for the X STOP procedure consists of LSS sufferers with moderate symptoms whose condition is not responding to conservative treatment or would be candidates for laminectomy procedures, a market we estimate to consist of over 200,000 X STOP procedures annually in the United States.

We believe that the principal benefits of our X STOP solution are:

Efficacious, Motion-Preserving Therapy. The results of our clinical trials indicate that the X STOP is more efficacious than conservative, non-operative therapy. In our pivotal clinical study, at 24-month follow-up, patients treated with the X STOP device reported significant symptom improvement including reduction in back, buttock and leg pain as well as overall satisfaction with the procedure. The X STOP has been found to significantly increase the dimensions of the spinal canal and the neural foramina while preserving the patient' s range of motion. In a study published in 2003, treatment outcomes for patients treated with the X STOP in our pivotal study were compared to outcomes from a study published in 1997 involving a group of laminectomy patients. Although this comparative data analysis should not be viewed as a substitute for a study directly comparing the X STOP procedure with laminectomy, the X STOP

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patients in our pivotal study reported symptom relief and overall satisfaction with the X STOP procedure that were similar to those reported by the laminectomy patients in the study.

Less Invasive, Same Day, Cost-Effective Procedure. The X STOP has been designed to be implanted under local or general anesthesia in a less invasive procedure that involves a relatively small incision. Patients implanted with the X STOP can return home from the procedure the same day. We believe the less invasive nature of the procedure, coupled with the short post-procedure recovery time, makes the X STOP a cost-effective alternative for the patients it can effectively treat.

Rapid Symptom Relief. The X STOP implant relieves the pinching of the nerves causing the pain associated with LSS by limiting extension of the spine. As a result, symptom relief is often experienced shortly after the procedure.

Preserves Treatment Options. Because the X STOP procedure does not result in the removal of, or permanent attachment to, bones and does not compromise connective tissue, the procedure is reversible without permanently damaging bone or soft tissue. As a result, the procedure does not limit a patient' s future treatment options. The X STOP procedure therefore fills the gap in the continuum of care between conservative, non-operative therapy and more invasive surgical procedures such as laminectomy.

May Enable Patients to Resume More Active Lifestyle. The symptom relief provided by the X STOP may enable patients to resume normal daily activities and, in many cases, return to a more active lifestyle including participation in recreational activities. Inactive, sedentary lifestyles have been linked to obesity, depression and general physical deterioration.

Ease of Use. We designed the X STOP and related instruments to be easy to use. In our experience, surgeons quickly understand how to use our system effectively after completing our surgeon training program. Surgeons implant the X STOP posterior to the spinal cord using a straight-forward, surgical technique, making the procedure less surgically-complex than many other spine surgeries. Due to the lack of complexity, the procedure requires very few surgical instruments and is typically completed in less than one hour.

Favorable Safety Profile. The X STOP is separated from the spinal cord by bone, which substantially reduces the risk of intraoperative injury to nerves or the spinal cord. During our pivotal clinical trial, there were no reports of neural injury associated with the X STOP procedure. The X STOP procedure generally results in only minor trauma to the spinal anatomy and can be performed under local anesthesia.

Available to Broad Patient Population. The X STOP enables physicians to treat elderly patients or seriously ill patients who may have other co-morbidities that make more invasive surgery inadvisable or impossible.

Our Strategy

Our goal is to be a leading provider of motion-preserving medical devices for the treatment of LSS and other spinal degenerative diseases. The key elements of our strategy include:

Establish the X STOP as the Standard of Care for the Treatment of Moderate LSS. We believe that the advantages of the X STOP in clinical efficacy, procedure reversability, and procedure recovery time will enable it to become the standard of care for treatment of moderate LSS. We intend to continue to establish the X STOP within the spine surgeon community through the publication of additional clinical results that demonstrate the benefits of the procedure compared to other treatment options.

Increase Awareness of LSS Among Physicians and Patients. We believe that LSS is currently underdiagnosed and undertreated, and we intend to educate physicians to raise awareness of LSS and available treatment alternatives, including the X STOP. As the U.S. baby-boomer population ages, we believe that this group will continue to pursue an active lifestyle

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and will seek treatments that enable them to continue to enjoy increased activity. Accordingly, we also intend to increase awareness through marketing to primary care physicians or other referring medical professionals who in many instances represent the initial point of patient contact. We also intend to investigate marketing directly to potential patients.

Expand our Sales and Marketing Infrastructure. We intend to continue to expand our sales and marketing efforts both in the United States and internationally. In the United States, we are increasing our direct sales organization to complement the efforts of our sales agents and distributors. Internationally, we are also expanding our direct sales efforts in Northern Europe and we will continue to seek product approvals and registrations in key Asian and other additional markets.

Expand Indications for the X STOP into New Markets. Our pre-clinical testing regarding the motion-preserving biomechanical properties of the X STOP showed a significant reduction of facet loads and disc pressures. We believe that these characteristics may make the X STOP a suitable treatment for low back pain and other degenerative spinal disorders. We expect to submit an investigational device exemption, or IDE, to the FDA during 2007 for a clinical trial of the X STOP to treat low back pain.

Establish a Motion-Preserving Franchise. We believe that we will be able to leverage our technology, existing sales and marketing infrastructure, and reputation within the physician community to introduce novel, motion-preserving products and technologies for the treatment of degenerative spinal disorders. For example, we are developing a proprietary device for the treatment of a degenerative condition of the cervical spine that can result in severe neck pain. We intend to supplement our internal development efforts through selective licenses, corporate partnerships or acquisitions of complementary products, technologies or businesses that can enhance our motion-preserving franchise. In addition, we intend to continue to expand our intellectual property position to protect the design and use of our products and further enhance our market leadership position in the less invasive treatment of degenerative spinal disorders.

The X STOP Product

The X STOP is the first less invasive, non-fusion motion-preserving device to receive FDA premarket approval for the treatment of LSS. We believe the X STOP represents a significant advancement in LSS treatment. The X STOP is a spinal implant designed to fit within the interspinous space. The X STOP mechanically limits extension and is able to:

increase the dimensions of the spinal canal and the neural foramina, thereby enlarging the openings through which nerve roots traverse;

reduce biomechanical loads on facet joints; and

decrease pressure on intervertebral discs.

The design of the X STOP enables it to be inserted without removing bone or ligaments, resulting in a procedure that can be performed under local anesthesia. The X STOP is not physically attached to bone or other structures in the spinal area. This makes the procedure reversible, which preserves future treatment options for the patient should they be necessary.

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The X STOP is depicted in the diagram below:

Components of the X STOP

The X STOP consists of two components:

Spacer Assembly. The spacer assembly, shown on the above left, is a "T" shaped implant that consists of a tapered edge and an oval spacer with a fixed wing. This design allows the device to be inserted laterally. The spacer is placed between the spinous processes through the interspinous ligament. The spacer assembly is designed to prevent forward or backward migration of the device.

Adjustable Wing. The adjustable wing, shown on the above right, is attached with a locking screw and the two wings together prevent lateral motion of the implant.

The current U.S. list price for the X STOP is $5,500. The X STOP is currently offered in five sizes in the United States, ranging from 6 to 14 mm and six sizes in Europe, ranging from 6 to 16 mm. The X STOP is currently made either entirely from titanium or with titanium wings and a PEEK spacer. Because PEEK has a stiffness profile that is similar to that of human bone, it is currently believed to be preferable for implantation around bones. Our initial FDA premarket approval for the X STOP received in November 2005 was for a titanium device. We received FDA approval for the PEEK device in August 2006 and intend to launch this device in the United States during mid- to late-2007. Both versions of the X STOP are commercially available in Europe.

In addition to the X STOP, we developed a range of surgical instruments for use by the surgeon in implanting the X STOP. These surgical instruments include tissue dilators, a sizing distractor for determining the appropriate size of the X STOP and tools for insertion of the spacer and attachment of the wing. These surgical instruments are sterilizable and reusable. The surgical instruments are available through our sales channels on a consignment basis and can also be purchased by hospitals. The principal X STOP surgical instruments are depicted below and include, from left to right, small dilator, large dilator, sizing distractor, spacer insertion tool, wing insertion tool and hex driver for adjustable wing attachment.

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X STOP Implantation Procedure

The X STOP is implanted by spine surgeons. In the United States, the procedure may be performed under local or general anesthesia in a hospital operating room. The procedure involves the following steps:

Position Patient and Administer Anesthesia. The patient is positioned on his or her side. Local or general anesthesia is then administered.

Gain Access to Spinous Space through Small Incision. The surgeon then locates the correct level for the implant and makes an incision of approximately two to four inches over the spinous processes of the symptomatic level(s) of the patient' s vertebrae. The small curved dilator is inserted through the interspinous ligament followed by the larger curved dilator.

Determine Appropriate X STOP Size. The patient' s spine is flexed, thereby distracting the space between the spinous processes and aiding in the sizing and insertion of the implant. The surgeon then uses the sizing distractor to measure for the proper size implant.

Position X STOP Spacer Assembly and Secure Adjustable Wing. The surgeon then inserts the spacer assembly in the opening and confirms the position of the implant with fluoroscopy. The opposing adjustable wing is then attached to the X STOP and is adjusted and tightened.

Confirm Final Position and Close Incision. The surgeon confirms the final position of the implant and closes the incision. Patients without significant co-morbidities may be allowed to return home the same day.

Approximately one-half of X STOP patients receive a single implant and approximately one-half of patients receive X STOP implants at two levels in their spinal column. The surgical procedure typically is performed in under one hour.

Current Indications for X STOP

The X STOP device is currently indicated for use in patients over the age of 50 with a confirmed diagnosis of LSS. Patients must have at least moderately impaired physical function and experience relief in flexion. Patients must also have undergone at least six months of conservative, non-operative therapy treatment regimens.

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Potential Indications for X STOP

We believe that the motion-preserving, biomechanical properties of the X STOP make it suited to use in treating other degenerative spinal disorders. Accordingly, we plan to conduct clinical studies to demonstrate the safety and efficacy of using the X STOP to treat the following spine disorders:

Low Back Pain. Low back pain is felt in the lumbar spine, known as mechanical pain, or in the legs, known as radicular pain. The incidence of back pain is substantial, with 15 to 20% of adults in the United States experiencing significant symptoms each year. Although these symptoms are usually acute and result from muscle spasms or strains, in 5 to 10% of patients the condition becomes chronic due to injury, osteoarthritis or nerve compression. We expect to submit an IDE to the FDA during 2007 for a clinical study of the X STOP for the treatment of patients with low back pain. The purpose of this clinical study is to support a low back pain indication for the X STOP. We expect that this clinical study will require two-year patient follow-up. Therefore, even if this clinical study is successful, we would not expect to receive FDA premarket approval for a low back pain indication for the X STOP until 2011 at the earliest.

Other Potential Indications. We also intend to explore use of the X STOP as a treatment for other degenerative spinal disorders, including herniated disc disease, adjacent level disease which involves degeneration of vertebrae adjacent to vertebrae that have been fused in fusion surgery and osteoarthritis of the facet joints. We are currently at an early stage of preclinical development with regard to these indications.

LSS Clinical Results and Studies

We have established a significant body of clinical data demonstrating the success of the X STOP in treating LSS. Our most important study was the X STOP pivotal clinical study. Data from this study was submitted to the FDA and supported premarket approval for use of the X STOP in the treatment of LSS. We also plan to conduct additional clinical studies related to the X STOP as a treatment for LSS.

X STOP Pivotal Trial (X STOP vs. Conservative, Non-Operative Therapy)

We conducted a multi-center, randomized, controlled clinical study pursuant to an IDE reviewed and cleared by the FDA to evaluate the safety and effectiveness of X STOP as a treatment for LSS. Patients enrolled in the study were, among other conditions, required to be 50 years of age or older and have symptoms commonly associated with LSS. Furthermore, patients had to be able to experience relief from symptoms (technically known as "neurogenic intermittent claudication") when in a sitting position or when in flexion, and completed at least six months of conservative, non-operative therapy, which may have included physical therapy, bracing, or systemic or injected medication. The pivotal study involved 191 patients at nine U.S. sites. Of these patients, 100 received the X STOP procedure and 91 were in the control group. Patients in the control group received ongoing conservative, non-operative therapy, including epidural corticosteroid injections, oral pain medications and physical therapy. The first patients were enrolled in June 2000 and enrollment was completed in July 2001.

The primary effectiveness endpoint was "overall treatment success," a multi-item composite endpoint. All control patients in the study had to satisfy four criteria to be considered as treatment successes, while X STOP patients had to satisfy three additional criteria.

Criteria applicable to all patients were:

improvement in symptom severity;

improvement in physical function;

a response of "somewhat satisfied" or "very satisfied" with treatment; and

no additional surgeries for LSS.

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Additional criteria applicable to X STOP treated patients were:

maintenance of distraction, or separation in the distance between the spinous processes at the point of the X STOP implant (confirmed by radiographic analysis performed by an independent radiologist);

no dislodgement of the X STOP; and

no implant-related complications associated with the X STOP.

Overall treatment success was determined for each patient at his or her last follow-up visit, which occurred two years after treatment. Symptom severity, physical function and overall treatment satisfaction were determined based on data collected using the patient-completed Zurich Claudication Questionnaire, or ZCQ. The ZCQ consists of questions regarding symptom severity and physical function elements that are completed both before and after treatment and questions regarding patient satisfaction that are completed after treatment. The ZCQ was chosen because it is the only condition-specific health outcomes instrument specifically designed and validated for use in evaluating LSS patients.

Of the 191 patients initially enrolled in the pivotal study, 96 X STOP patients and 87 control group patients were evaluable at the conclusion of the two-year follow-up period. Four patients in each arm of the study died prior to the conclusion of the two-year follow-up period. None of the deaths of the X STOP treated patients were attributed to the X STOP procedure. Of the evaluable patients, 73 X STOP patients and 66 control group patients had baseline, pre-treatment physical function scores above 2.0. ZCQ physical function scores can range from 1.0 to 4.0, with a lower number indicating milder impairment in the patient' s physical function due to his or her LSS symptoms and a higher number indicating more severe impairment. A ZCQ physical function score of 2.0 indicates that the patient is experiencing moderate impairment in physical function. The patients in the clinical study with ZCQ physical function scores above 2.0 were the patients experiencing moderate LSS symptoms, which is the group of patients for whom X STOP treatment is currently indicated and approved. These patients are referred to as the "indicated population." Two-year results from both the evaluable and indicated patient populations demonstrate that the X STOP procedure is superior to non-operative care. These results are summarized in the table below:

Overall Treatment Success at 24 Month Follow-Up

	Evaluable Population		Indicated Population	
Outcome Parameter	**X STOP % (n/N)**	**Control % (n/N)**	**X STOP % (n/N)**	**Control % (n/N)**
ZCQ Success Rate by Domain				
Physical Function	55% (53/96)	14% (12/87)	66% (48/73)	17% (11/66)
Symptom Severity	58% (56/96)	17% (15/87)	64% (47/73)	17% (11/66)
Patient Satisfaction	71% (68/96)	32% (28/87)	73% (53/73)	24% (16/66)
Percent of Patients Meeting all 3 ZCQ Criteria				
ZCQ Success	47% (45/96)	5% (4/87)	56% (41/73)	6% (4/66)
Overall Treatment Success				
Overall Success*	44% (41/94)	5% (4/87)	54% (38/71)	6% (4/66)

* Two X STOP patients who received epidural injections during their follow-up period but met all success criteria were excluded from the overall success rate calculation.

Although the ZCQ success rates and overall treatment success rates for the X STOP treated patients at all nine clinical sites were superior to those of the control group patients, X STOP patients at one clinical site had overall treatment success rates that were significantly higher than those reported for X STOP patients at the other sites. Control group patients at this site also had better ZCQ success outcomes than control group patients at the other eight sites. If the clinical data from this site are excluded, the ZCQ success rates and

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overall treatment success rates for X STOP treated patients in the evaluable population would have been 37% and 34%, respectively, and the ZCQ success rate for control group patients would have been 3%.

Secondary effectiveness endpoints included another outcomes measurement, the SF-36, which is a short form health outcomes questionnaire consisting of questions relating to a patient' s physical and mental state. The SF-36 results also demonstrated the superiority of the X STOP over non-operative control patients with respect to improved physical function, and were consistent with the results of the ZCQ. There were no significant differences in mental SF-36 scores between the treated group and the control group at either baseline or two-year follow-up.

Radiographic measurements were also made at each routine follow-up visit to monitor general changes that might have occurred to the spine as a result of implanting the X STOP. There were no significant differences at either 12 or 24 months between the X STOP group and the control group in any of these measurements. These included disc heights (the distance between two vertebrae measured from the front and back of the spine), curvature of the spine, angulation of the spine, and degree of forward slip of one vertebrae relative to an adjacent vertebrae. At the final two-year post-treatment follow-up, distraction was maintained in 96% of the spinal levels in which the X STOP had been implanted.

Several investigators in our pivotal study are stockholders of ours. Drs. James Zucherman and Ken Hsu, who are co-founders of our company and co-inventors of the X STOP, each own 1,201,000 shares of our common stock. Dr. Charles Hartjen own 10,000 shares of our common stock. These individuals served as clinical investigators in the pivotal study and were therefore involved in treating patients, performing follow-up examinations of patients and collecting patient data during the course of the pivotal study. Other surgeons, who were not investigators in our pivotal study, own an aggregate of 20,000 shares of our common stock and options to purchase 52,500 shares of our common stock as of September 30, 2006.

Reported ZCQ Domain Outcome in Laminectomy Patients

To date, there has not been a published head-to-head study comparing the effectiveness of the X STOP and laminectomy. There has been an attempt to assess, on a retrospective basis, comparative patient outcomes in X STOP and laminectomy patients using the ZCQ, one of the components of success in our pivotal trial. In a study first published in the journal *Spine* in May 1997, the authors reported on patient selection and predictors of surgical outcomes using results from a prospective, multi center study of LSS patients undergoing decompressive laminectomy with or without fusion. Of the 272 patients treated in this study, there were two-year data available on 199 patients. All patients were 50 years or older and had back, buttock, and/or lower extremity pain. Patients who had undergone previous surgery for LSS were excluded. Patients in the study were treated during the period from 1989 through 1993. Patients were assessed with the ZCQ pre-operatively and at the two-year post-operative visit, and a subset of ZCQ results were reported. However, results for each ZCQ domain and overall ZCQ success rates were not reported by the authors.

In 2003, the principal investigator in the 1997 study conducted a new analysis of his data using the same criteria for success as used in the X STOP pivotal study. All laminectomy patients for whom two-year ZCQ data were available were included in this analysis. Similarly, all X STOP patients who survived through the two-year follow-up period, including those patients with mild LSS defined as baseline ZCQ symptom scores at or below 2.0, were included in the X STOP comparison group. Patients that did not complete follow-up were excluded from laminectomy group; however, X STOP patients that did not complete follow-up were counted as treatment failures. As shown in the table below, the success rates of the laminectomy patients at two years postoperatively were similar to the X STOP treated arm in our pivotal trial when the ZCQ domain criteria were applied.

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ZCQ Domain	X STOP Pivotal Study (N=96)	Laminectomy Study (N=197)
Symptom Severity	58 %	63 %
Physical Function	55 %	59 %
Patient Satisfaction	71 %	72 %
"ZCQ Success" (All 3 Criteria)	47 %	47 %

Notwithstanding the data reported in this study, we cannot assure you that similar results would be achieved in a controlled, randomized study in which patient outcomes in an X STOP treated group were compared to patient outcomes in a laminectomy group. The patient populations were different, and the criteria for patient selection and enrollment were not identified. The laminectomy patients were also treated between 8 and 12 years prior to the patients in the X STOP pivotal study. In addition, laminectomy patients that did not complete follow-up, rather than being treated as failures, were excluded from the study. Accordingly, these data should not be viewed as a substitute for a two-arm study directly comparing laminectomy with the X STOP.

Other Ongoing Clinical Studies

X STOP Pivotal Study Follow-up. As a condition of approval of the X STOP by the FDA, we are required to follow all patients who received the X STOP prior to FDA premarket approval for a period of five years from treatment. There are a total of 149 patients in three patient groups who received the X STOP prior to FDA approval. These include 96 patients from the treated group in the pivotal study, 40 patients who as part of a continued access program were enrolled following completion of the pivotal study and 13 patients who were part of the control group in the study but elected to receive an X STOP after completion of two-year follow-up. In this study, pain and function evaluations will be performed annually using the ZCQ on all patients through the fifth postoperative year. Clinical examinations and X-rays will also be used to confirm the absence of complications. Secondary endpoints will include mean scores from the SF-36, as well as the incidence of adverse events, device failures and secondary surgeries. Five-year results from the follow-up of pivotal study patients are expected to be available in 2007. Five year follow-up results from all crossover and continued access patients are expected to be available in 2010.

Condition of Approval Study. As a condition of FDA approval of the X STOP, the FDA has required us to conduct a single-arm study involving 240 patients, all of whom will undergo an X STOP procedure. This condition of approval study is being conducted to determine whether patient selection criteria based on our approved labeling are adequate, and to evaluate whether the results from the pivotal study can be generalized to a larger group of patients who meet the selection criteria (that is, patients with moderately impaired physical function who have a confirmed diagnosis of LSS). Pain and function evaluations will be performed annually using the ZCQ, through five years postoperatively. Clinical examinations and X-rays will also be used to confirm the absence of complications. This study is expected to begin in late 2006, and five-year results are expected to be available in 2012.

LSS Economic Outcomes Study. We are conducting an economic outcomes study comparing data collected from the X STOP pivotal study with laminectomy and conservative, non-operative therapies. The purpose of this study is to demonstrate the cost-effectiveness of the X STOP as compared to other LSS treatment alternatives. This study is currently underway and is expected to be completed during 2007.

Other X STOP LSS Studies. We are also sponsoring additional clinical studies related to use of the X STOP to treat LSS. These studies are primarily being conducted in international locations, and include studies comparing the X STOP to laminectomy. In addition, there are several investigator-sponsored studies that are either underway or are being planned.

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Sales, Marketing and Training

Sales and Marketing

We market and sell the X STOP in the United States through a network of 24 specialty sales agent firms and five direct sales representatives covering specific geographic regions. We have agreements with all of our sales agent firms for an initial one year term that compensate them based on a percentage of the net sales that they generate. These firms typically have deep sales experience in surgical instrumentation, and usually represent several manufacturers, including companies that market other orthopedic devices. We selected these firms based on the complementary nature of the X STOP to their existing product offerings, their experience in bringing new technologies to market and their preexisting relationships with spine surgeons. Although our sales and marketing efforts are directed at spine surgeons because they are the purchase decision maker, the hospital where the procedure is performed is generally our customer.

Our initial sales and marketing effort has primarily targeted thought leaders and high volume practitioners. Our target market will consist of the approximately 5,000 U.S. spine surgeons. These surgeons practice at approximately 2,500 hospitals in the United States.

Our European subsidiary, SFMT Europe B.V., currently manages our sales activities outside of the United States, where we use a mix of distributors, sales agents and direct sales personnel. To date, the majority of our international sales have been in Europe. We intend to target key Asian and other international markets in the future. In Japan, although we received Japanese regulatory clearance to market the X STOP in June 2001, we do not plan to market the X STOP until the reimbursement for our procedure improves. In addition, we may be required to conduct further clinical evaluation of the X STOP in Japan before we can reintroduce the product.

We primarily target our marketing efforts to practitioners through marketing materials, medical conferences and journals. We also host seminars where industry leaders review case studies and surgical techniques using the X STOP. In addition, our direct sales force uses peer-reviewed publications, cost-benefit data and case studies in the selling process. We also involve thought leaders in the spine surgeon community as well as early adopters of the X STOP procedure in our marketing efforts as we believe that these surgeons will serve as advocates for our products and will be instrumental in generating valuable clinical data and demonstrating the benefits of our products to the medical community. We also intend to increase awareness through marketing to primary care physicians or other referring medical professionals who in many instances represent the initial point of patient contact.

In the future, we intend to develop and implement marketing programs targeted at potential patients through advertising, local and national health news broadcast segments, possible endorsements from well-known personalities that have received X STOP implants and other patient-oriented marketing efforts.

Surgeon Training

We devote significant resources to training and educating spine surgeons on the skills involved in the proper use of our surgical instruments and the X STOP. While we believe that the X STOP procedure is relatively straight-forward, we believe that proper surgeon preparation and training leads to improved surgical outcomes. Accordingly, the most effective way to introduce and build market demand for our products is by training leading spine surgeons in the use of our products. During the market introduction of the X STOP, we used a combination of national and regional cadaver surgery training sessions to train surgeons to perform the X STOP procedure. We are currently expanding to include an online, web based training program. For the nine months ended September 30, 2006, we had trained approximately 1,000 spine surgeons in the use of our products. As part of our training effort, we typically have a trained representative (an employee, sales agent or specifically engaged consultant with requisite operating room experience and prior training) present during the X STOP procedure for at least the first case performed by a newly-trained spine surgeon.

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Third-Party Reimbursement

In the United States, healthcare providers generally rely on third-party payors, principally private insurers and governmental payors such as Medicare and Medicaid, to cover and reimburse all or part of the cost of a medical device and of the procedure in which the medical device is used. Our ability to commercialize our products successfully depends in significant part on the extent to which appropriate coverage and reimbursement for our products and related procedures are obtained from third-party payors.

Establishing adequate coverage and reimbursement for any new medical technology is a challenge given the current emphasis on cost-containment. To successfully establish coverage and reimbursement for our technology, generally we must demonstrate that our technology improves health outcomes and does so in a cost-effective manner.

Because a large percentage of the population for which the X STOP is intended includes elderly individuals who are Medicare beneficiaries, Medicare' s coverage and reimbursement policies are particularly significant to our business. Medicare coverage and reimbursement policies are developed by CMS, the federal agency responsible for administering the Medicare program and its contractors. Medicare reimbursement rates for the same or similar procedures vary due to geographic location, nature of the facility in which the procedure is performed (e.g. teaching or community hospital) and other factors. In addition, private payors often follow the coverage and reimbursement policies of Medicare. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

Medicare coverage for procedures using our technology currently exists in the hospital setting (inpatient and outpatient departments). For both inpatient and outpatient X STOP procedures, Medicare generally reimburses the facilities in which the procedures are performed based upon prospectively determined amounts. For hospital inpatient stays, the prospective payment is determined by the patient' s condition and other patient data and procedures performed during the inpatient stay, using a classification system known as diagnosis-related groups, or DRGs. Procedures for hospital inpatient billing are referenced by international classifications of diseases, clinical modification, or ICD-9-CM, volume 3 procedure codes. Currently, inpatient X STOP procedures are coded under ICD-9-CM procedure code 84.58 ("Implantation of interspinous process decompression device"). Hospitals performing inpatient X STOP procedures generally are paid based on the DRG payment rate for the inpatient stay, notwithstanding the actual cost of such treatment. Payments prior to October 1, 2006 for Medicare hospital reimbursement rates for X STOP procedures without complications and without treatment for other conditions typically ranged from $6,000 to $15,000. In addition to reimbursement at the applicable DRG payment rate, CMS has approved an add-on payment of up to $4,400 per procedure for the X STOP, which became effective as of October 1, 2006. This add-on payment will increase the amount hospitals may be reimbursed for the X STOP procedure.

For X STOP procedures performed in hospital outpatient departments, Medicare payments also are generally made under a prospective payment system, which is based on the ambulatory payment classifications, or APCs, under which procedures are categorized. Hospital claims for payment use billing codes, including Current Procedure Terminology, or CPT, codes. Currently, most X STOP procedures are coded under CPT code 22899, which describes general spine surgery. CMS assigns procedures that are comparable, both clinically and in terms of the resources required, to the same clinical APCs. Currently, procedures categorized as general spine surgeries under CPT 22899 have been assigned by CMS to an APC that relates to APC 0043 ("Closed treatment fracture finger/toe/trunk"). Hospitals paid under the prospective payment system and performing outpatient procedures for Medicare patients using our products are paid the applicable APC payment rate for the outpatient procedure, regardless of the actual cost for such treatment. CMS has notified us that a new device category for transitional pass-through payment will be established for the X STOP, effective January 1, 2007. Therefore, hospitals performing outpatient X STOP procedures will be eligible for this additional pass-through payment to cover the costs of the X STOP device.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services. In all 50 states and in the District of Columbia,

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Medicare reimburses physicians for their professional services when they perform X STOP procedures. Currently, Medicare payment is based on CPT 22899. Because this is a general surgery code that is used for many different procedures, Medicare contractors establish payment levels for the procedure for their geographic areas.

In the United States, we believe that a majority of private healthcare payors provide coverage for X STOP procedures under their plans. In many cases, this reimbursement is being provided on a case by case basis. In July 2006, we initiated an effort to develop formal policies for coverage of the X STOP by private payors, and to date we have contacted over 70 private payors in this regard. We also have an internal reimbursement support organization that works with healthcare providers to assist them in obtaining reimbursement for X STOP procedures.

Effective January 1, 2007, the following two new Category III CPT codes have been developed: CPT codes 0171T ("Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level") and 0172T ("Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level"). Category III codes are temporary codes for emerging technology and services, and we cannot assure you at this time how the level of reimbursement would be impacted by the new codes. We expect that Medicare reimbursement for physicians and for hospital outpatient departments would be based on such procedure-specific codes, rather than under unspecified spine surgery codes. In the future, new, Category I codes could be implemented with respect to X STOP. In the event such new codes are implemented, it is possible that reimbursement under such codes could be at lower levels than what physicians and hospitals are currently receiving under general codes or will receive under Category III CPT codes. However, the availability of national payment levels may simplify the process of submitting claims for payment. As of now, it is not possible to assess the full impact of procedure specific X STOP CPT codes on our business or results of operations.

Internationally, reimbursement and healthcare payment systems vary substantially from country to country and include single-payor, government managed systems as well as systems in which private payors and government-managed systems exist side-by-side. Our ability to achieve market acceptance or significant sales volume in international markets we enter will be dependent in large part on the availability of reimbursement for procedures performed using our products under the health care payment systems in such markets. For example, even though we have obtained clearance to market the X STOP in Japan, we do not plan to market the X STOP in Japan until we receive approval for higher levels of reimbursement for X STOP procedures in that country. We may be required to conduct clinical studies of the X STOP in Japan in order to obtain such approvals.

Research and Development

As of September 30, 2006, we had 12 employees in our research and development function. The primary focus of this group is to leverage our existing technology platform for new applications, to develop new technology platforms and to develop improvements and enhancements to the X STOP. Research and development expenses for 2003, 2004, 2005 and the nine months ended September 30, 2006 were $2.2 million, $2.8 million, $2.5 million and $3.0 million, respectively. We expect our research and development expenses to increase in absolute dollar terms but decrease as a percentage of revenues.

Manufacturing and Supply

We rely on third parties for the manufacture of our products and surgical instruments. Our outsourcing partners are manufacturers that meet FDA, International Organization for Standardization, or ISO, and other quality standards. We believe these manufacturing relationships minimize our capital investment and allow us to focus on core competencies.

Following the receipt of products or product components from our third-party manufacturers, we conduct inspections and warehouse the material at our headquarters facility. Product is sent out for

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sterilization in smaller lots as needed to preserve the shelf life of the sterilized inventory. We are currently in the process of outsourcing sterilization of the X STOP to our contract manufacturer. Once this process is complete, we receive packaged and ready to ship product at our facility. Under our existing contracts, we reserve the right to inspect and assure conformance of each product and product component to our specifications. We may consider manufacturing certain products or product components internally, if and when demand or quality requirements make it appropriate to do so. We have procured some of the necessary equipment to provide for contingency manufacturing in the event of a supply chain disruption, but substantial regulatory work would need to be performed before a contingency manufacturing plan would be fully operational.

We currently use a single contract manufacturer for the X STOP. We are currently in the process of qualifying a second source for manufacturing the X STOP. We do not expect to have the qualification process complete until the end of 2007. In addition, the biocompatible PEEK material used in the X STOP is a proprietary polymer that is available from only one supplier. We have a supply agreement with this supplier pursuant to which we have agreed to purchase our requirements of PEEK. To date, we have not experienced any significant supply constraints or delays in procuring PEEK. We are currently working with our X STOP contract manufacturer and other suppliers to increase manufacturing capabilities as we increase our commercialization efforts. Manufacturers often experience difficulties in scaling-up production, including problems with production yields and quality control and assurance. If our third-party manufacturers and key suppliers are unable to manufacture our products to keep up with demand, we would not meet expectations for growth of our business.

We and our third-party manufacturers are subject to the FDA' s quality system regulations, state regulations, such as the regulations promulgated by the California Department of Health Services, and regulations promulgated by the European Union. We are FDA registered, California licensed, CE marked (European conformity) and ISO certified. Our facility and the facilities of our third-party manufacturers are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state agencies. For example, we and our third-party contract manufacturers underwent FDA inspections during 2004 and 2006, respectively, which did not yield any observations on Form FDA 483. However, the FDA may impose additional enforcement, inspections or audits at any time. We cannot assure you that we or our third-party contractors will comply with all applicable manufacturing regulations.

Patents and Proprietary Technology

In order to remain competitive, we must develop and maintain protection on the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. We have 34 issued U.S. patents and 10 issued foreign patents covering the X STOP and our surgical instruments. In addition, we have 23 pending U.S. patent applications and 18 pending foreign patent applications. We intend to file for additional patents to further strengthen and extend our intellectual property rights.

All employees and technical consultants are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. We also require them to agree to disclose and assign to us all inventions conceived in connection with the relationship. We cannot provide any assurance that employees and consultants will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of the X STOP or obtain and use information that we regard as proprietary.

Our patent applications may not result in issued patents, and we cannot assure you that any patents that have issued or might issue will protect our intellectual property rights. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. We cannot be certain that the steps we have taken will prevent the misappropriation of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

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Competition

We believe that the principal competitive factors in our markets include:

efficacy in the treatment of LSS;

acceptance by spine surgeons;

ease of use and reliability;

pricing and qualification for coverage and reimbursement;

technical leadership and superiority;

effective marketing and distribution; and

speed to market.

The primary competition in the United States, at least for the next several years, is expected to be conservative, non-operative therapy and decompressive laminectomy with or without fusion. In Europe, there are three devices commercially available or in clinical evaluation that are or may become competitive with the X STOP: the DIAM Spinal Stabilization System from Medtronic, Inc., the Wallis system from the Abbott Spine division of Abbott Laboratories, and the coflex from Paradigm Spine. Although none of these devices is approved for commercial sale in the United States, their manufacturers have recently received FDA approval for the commencement of pivotal clinical studies under IDEs issued by the FDA. Many of our competitors have significantly greater financial and human capital resources than we do and have established reputations with our target customers, as well as worldwide distribution channels that are more effective than ours.

Government Regulation

The X STOP is a medical device subject to extensive and rigorous regulation by FDA, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries. FDA regulations govern the following activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

product design, development and manufacture;

product safety, testing, labeling and storage;

premarketing clearance or approval;

record keeping procedures;

product marketing, sales and distribution; and

post-marketing surveillance, reporting of deaths or serious injuries and medical device reporting.

FDA's Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require either prior 510(k) clearance or approval of a PMA from the FDA. Medical devices are classified into one of three classes– Class I, Class II, or Class III–depending on the degree or risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Devices deemed to pose lower risks are placed in either Class I or II, which generally requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring premarket approval. The X STOP implantable device, the wing assembly insertion unit and the spacer assembly insertion instrument are Class III devices and are marketed under an FDA approved PMA.

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510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 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 a PMA application. By statute, 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 often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the FDA will place the device, or the particular use, into Class III. Four other surgical instruments we provide for use in performing X STOP procedures are Class I devices and are therefore exempt from 510(k) clearance requirements.

Premarket Approval Pathway

A PMA application must be submitted to the FDA if the device cannot be cleared through the 510(k) process. The PMA application process is generally much more demanding than the 510(k) premarket notification process. A PMA application must 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.

After a PMA application is submitted and the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for review. By statute, the FDA has 180 days to review an "accepted" PMA application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may 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. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New PMA applications or PMA application supplements are required for significant modification to the manufacturing process, labeling and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application and may not require as extensive clinical data or the convening of an advisory panel.

We currently market the X STOP in the United States under an FDA approved PMA for the treatment of patients aged 50 or older suffering from neurogenic intermitten claudication secondary to a confirmed diagnosis of LSS, and who have undergone regimens of conservative, non-operative therapies for at least six months. Patients must have at least moderately impaired physical function. If we seek to expand the indications for the X STOP to treatment of lower back pain, herniated disc disease or adjacent level disease we will be required to submit an application for and obtain a PMA for the X STOP for these indications. The PMA submissions will require clinical data supporting the safe and effective use of the device in those indications. We cannot assure you that we will successfully complete a clinical study in lower back pain, herniated disc disease or adjacent level disease patients or will submit and obtain approval for the X STOP for use in any of those indications.

Clinical Trials

Clinical trials are almost always required to support an FDA approval of a PMA and are sometimes required for 510(k) clearance. In the United States, these trials generally require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific

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number of patients unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. Our clinical trials must be conducted under the oversight of an IRB at the relevant clinical trial sites and in accordance with FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain patients' informed consent that complies with both FDA requirements and state and federal privacy regulations. We, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval of the product. Similarly, in Europe the clinical study must be approved by the 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. These include:

FDA' s Quality System Regulation, or 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 manufacturing process;

labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;

medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

After a device receives 510(k) clearance or a PMA approval, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change change in manufacturing or in its intended use, will require a new clearance or approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer' s determination. We have modified various aspects of our X STOP since receiving regulatory approval, filed PMA supplements and received approval for those modifications. In certain situations, we might determine that no supplement is required. If the FDA disagrees with our determination not to seek a new approval, the FDA may retroactively require us to seek premarket approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until premarket approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines, penalties and warning letters.

We registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDHS. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDHS, or FDB, to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. We were inspected by the FDA in July 2004 prior to approval and there were no noncompliance matters noted. In the past, our current facility has satisfactorily completed a GMP inspection and all observations have been closed. We are currently undergoing an FDA Quality System inspection, which is our first post-approval inspection by the FDA. We cannot assure you that this inspection will not reveal material compliance matters or that we will be deemed to be in compliance with QSR.

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Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refunds, recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;

withdrawing 510(k) clearance or premarket approvals that have already been granted; and

criminal prosecution.

Fraud and Abuse

We may directly or indirectly be subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service, for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General, or OIG, has issued a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

International

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

The primary regulatory environment in Europe is that of the EU, which has adopted numerous directives and has promulgated voluntary standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the EU, and other countries that comply with or mirror these directives. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer' s quality system and specific testing of the manufacturer' s device. Such an assessment is required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 9001 and ISO 13845 certifications are voluntary harmonized standards. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking. We have the authorization to affix the CE Mark to the X STOP and to commercialize the device in the EU for Neurogenic

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Intermittent Claudication due to lumbar spinal stenosis, lower back pain, facet syndrome, degenerative disc syndrome, contained herniated or bulging disc and adjacent level disease. The X STOP has obtained regulatory approval in Japan but has not been launched there due to the current reimbursement environment.

Facilities

Our corporate headquarters is located in a 31,600 square foot facility in Alameda, California, and is where we conduct our principal executive and administrative, research and development and warehouse operations. This facility is leased through September 2011. Our Driebergen, Netherlands office is approximately 1,600 square feet, consisting primarily of office space, and is leased through March 2009. We believe that our existing facilities are adequate for our current needs.

Litigation

We are not party to any material pending or threatened litigation.

Employees

As of September 30, 2006, we had 70 employees, of which 58 are in the United States and 12 are in our European subsidiary. In the United States, 18 employees are in sales and marketing, 12 are in reimbursement support, 10 are in general and administrative, nine are in clinical and regulatory, six are in operations and three are in research and development. In Europe, six employees are in sales and marketing, four are in general and administrative and two are in clinical and regulatory. We believe that our future success will depend on our continued ability to attract, hire and retain qualified personnel. None of our employees are represented by a labor union or are parties to a collective bargaining agreement, and we believe our employee relations are good.

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MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information concerning our executive officers and directors as of September 30, 2006:

Name	Age	Position
Kevin K. Sidow	49	President, Chief Executive Officer and Director
Michael A. Bates	48	Chief Financial Officer and Secretary
Christopher T. Fair	36	Vice President, Sales
Matthew Frushell	45	Vice President, Marketing
T. Yvonne Lysakowski	47	Vice President, Regulatory, Clinical Affairs and Quality Assurance
Scott A. Yerby, Ph.D.	38	Vice President, Research and Development
David M. Clapper(2)	55	Director
Joseph R. Cutts(1)	43	Director
Ross A. Jaffe, M.D.(2)(3)	48	Director
Alan L. Kaganov, Sc.D.(2)	67	Director
Martin P. Sutter	51	Director
Allan M. Weinstein, Ph.D.(1)	61	Director
Philip M. Young(1)(3)	66	Director

(1) Member of our audit committee.

(2) Member of our compensation committee.

(3) Member of our nominating and governance committee.

Kevin K. Sidow has served as our President and Chief Executive Officer and as a member of our board of directors since May 2004. From March 1998 to May 2004, Mr. Sidow held a number of executive positions with DePuy, Inc., a subsidiary of Johnson & Johnson and designer, manufacturer and distributor of medical devices for reconstruction, spinal, trauma and sports medicine. From October 2003 to May 2004, he was Worldwide President of DePuy, Inc., and responsible for all DePuy companies, and from March 2001 to October 2003, he served as Worldwide President of DePuy Orthopaedics, ACE and Casting. From August 2000 to March 2001, Mr. Sidow served as President of DePuy Orthopaedics. From March 1998 to August 2000, he served as Area Vice President and Vice President of Sales for DePuy Orthopaedics. Mr. Sidow holds a B.S. in Accounting from West Virginia University.

Michael A. Bates has served as our Chief Financial Officer since January 2005 and as our Secretary since January 2006. From April 2000 to October 2004, Mr. Bates served as Vice President of Finance and Administration and Chief Financial Officer of Silicon Genetics, a bioinformatics company. From January 1999 to February 2000, Mr. Bates served as Vice President of Finance and Chief Financial Officer of Collagen Aesthetics, Inc., a medical device company. From 1995 to 1998, Mr. Bates served in various financial positions at Penederm, Inc., a dermatology pharmaceutical company, most recently as its Chief Financial Officer. Mr. Bates is a C.P.A., and holds a B.S. in Business Administration from California State University at Hayward and an M.B.A. in Finance from the University of California at Berkeley.

Christopher T. Fair has served as our Vice President, Sales since February 2004. From September 1995 to February 2004, Mr. Fair served in a variety of marketing and sales roles at DePuy Spine, the spine division of Johnson & Johnson, most recently as territory General Manager. Mr. Fair holds a B.S. in Business Administration from the University of Richmond.

Matthew Frushell has served as our Vice President, Marketing since June 2006. From February 2004 to March 2006, he was Vice President of Marketing of Blackstone Medical, Inc., a medical device company.

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From April 2001 to February 2004, Mr. Frushell was principal owner of Frushell & Associates, Inc., a medical device industry consulting firm. Mr. Frushell holds a B.S. degree in Mechanical Engineering from the Rose-Hulman Institute of Technology.

T. Yvonne Lysakowski has served as our Vice President, Regulatory and Clinical Affairs since November 2003, and as Vice President, Regulatory, Clinical Affairs and Quality Assurance since November 2005. From February 1999 to November 2003, Ms. Lysakowski served in various clinical affairs positions at Nellcor Puritan Bennett, a division of Tyco Healthcare, a medical device company, most recently as a Director, Clinical Affairs. From 1991 to 1997, she served in various clinical research positions at Advanced Bioresearch Associates, a regulatory consulting firm, most recently as Vice President, Clinical Research. Ms. Lysakowski holds B.S. degrees in Biology and Nursing, and an M.S. degree in Perinatal Nursing from the University of Illinois.

Scott A. Yerby, Ph.D. has served as our Vice President, Research and Development since January 2006. From October 2005 to January 2006, he served as Chief Technical Officer of Baxano, Inc., a medical device company. From June 2000 to October 2005, he served as our Director of Research and Development. From June 1997 to June 2000, Dr. Yerby was Director of Experimental Biomechanics at the Palo Alto Veterans Administration Hospital. From September 1998 to June 2000, he held an appointment as Consulting Assistant Professor at Stanford University in the Department of Functional Restoration, Division of Orthopedic Surgery. In addition, from October 1999 to June 2000, he held an appointment as Consulting Assistant Professor at Stanford University in the Department of Mechanical Engineering, Division of Biomechanical Engineering. Dr. Yerby holds a B.S. degree and an M.S. degree in Mechanical Engineering, and a Ph.D. in Biomechanical Engineering from the University of California at Davis.

David M. Clapper was appointed to our board of directors in May 2006. Since January 2005, Mr. Clapper has served as President and Chief Executive Officer of SurgRx, a medical device company. From 1999 to March 2004, he served as President and Chief Executive Officer and a director of Novacept, a women' s surgical device company that was acquired by Cytyc Corporation in March 2004. From 1993 to 1999, Mr. Clapper served as President and Chief Executive Officer of Focal, Inc., a medical device company. Mr. Clapper serves as a director of Conor Medsystems, Inc., a publicly-held medical device company, and SVB Financial Group, a publicly-held financial holding company. Mr. Clapper holds a B.S. in Marketing from Bowling Green State University.

Joseph R. Cutts was appointed to our board of directors in May 2006. Mr. Cutts currently serves as Chief Operating Officer and Corporate Secretary of Electronics for Imaging, Inc., or EFI, a publicly-held digital imaging and print management company. From April 2000 to April 2006, he served as Chief Financial Officer of EFI. From January 1999 to April 2000, he served as Vice President of Finance of EFI. From March 1997 to January 1999, he served as Director of Finance of EFI. From June 1994 until March 1997, Mr. Cutts served as the Director of Finance for the Nestlé Beverage Company, a subsidiary of Nestlé SA. Mr. Cutts holds a B.S. in Finance from Pennsylvania State University and an M.M. from Northwestern University.

Ross A. Jaffe, M.D. was appointed to our board of directors in November 2000. Dr. Jaffe is a managing director of Versant Ventures, a venture capital firm that he co-founded in 1999. Dr. Jaffe joined Brentwood Venture Capital, a venture capital firm, in 1990 and since 1993 has served as a partner of the firm. Dr. Jaffe holds an M.D. from the Johns Hopkins University School of Medicine, an A.B. in Policy Studies from Dartmouth College and an M.B.A. from Stanford University.

Alan L. Kaganov, Sc.D. was appointed to our board of directors in June 1999. Since February 1996, Dr. Kaganov has been an employee, venture partner, partner, assignee or member of various entities generally known as U.S. Venture Partners, a venture capital firm. From March 1993 to June 1996, Dr. Kaganov served as Vice President of Business Development and Strategic Planning for Boston Scientific Corporation, a medical device manufacturer. Dr. Kaganov holds a B.S. in Mechanical Engineering from Duke University, Sc.D. and M.S. degrees in Biomedical Engineering from Columbia University and an M.B.A. from New York University.

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Martin P. Sutter was appointed to our board of directors in September 2006. Mr. Sutter serves as managing director of Essex Woodlands Health Ventures, a venture capital firm he co-founded in 1994. Mr. Sutter serves as a director of LifeCell Corporation, a publicly-held medical device company that develops and markets products to promote regenerative growth of human tissue, and La Jolla Pharmaceutical Company, a publicly-held biopharmaceutical company that develops products for treatment of autoimmune diseases. Mr. Sutter holds a B.S. from Louisiana State University and an M.B.A. from the University of Houston.

Allan M. Weinstein, Ph.D. was appointed to our board of directors in April 1999. Dr. Weinstein founded Orthologic Corp., an advanced orthopedic device company, in 1987 and served as its President and Chief Executive Officer until 1997. From July 1983 to July 1987, he served as President and Chief Executive Officer of the Harrington Arthritis Research Center. He holds a B.S. and M.S. in Metallurgical Engineering and a Ph.D. in Physical Metallurgy from the Polytechnic Institute of Brooklyn.

Philip M. Young was appointed to our board of directors in April 1999. Since 1990, Mr. Young has been an employee, general partner or managing member of various entities generally known as U.S. Venture Partners, a venture capital firm. Mr. Young was a Managing Director of Dillon Read & Co., a financial services company, and Concord Partners, a venture capital firm managed by Dillon Read, from 1986 to 1990. From August 1977 to June 1985, Mr. Young was President and Chief Executive Officer of Oximetrix, Inc., a medical instruments and sterile disposable products manufacturer. Mr. Young serves as a director of Zoran Corporation, a publicly-held imaging solutions company. Mr. Young holds a B.M.E. from Cornell University, an M.S. from George Washington University and an M.B.A. from Harvard University.

Voting Agreement

All of our current directors serve as members of our board pursuant to a voting rights agreement among us, various founding stockholders, the holders of our Series A preferred stock, the holders of our Series B preferred stock and the holders of our Series C preferred stock. This agreement will terminate upon the closing of this offering.

Executive Officers

Our executive officers are elected by, and serve at the discretion of, our board of directors. There are no family relationships between our directors and executive officers.

Board of Directors

Upon the closing of this offering, our authorized number of directors will be eight. Upon the closing of this offering, our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes, each with staggered three-year terms. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Dr. Weinstein and Messrs. Sutter and Young have been designated as Class I directors, whose terms will expire at the 2007 annual meeting of stockholders. Drs. Jaffe and Kaganov and Mr. Clapper have been designated as Class II directors, whose terms will expire at the 2008 annual meeting of stockholders. Mr. Sidow and Mr. Cutts have been designated as Class III directors, whose terms will expire at the 2009 annual meeting of stockholders. This classification of the board of directors may delay or prevent a change in control of our company or our management. For more information about some of the possible effects of this classification, please see "Description of Capital Stock−Anti-Takeover Effects of Provisions of the Amended and Restated Certificate of Incorporation and Bylaws."

Board Committees

Our board of directors has an audit committee, a compensation committee and a nominating and governance committee.

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Audit Committee

The audit committee of our board of directors appoints our independent registered public accounting firm, reviews our internal accounting procedures and financial statements and consults with and reviews the services provided by our independent registered public accounting firm, including the results and scope of their audit. The audit committee is chaired by Mr. Cutts and also includes Mr. Young and Dr. Weinstein, each of whom will be independent, within the meaning of applicable NASDAQ rules, and, other than Mr. Young, within the meaning of applicable SEC rules upon completion of this offering. Mr. Cutts is our audit committee financial expert, as currently defined under the SEC rules implementing SOX. We believe that the composition and functioning of our audit committee complies with all applicable requirements of SOX, The NASDAQ Global Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

The compensation committee of our board of directors reviews and recommends to our board of directors the compensation and benefits for all of our executive officers, administers our stock plans, and establishes and reviews general policies relating to compensation and benefits for our employees. The compensation committee consists of Drs. Jaffe and Kaganov and Mr. Clapper, each of whom will be independent, within the meaning of applicable NASDAQ rules, upon completion of this offering. We believe that the composition and functioning of our compensation committee complies with all applicable requirements of SOX, The NASDAQ Global Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and Governance Committee

The nominating and governance committee of our board of directors is responsible for:

- reviewing the appropriate size, function and needs of the board of directors;
- developing the policy of the board of directors regarding tenure and retirement of directors;
- establishing criteria for evaluating and selecting new members of the board of directors, subject to board approval thereof;
- identifying and recommending to the board of directors of individuals qualified to become members of the board of directors, consistent with criteria established by the committee and by the board of directors;
- overseeing the evaluation of management and the board of directors; and
- monitoring and making recommendations to the board of directors on matters relating to corporate governance.

The nominating and governance committee consists of Mr. Young and Dr. Jaffe, each of whom will be independent, within the meaning of applicable NASDAQ rules, upon completion of this offering. We believe that the composition and functioning of our nominating and governance committee complies with all applicable requirements of SOX, The NASDAQ Global Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time been one of our executive officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

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Director Compensation

Each of our non-employee directors is paid $20,000 annually and is reimbursed for reasonable expenses incurred in connection with the performance of their duties as directors. Upon their election to our board of directors, each of our non-employee directors is granted an initial option to purchase up to 30,000 shares of our common stock at the then fair market value pursuant to the terms of our 2006 Stock Plan. In addition, each non-employee director is automatically granted an option to purchase up to 7,500 shares of our common stock if he or she remains on the board of directors on the date of each annual meeting of stockholders unless he or she joined our board of directors within twelve months of such meeting. Each non-employee director will also receive cash compensation of $1,500 for in-person attendance at a board meeting and $500 for telephonic attendance at a board meeting. Additionally, the chairperson of the audit committee and the chairperson of the compensation committee will receive an additional annual retainer fee of $10,000, the chairperson of the nominating and governance committee will receive an annual retainer fee of $5,000 and the remaining members of each of our standing committees will receive additional annual retainers of $2,500.

Executive Compensation

The following table sets forth summary information concerning compensation of our chief executive officer and each of our other four most highly compensated executive officers as of the end of the last fiscal year. We refer to these persons as our named executive officers elsewhere in this prospectus. Except as provided below, none of our named executive officers received any other compensation required to be disclosed by law or in excess of 10% of their total annual compensation.

Summary Compensation Table

		Annual Compensation		Long Term Compensation Awards	
Name and Position	Year	Salary	Bonus	Number of Securities Underlying Options	All Other Compensation
Kevin K. Sidow President and Chief Executive Officer	2005	$ 275,000	$ 100,000	–	$ 131,184(1)
Michael A. Bates(2) Chief Financial Officer and Secretary	2005	187,949	35,000	230,000	–
Christopher T. Fair(3) Vice President, Sales	2005	141,211	–	230,000	–
T. Yvonne Lysakowski Vice President, Regulatory, Clinical Affairs and Quality Assurance	2005	189,000	20,000	45,000	–
Scott A. Yerby(4) Vice President, Research and Development	2005	118,877	–	–	–

(1) Includes forgiveness of $60,000 of principal under a relocation loan and forgiveness of interest of $6,000; cost of living adjustment of $52,448; and $12,736 differential between the interest rate on Mr. Sidow' s February 2005 loan and prevailing market rates.

(2) Mr. Bates' employment with us began in January 2005.

(3) Mr. Fair left the company in June 2005 and rejoined us in October 2005.

(4) Dr. Yerby left the company in September 2005 and rejoined us in January 2006.

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Option Grants in Last Fiscal Year

In 2005, we granted options to purchase an aggregate of 923,500 shares of our common stock to our employees, directors and consultants, all of which were granted under our Stock Incentive Plan. These options are fully exercisable upon the date of grant. Except as otherwise noted, one quarter of the shares subject to each option vests at the end of the first year after the vesting commencement date, and the remaining shares subject to each option vest ratably on a daily basis over a three-year period thereafter. Options granted under our Stock Incentive Plan have a term of 10 years. All options may terminate before their expiration dates if the optionee' s status as an employee, director or consultant is terminated, or upon the optionee' s death or disability. For additional information on our employee benefit plans see "–Employee Benefit Plans."

The following table sets forth certain information with respect to stock options granted to each of our named executive officers during 2005.

2005 Option Grants

Name	Number of Securities Underlying Options Granted	Percent of Total Options Granted to Employees	Exercise Price Per Share	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term	
					5%	10%
Kevin K. Sidow	–	–	–	–	$ –	$ –
Michael A. Bates	225,000	24.4 %	$0.65	1/23/15		
	5,000 (1)	0.5	0.65	10/04/15		
Christopher T. Fair	100,000	10.8	0.65	9/15/15		
	90,000 (2)	9.7	0.65	10/04/15		
	40,000 (3)	4.3	0.65	10/04/15		
T. Yvonne Lysakowski	45,000	4.9	0.65	10/05/15		
Scott A. Yerby	–	–	–	–	–	–

(1) Shares vest as to 1/1,460 of the total number of shares subject to the option each day starting from the vesting commencement date.

(2) Shares vest subject to meeting certain performance based milestones starting from the vesting commencement date.

(3) Shares vest as to 1/1,460 of the total number of shares subject to the option each day starting from the vesting commencement date.

With respect to the amounts disclosed in the column captioned "Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term," the 5% and 10% assumed annual rates of compounded stock price appreciation are mandated by rules of the SEC, and do not represent our estimate or projection of our future common stock prices. The potential realizable values are calculated based on an assumed initial public offering price of $ per share, and assume that the common stock appreciates at the indicated rate for the entire term of the option, and that the option is exercised at the exercise price and sold on the last day of the option term at the appreciated price. Actual gains, if any, on stock option exercises are dependent on the future performance of our common stock and overall stock market conditions. The amounts reflected in the table may not necessarily be realized.

Aggregated Option Exercises in 2005 and Year-End Option Values

The following table sets forth certain information concerning the number and value of unexercised options held by each of our named executive officers as of December 31, 2005. The amount described in the column captioned "Value of Unexercised In-The-Money Options at December 31, 2005" represents the positive spread between the exercise price of stock options and the fair market value of the options, which is based upon the assumed initial public offering price of $ per share, minus

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the exercise price per share. As of September 30, 2006, the option grants in the table below may be exercised in full subject to our right to repurchase some or all unexercisable shares at the original exercise price if their employment relationship terminates for any reason.

2005 Aggregated Option Exercises and Year-End Values

Name	Number of Shares Acquired on Exercise		Value Received(1)	Number of Securities Underlying Unexercised Options at December 31, 2005		Value of Unexercised In-The-Money Options at December 31, 2005(1)	
				Exercisable	Unexercisable	Exercisable	Unexercisable
Kevin K. Sidow	–		–	–	–	$ –	$ –
Michael A. Bates	230,000	(2)	$	–	–	–	–
Christopher T. Fair	–		–	230,000			
T. Yvonne Lysakowski	150,000	(3)		45,000			
Scott A. Yerby	55,579			–	–	–	–

(1) Based on the assumed public offering price of $ per share, minus the exercise price, multiplied by the number of shares issued or issuable upon the exercise of the options.

(2) As of September 30, 2006, 135,000 shares remain subject to our repurchase right upon the termination of Mr. Bates' employment.

(3) As of September 30, 2006, 40,650 shares remain subject to our repurchase right upon the termination of Ms. Lysakowski' s employment.

Employee Benefit Plans

Amended and Restated 1999 Stock Option Plan

Our Amended and Restated 1999 Stock Option Plan was adopted by our board of directors in January 1999 and approved by our stockholders in February 1999. The plan was amended and restated in April 1999, and our stockholders approved the amendment and restatement in May 1999. Our Amended and Restated 1999 Stock Option Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, to our employees and any parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options to our employees, directors and consultants and any parent and subsidiary corporations' employees and consultants. We will not grant any additional awards under our Amended and Restated 1999 Stock Option Plan. However, our Amended and Restated 1999 Stock Option Plan will continue to govern the terms and conditions of outstanding awards granted thereunder.

We have reserved a total of 4,585,000 shares of our common stock for issuance pursuant to the Amended and Restated 1999 Stock Option Plan. As of September 30, 2006, there were no options to purchase shares of common stock outstanding and no shares were available for future grant under this plan.

Our board of directors or a committee appointed by our board of directors administers our Amended and Restated 1999 Stock Option Plan. Under our Amended and Restated 1999 Stock Option Plan, the administrator has the power to determine the terms of the awards, including the type of option, the number of shares subject to each such award, and the time or times at which awards will be granted.

With respect to all incentive stock options, the exercise price must at least be equal to the fair market value of our common stock on the date of grant. With respect to all nonstatutory stock options, the exercise price must at least be equal to 85% of the fair market value of our common stock on the date of grant; provided, however, that after this offering, nonstatutory stock options must have an exercise price equal to 100% of the fair market value on the date of grant. The term of an option may not exceed ten years, except that with respect to any participant who owns 10% of the voting power of all classes of our outstanding stock as of the grant date, the term must not exceed five years and the

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exercise price must equal at least 110% of the fair market value on the grant date. The administrator determines the term of all other options.

After termination of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in the option agreement. Generally, if termination is due to disability, or in the event of death within thirty days after termination, the option will remain exercisable for six months. In all other cases, the option will generally remain exercisable for thirty days. However, an option generally may not be exercised later than the expiration of its term.

Our Amended and Restated 1999 Stock Option Plan does not allow for the transfer of awards other than by will or the laws of descent and distribution and only the recipient of an award may exercise an award during his or her lifetime.

Our Amended and Restated 1999 Stock Option Plan provides that the administrator may determine, at the time of granting an award or thereafter, that awards will become fully vested in the event of our change in control. If the administrator finds that there is a reasonable possibility that, within the succeeding six months, a change in control will occur with respect to shares of our common stock, then the administrator may determine that all awards will be fully vested on an accelerated basis.

Our Amended and Restated 1999 Stock Option Plan will automatically terminate in January 2009, unless we terminate it sooner. In addition, our board of directors has the authority to amend or terminate the Amended and Restated 1999 Stock Option Plan provided such action does not impair the rights of any participant. Certain amendments require shareholder approval.

Stock Incentive Plan

Our board of directors adopted our Stock Incentive Plan in July 1999, and our stockholders approved it in November 1999. In April 2003, our board of directors amended and restated our Stock Incentive Plan, and our stockholders approved the amendment and restatement in April 2003. Our Stock Incentive Plan provides for the grant of nonstatutory stock options and restricted shares to our employees, consultants and directors and our parent' s or subsidiaries' employees, consultants and directors. Incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, may also be granted to our employees and our parent' s or subsidiaries' employees. We will not grant any additional awards under our Stock Incentive Plan following this offering. Instead we will grant awards under our 2006 Stock Plan. However, our Stock Incentive Plan will continue to govern the terms and conditions of outstanding awards granted thereunder.

The aggregate number of shares which may be issued or transferred pursuant to an award under our Stock Incentive Plan cannot exceed 2,335,000 shares of our common stock. The number of shares available under our Stock Incentive Plan is increased by shares subject to unexercised or expired options or forfeited shares under our Amended and Restated 1999 Stock Option Plan; provided, however, that the total number of shares available under our Stock Incentive Plan cannot exceed 2,335,000. As of September 30, 2006, options to purchase 1,251,200 shares of our common stock were outstanding and 453,712 shares were available for future grant under this plan.

Our board of directors or one or more committees appointed by our board of directors administers our Stock Incentive Plan. The administrator has the authority to determine the terms and conditions of awards granted under our Stock Incentive Plan, including the service providers who will receive awards, the time or times awards will be made, and the number of shares subject to each award.

With respect to all incentive stock options, the exercise price must at least be equal to the fair market value of our common stock on the date of grant. With respect to all nonstatutory stock options, the exercise price must at least be equal to 85% of the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years, except that with respect to any participant who owns 10% of the voting power of all classes of our outstanding stock as of the grant date, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator determines the term of all other options.

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Our Stock Incentive Plan provides that in the event we are party to a merger or reorganization, outstanding options will be subject to the agreement of merger or reorganization, which may, without the optionee' s consent, provide for the assumption or substitution of outstanding options by the surviving corporation or its parent, the payment of a cash settlement for exercisable options equal to the difference between the amount to be paid for one share under such agreement and the exercise price for one share under the option, and for the cancellation of options not exercised or settled.

After termination of an employee, director or consultant, he or she may exercise his or her option for the period of time specified in his or her stock option agreement. To the extent required by applicable law, the option agreement will provide that the optionee may exercise the vested portion of his or her option for thirty days following termination for any reason, or for at least six months if the termination is due to death or disability.

Our Stock Incentive Plan will automatically terminate in July 2009, unless we terminate it sooner. In addition, our board of directors has the authority to amend or terminate our Stock Incentive Plan provided such action does not impair the rights of any participant.

2006 Stock Plan

Our board of directors adopted the 2006 Stock Plan, effective as of the completion of this offering, in September 2006 and our stockholders approved our 2006 Stock Plan in October 2006. Our 2006 Stock Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and any parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants.

We have reserved a total of 1,500,000 shares of our common stock for issuance under the 2006 Stock Plan, plus (a) any shares which have been reserved but not issued under our Stock Incentive Plan as of the effective date of this offering and (b) any shares returned to our Stock Incentive Plan on or after the effective date of this offering as a result of termination of options or the repurchase of shares issued under the Stock Incentive Plan. The maximum number of shares that may be added to the 2006 Stock Plan from the Stock Incentive Plan is 460,000 shares. In addition, our 2006 Stock Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year, beginning with our 2008 fiscal year, equal to the least of:

5% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year;

2,500,000 shares; or

such other lesser amount as our board of directors may determine.

Our board of directors or a committee of our board administers our 2006 Stock Plan. Our compensation committee will be responsible for administering all of our equity compensation plans. In the case of options intended to qualify as "performance based compensation" within the meaning of Section 162(m) of the Internal Revenue Code of 1986, the committee will consist of two or more "outside directors" within the meaning of Section 162(m) of the Internal Revenue Code of 1986, as amended. The administrator has the power to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards and the form of consideration payable upon exercise. The administrator also has the authority to institute an exchange program whereby the exercise prices of outstanding awards may be reduced, outstanding awards may be surrendered in exchange for awards with a lower exercise price or outstanding awards may be transferred to a third party.

The exercise price of options granted under our 2006 Stock Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed ten years, except that with respect to any participant who owns 10% of the voting power of all

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classes of our outstanding stock as of the grant date, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator determines the term of all other options.

After termination of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in the option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for three months. However, an option generally may not be exercised later than the expiration of its term.

Stock appreciation rights may be granted under our 2006 Stock Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. The administrator determines the terms of stock appreciation rights, including when such rights become exercisable and whether to pay the increased appreciation in cash or with shares of our common stock, or a combination thereof. Stock appreciation rights expire under the same rules that apply to stock options.

Restricted stock may be granted under our 2006 Stock Plan. Restricted stock awards are shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee. The administrator may impose whatever conditions to vesting it determines to be appropriate. For example, the administrator may set restrictions based on the achievement of specific performance goals. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted stock units may be granted under our 2006 Stock Plan. Restricted stock units are awards of restricted stock, performance shares or performance units that are paid out in installments or on a deferred basis. The administrator determines the terms and conditions of restricted stock units including the vesting criteria and the form and timing of payment.

Performance units and performance shares may be granted under our 2006 Stock Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants. Performance units shall have an initial dollar value established by the administrator prior to the grant date. Performance shares shall have an initial value equal to the fair market value of our common stock on the grant date. Payment for performance units and performance shares may be made in cash or in shares of our common stock with equivalent value, or in some combination, as determined by the administrator.

Our 2006 Stock Plan also provides for the automatic grant of non-statutory options to our non-employee directors. Each non-employee director appointed to the board of directors after the completion of this offering will receive an initial option to purchase 30,000 shares upon such appointment except for those directors who become non-employee directors by ceasing to be employee directors. This option will vest ratably each month, so that the option will be fully vested and exercisable on the third anniversary of its grant date, subject to the director' s continued service on each relevant vesting date. In addition, beginning in 2007, non-employee directors who have been directors for at least twelve months will receive a subsequent option to purchase 7,500 shares immediately following each annual meeting of our stockholders. This option will vest ratably each month, so that the option will be fully vested on the first anniversary of its grant date, subject to the director' s continued service on such date. All options granted under the automatic grant provisions have a term of ten years and an exercise price equal to the fair market value on the date of grant.

Unless the administrator provides otherwise, our 2006 Stock Plan does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

Our 2006 Stock Plan provides that in the event of our change in control, as defined in the 2006 Stock Plan, each outstanding award will be treated as the administrator determines, including that the

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successor corporation or its parent or subsidiary will assume or substitute an equivalent award for each outstanding award. The administrator is not required to treat all awards similarly. If there is no assumption or substitution of outstanding awards, the awards will fully vest, all restrictions will lapse and the awards will become fully exercisable. The administrator will provide notice to the recipient that he or she has the right to exercise the option and stock appreciation right as to all of the shares subject to the award, all restrictions on restricted stock will lapse and all performance goals or other vesting requirements for performance shares and units will be deemed achieved at 100% of target levels, and all other terms and conditions met. The option or stock appreciation right will terminate upon the expiration of the period of time the administrator provides in the notice. In the event the service of an outside director is terminated on or following a change in control, other than pursuant to a voluntary resignation, his or her options and stock appreciation rights will fully vest and become immediately exercisable, all restrictions on restricted stock will lapse and all performance goals or other vesting requirements for performance shares and units will be deemed achieved at 100% of target levels, and all other terms and conditions met.

Our 2006 Stock Plan will automatically terminate in 2016, unless we terminate it sooner. In addition, our board of directors has the authority to amend, suspend or terminate the 2006 Stock Plan provided such action does not impair the rights of any participant.

2006 Employee Stock Purchase Plan

Concurrently with the completion of this offering, we intend to establish our 2006 Employee Stock Purchase Plan. Our board of directors adopted the 2006 Employee Stock Purchase Plan, effective as of the completion of this offering, in September 2006 and our stockholders approved our 2006 Employee Stock Purchase Plan in October 2006.

A total of 300,000 shares of our common stock will be made available for sale under our 2006 Employee Stock Purchase Plan. In addition, our 2006 Employee Stock Purchase Plan provides for annual increases in the number of shares available for issuance under the plan on the first day of each fiscal year, beginning with our 2008 fiscal year, equal to the least of:

1.5% of the outstanding shares of our common stock on the first day of the fiscal year;

1,000,000 shares; or

such other amount as may be determined by our board of directors.

Our board of directors or a committee of our board administers the 2006 Employee Stock Purchase Plan. Our compensation committee will be responsible for administering all of our equity compensation plans.

All of our employees are eligible to participate if they are customarily employed by us or any participating subsidiary for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted rights to purchase stock if:

such employee immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or

such employee' s rights to purchase stock under all of our employee stock purchase plans would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year in which such rights are outstanding.

Our 2006 Employee Stock Purchase Plan is intended to qualify under Section 423 of the Internal Revenue Code, and provides for consecutive, non-overlapping six-month offering periods. The offering periods generally start on the first trading day on or after May 15 and November 15 of each year, except for the first such offering period which will commence on the first trading day on or after the effective date of this offering and will end on the first trading day on or after the earlier of May 15, 2007 or 27 months from the beginning of the offering period.

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Our 2006 Employee Stock Purchase Plan permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation which includes a participant' s straight time gross earnings, commissions, overtime and shift premium, exclusive of payments for incentive compensation, bonuses and other compensation. A participant may purchase a maximum of 2,000 shares of common stock during a six-month offering period.

Amounts deducted and accumulated by the participant are used to purchase shares of our common stock at the end of each six-month offering period. The purchase price is 85% of the fair market value of our common stock at the exercise date. Participants may end their participation at any time during an offering period, and will be paid their payroll deductions to date. Participation ends automatically upon termination of employment with us.

A participant may not transfer rights granted under the 2006 Employee Stock Purchase Plan other than by will, the laws of descent and distribution or as otherwise provided under the 2006 Employee Stock Purchase Plan.

In the event of our merger or change in control, as defined under the 2006 Employee Stock Purchase Plan, a successor corporation may assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase rights, the offering period then in progress will be shortened, and a new exercise date will be set.

Our 2006 Employee Stock Purchase Plan will automatically terminate in 2026, unless we terminate it sooner. In addition, our board of directors has the authority to amend, suspend or terminate our 2006 Employee Stock Purchase Plan, except that, subject to certain exceptions described in the 2006 Employee Stock Purchase Plan, no such action may adversely affect any outstanding rights to purchase stock under our 2006 Employee Stock Purchase Plan.

401(k) Plan

We maintain a retirement savings plan, or 401(k) Plan, for the benefit of our eligible employees. Our 401(k) Plan is intended to qualify as a defined contribution arrangement under Sections 401(a), 401(k) and 501(a) of the Internal Revenue Code. In general, contributions to the 401(k) Plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) Plan, and all contributions are deductible by us when made. Employees eligible to participate in our 401(k) Plan are those common law employees on our payroll who have attained the age of 21. Participants may elect to defer a percentage of their eligible pretax earnings each year or contribute a fixed amount per pay period up to the maximum contribution permitted by the Internal Revenue Code. All participants' plan accounts are 100% vested at all times. All assets of our 401(k) Plan are currently invested, subject to participant-directed elections, in a variety of mutual funds chosen from time to time by the plan administrator. Distribution of a participant' s vested interest generally occurs upon termination of employment, including by reason of retirement, death or disability. We may make matching contributions at our discretion for 100% of an employee' s contributions to the 401(k) Plan, up to a maximum amount equal to 4% of such employee' s base salary.

Change in Control Arrangements

Employment at our company is at will. Pursuant to our employment offer letter to Kevin K. Sidow, if we undergo a change of control, 33% of the then unvested shares held by Mr. Sidow will immediately vest, and if Mr. Sidow is terminated without cause, or resigns for good reason, within 12 months following such change of control, 100% of the then unvested shares held by Mr. Sidow will immediately vest. Any shares remaining unvested after a change of control will vest in notable monthly amounts over the 12 month period following such change of control.

Limitations on Liability and Indemnification

Our amended and restated certificate of incorporation and bylaws provide that we will indemnify our directors and executive officers, and may indemnify our other officers, employees and agents, to the

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fullest extent permitted by the General Corporation Law of the State of Delaware. Under our bylaws, we are also empowered to enter into indemnification agreements with our directors and officers and to purchase insurance on behalf of any person whom we are required or permitted to indemnify. We have procured and intend to maintain a directors' and officers' liability insurance policy that insures such persons against the costs of defense, settlement or payment of a judgment under certain circumstances.

We have entered into indemnification agreements with each of our directors, president and chief executive officer and chief financial officer. Under these agreements, we are required to indemnify them against all expenses, judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any actual or threatened litigation or proceeding, if any of them may be made a party to such proceeding because he or she is or was one of our directors or officers. We are obligated to pay these amounts only if the officer or director acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, our best interests. With respect to any criminal proceeding, we are obligated to pay these amounts only if the officer or director had no reasonable cause to believe that his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification thereunder.

In addition, our amended and restated certificate of incorporation provides that the liability of our directors for monetary damages shall be eliminated to the fullest extent permissible under the General Corporation Law of the State of Delaware. This provision in our amended and restated certificate of incorporation does not eliminate a director' s duty of care and, in appropriate circumstances, equitable remedies such as an injunction or other forms of non-monetary relief would remain available. Each director will continue to be subject to liability for any breach of the director' s duty of loyalty to us and for acts or omissions not in good faith or involving intentional misconduct or knowing violations of law. This provision also does not affect a director' s responsibilities under any other laws, such as the federal securities laws or other state or federal laws.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

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RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions that have occurred this year or during our last three fiscal years to which we were a party or will be a party in which:

- the amounts involved exceeded or will exceed $60,000; and
- a director, executive officer, holder of more than 5% of our common stock or any member of their immediate family had or will have a direct or indirect material interest.

We believe that the transactions described below have been negotiated as arms-length transactions.

Sales of Preferred Stock

In 2003, we issued an aggregate of 6,364,977 shares of our Series C preferred stock at a price of $2.37 per share for net proceeds of approximately $14,984,000. Each share of Series C preferred stock will automatically convert into one share of common stock immediately prior to the closing of this offering. The purchasers of our Series C preferred stock included, among others, the following member of our board of directors and holders of more than 5% of our outstanding Series C preferred stock:

Investor	Shares of Series C Preferred Stock	Aggregate Consideration
Holders of More than 5%		
Funds affiliated with U.S. Venture Partners(1)	1,898,735	$4,500,002
Funds affiliated with Versant Ventures(2)	1,476,793	3,499,999
Essex Woodlands Health Ventures Fund V, L.P.(3)	2,742,616	6,500,000
Henry Klyce	31,645	74,999
Director		
Alan L. Kaganov(4)	31,645	74,999

(1) Represents: 1,737,342 shares held by U.S. Venture Partners VI, L.P., 51,266 shares held by USVP Entrepreneur Partners VI, L.P., 79,747 shares held by USVP VI Affiliates Fund, L.P. and 30,380 shares held by 2180 Associates Fund VI, L.P. Since February 1996, Dr. Kaganov has been an employee, venture partner, partner, assignee or member of various entities generally known as U.S. Venture Partners, or USVP, a venture capital firm, including Presidio Management Group, VI, LLC, the general partner of the USVP VI entities that are stockholders of ours. Dr. Kaganov does not have any voting or investment power over the securities held by these entities and disclaims ownership of the securities held by USVP entities, except as to his pecuniary interest therein. Mr. Young is a managing member of Presidio Management Group VI, LLC, the general partner of the USVP VI entities that are stockholders of ours. Mr. Young disclaims ownership of the securities held by USVP entities, except as to the extent of his proportionate partnership interest therein.

(2) Represents: 1,358,650 shares held by Versant Venture Capital I, L.P., 26,582 shares held by Versant Side Fund I, L.P., 29,536 shares held by Versant Affiliates Fund I-A, L.P. and 62,025 shares held by Versant Affiliates I-B, L.P. Ross A. Jaffe is a managing director of Versant Ventures, the general partner of each of the above-listed entities. Dr. Jaffe disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(3) Martin P. Sutter is a managing partner of Essex Woodlands Health Ventures V, L.L.C., the general partner of Essex Woodlands Health Ventures Fund V, L.P., which holds these shares under Essex Woodlands Health Ventures Fund V, L.P. Mr. Sutter disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(4) These shares are held by Alan L. Kaganov and Carol M. Kaganov, Trustees of the Kaganov Family Revocable Trust of 10/16/02.

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Sales of Common Stock

Since January 1, 2003, we issued an aggregate of 1,825,579 shares of common stock to the following named executive officers or directors:

Investor	Shares of Common Stock	Aggregate Consideration
Named Executive Officers and Directors		
Kevin K. Sidow(1)	1,275,000	$828,750
Michael A. Bates(2)	230,000	149,500
T. Yvonne Lysakowski(3)	150,000	82,500
Scott A. Yerby(4)	115,579	22,426
Allan M. Weinstein(5)	55,000	24,250

(1) As of September 30, 2006, 531,248 shares remain subject to our repurchase right upon the termination of Mr. Sidow' s employment. Mr. Sidow purchased his shares of common stock in March 2005 at $0.65 per share.

(2) As of September 30, 2006, 135,000 shares remain subject to our repurchase right upon the termination of Mr. Bates' employment. Mr. Bates purchased his shares of common stock in October 2005 at $0.65 per share.

(3) As of September 30, 2006, 40,650 shares remain subject to our repurchase right upon the termination of Ms. Lysakowski' s employment. Ms. Lysakowski purchased her shares of common stock in October 2005 at $0.55 per share.

(4) Dr. Yerby purchased 60,000 of his shares of common stock in March 2004 at $0.12 per share, 30,000 of his shares of common stock in March 2005 at $0.12 per share, 17,900 of his shares of common stock in March 2005 at $0.40 per share, 2,100 of his shares of common stock in September 2005 at $0.40 per share and 5,579 of his shares of common stock in September 2005, at $0.65 per share.

(5) As of September 30, 2006, 18,333 shares remain subject to our repurchase right upon the termination of Dr. Weinstein' s membership on our board of directors. Dr. Weinstein purchased 40,000 of his shares of common stock in April 2003 at $0.40 per share and 15,000 of his shares of common stock in March 2004 at $0.55 per share.

Loans to Management

On March 22, 2005, we provided Kevin K. Sidow with a full recourse loan, secured by shares of our common stock purchased by Mr. Sidow in connection with the loan, per a promissory note dated March 22, 2005, in the amount of $827,475 and an interest rate of 3.76% per annum. Accrued interest and the original principal balance is due and payable on March 22, 2009. On September 20, 2006, Mr. Sidow paid the balance of this loan in full.

On May 13, 2004, we provided Mr. Sidow with a loan for relocation expenses, per a promissory note dated July 29, 2004, in the amount of $120,000 and an interest rate of 5% per annum. The terms of the promissory note provided that 50% of the principal and all accrued interest of the loan would be forgiven if Mr. Sidow remained an employee as of June 30, 2005, and that all of the principal and interest would be forgiven if he remained an employee as of June 30, 2006. As of June 30, 2006, all principal and interest of this loan was forgiven.

SVB Loan and Security Agreement

On April 24, 2006, we entered into a Loan and Security Agreement with Silicon Valley Bank, a part of the SVB Financial Group, pursuant to which we have a revolving line of credit for up to $2,000,000 based on our accounts receivable, inventory, outstanding letters of credit and outstanding advances. David Clapper, a member of our board of directors, is a member of the board of directors of the SVB Financial Group.

Registration Rights

We have entered into an agreement with holders of our preferred stock, including entities affiliated with some of our directors and entities that hold more than 5% of our outstanding common and preferred stock whereby we granted them registration rights with respect to their shares of common

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stock issuable upon conversion of their preferred stock. For more information regarding registration rights, see "Description of Capital Stock−Registration Rights."

Director and Officer Indemnification

We have entered into an indemnification agreement with each of our directors and executive officers. These indemnification agreements and our amended and restated certificate of incorporation and bylaws indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. For information regarding these indemnification arrangements, please refer to the section entitled "Management−Limitations on Liability and Indemnification."

Stock Option Grants

Since January 1, 2003 we have granted options to purchase an aggregate of 2,385,000 shares of our Common Stock to our current executive officers, including certain of our executive officers named in the Summary Compensation Table in the Management Section, at a weighted-average exercise price of $0.66 per share.

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PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth certain information with respect to beneficial ownership of our common stock, as of September 30, 2006, by:

- each beneficial owner of 5% or more of the outstanding shares of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of September 30, 2006 are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person' s name. Except as otherwise indicated, the address of each of the persons in this table is c/o St. Francis Medical Technologies, Inc., 1201 Marina Village Parkway, Suite 200, Alameda, CA 94501.

Each stockholder' s percentage ownership before the offering is based on 23,382,608 shares of our common stock outstanding as of September 30, 2006 (as adjusted to reflect at that date the conversion of all shares of our preferred stock outstanding into 14,492,520 shares of common stock). Each stockholder' s percentage ownership after the offering is based on shares of our common stock outstanding immediately after the completion of this offering. We have granted the underwriters an option to purchase up to additional shares of our common stock to cover over-allotments, if any, and the table below assumes no exercise of that option.

	Before the Offering			After the Offering	
Beneficial Owner	Shares	Percentage of Shares Outstanding	Shares Being Offered	Shares	Percentage of Shares Outstanding
Holders of More than 5%					
Entities affiliated with U.S. Venture Partners(1) 2735 Sand Hill Road Menlo Park, CA 94025	6,253,415	26.7%	–	6,253,415	%
Entities affiliated with Versant Venture Capital Fund (2) 3000 Sand Hill Road, Bldg. 4, Suite 210 Menlo Park, CA 94025	4,762,507	20.4%	–	4,762,507	
Entities affiliated with Essex Woodlands Health Ventures(3) 435 Tasso Street, Suite 305 Palo Alto, CA 94301	2,742,616	11.7%	–	2,742,616	
Henry Klyce(4) 231 Sandringham Road Piedmont, CA 94611	2,241,645	9.6 %	50,000 (5)	2,191,645	
Additional Selling Stockholder					
Charles J. Winslow, Jr.(6) 25 Hilton Ct. Walnut Creek, CA 94595	754,887	3.2 %	15,000 (5)	739,887	

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Beneficial Owner	Before the Offering: Shares	Before the Offering: Percentage of Shares Outstanding	Shares Being Offered	After the Offering: Shares	After the Offering: Percentage of Shares Outstanding
Named Executive Officers and Directors					
Kevin K. Sidow(7)	1,275,000	5.5 %	–	1,275,000	%
Michael A. Bates(8)	230,000	*	–	230,000	
Christopher T. Fair (9)	230,000	*	–	230,000	
T. Yvonne Lysakowski(10)	195,000	*	–	195,000	
Scott A. Yerby(11)	245,579	*	–	245,579	
David M. Clapper(12)	40,000	*	–	40,000	
Joseph R. Cutts (13)	40,000	*	–	40,000	
Ross A. Jaffe(14)	4,762,507	20.4	–	4,762,507	
Alan L. Kaganov (15)	6,489,839	27.8	–	6,489,839	
Martin P. Sutter(16)	2,742,616	11.7	–	2,742,616	
Allan M. Weinstein (17)	165,000	*	–	165,000	
Philip M. Young(18)	6,253,415	26.7	–	6,253,415	
All executive officers and directors as a group (13 persons)	16,515,541	70.6	–	16,515,541	

* Indicates ownership of less than 1%.

(1) Represents: (a) 5,787,194 shares held by U.S. Venture Partners VI, L.P., (b) 192,969 shares held by USVP VI Affiliates Fund, L.P., (c) 177,552 shares held by USVP Entrepreneur Partners VI, L.P. and (d) 95,700 shares held by 2180 Associates Fund VI, L.P. Presidio Management Group VI, L.L.C. is the general partner of each of U.S. Venture Partners VI, L.P., USVP VI Affiliates Fund, L.P., USVP Entrepreneur Partners VI, L.P. and 2180 Associates Fund VI, L.P. Presidio Management Group VI, L.L.C. and its managing members may be deemed to share voting and disposition control over the shares that the previously listed funds hold, and each managing member of Presidio Management Group VI, L.L.C. disclaims beneficial ownership of such shares, except as to their pecuniary interest therein. The managing members of Presidio Management Group VI, L.L.C. are Irwin Federman, Steven Krausz, Stuart Phillips, Jonathan Root and Philip Young.

(2) Represents: (a) 4,381,507 shares held by Versant Venture Capital I, L.P., (b) 200,025 shares held by Versant Affiliates Fund I-B, L.P., (c) 95,250 shares held by Versant Affiliates Fund I-A, L.P. and (d) 85,725 shares held by Versant Side Fund I, L.P. The people who have investment control of the Versant Venture Capital I, L.P., Versant Affiliates Fund I-B, L.P., Versant Affiliates Fund I-A, L.P. and Versant Side Fund I, L.P. shares are Brian G. Atwood, Samuel D. Colella, Ross A. Jaffe, William J. Link, Barbara N. Lubash, Donald B Milder and Rebecca B. Robertson, each of whom disclaims beneficial ownership except to the extent of their pecuniary interest therein.

(3) Represents 2,742,616 shares held by Essex Woodlands Health Ventures Fund V, L.P. The people who have investment control of the Essex Woodlands Health Ventures Fund V, L.P. shares are James L. Currie, J. Douglas Eplett, Martin P. Sutter and Immanuel Thangaraj, each of whom disclaims beneficial ownership except to the extent of their pecuniary interest therein.

(4) Represents: (a) 1,581,645 shares held by Henry Klyce, (b) 75,000 shares held by the Genevieve Perrow Klyce Irrevocable Trust, (c) 75,000 shares held by the Matthew Arnold Klyce Irrevocable Trust, (d) 425,000 shares held by Henry Adam R. Klyce and Lisa H. Klyce, as Trustees of the Klyce Revocable Trust, (e) 30,000 shares held by the Sybil Pegg Irrevocable Trust and (f) 55,000 shares held by Henry A. Klyce and Caroline P. Klyce, as Trustees of the Klyce Education Trust of 2002. Henry Klyce is a founder of ours, a former member of our board of directors and our former President and Chief Executive Officer.

(5) Up to this number of shares may be sold if the underwriters exercise their over-allotment option.

(6) Mr. Winslow is a founder and former Vice President, Engineering of ours.

(7) As of September 30, 2006, 531,248 shares remain subject to our repurchase right upon the termination of Mr. Sidow' s employment.

(8) As of September 30, 2006, 135,000 shares remain subject to our repurchase right upon the termination of Mr. Bates' employment.

(9) Represents 230,000 shares underlying options held by Mr. Fair that are exercisable within 60 days of September 30, 2006.

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(10) Represents: (a) 150,000 shares held by Ms. Lysakowski and (b) 45,000 shares underlying options held by Ms. Lysakowski that are exercisable within 60 days of September 30, 2006. As of September 30, 2006, 85,650 shares remain subject to our repurchase right upon the termination of Ms. Lysakowski' s employment.

(11) Represents: (a) 115,579 shares held by Dr. Yerby and (b) 130,000 shares underlying options held by Dr. Yerby that are exercisable within 60 days of September 30, 2006.

(12) As of September 30, 2006, 37,500 shares remain subject to our repurchase right upon the termination of Mr. Clapper' s membership on our board of directors.

(13) As of September 30, 2006, 39,583 shares remain subject to our repurchase right upon the termination of Mr. Cutts' membership on our board of directors.

(14) Represents 4,381,507 shares held by Versant Venture Capital Fund I, L.P., 200,025 shares held by Versant Affiliates Fund I-B, L.P., 95,250 shares held by Versant Affiliates Fund I-A, L.P. and 85,725 shares held by Versant Side Fund I-B, L.P. Dr. Jaffe is a managing director of Versant Ventures. Dr. Jaffe disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

(15) Represents: (a) 236,424 shares held by the Kaganov Family Revocable Trust and Dr. Kaganov, (b) 5,815,676 shares held by U.S. Venture Partners VI, L.P., (c) 181,349 shares held by USVP Entrepreneur Partners VI, L.P., (d) 162,589 shares held by USVP VI Affiliates Fund, L.P. and (e) 93,801 shares held by 2180 Associates Fund VI, L.P. Since February 1996, Dr. Kaganov has been an employee, venture partner, partner, assignee or member of various entities generally known as U.S. Venture Partners, or USVP, a venture capital firm, including Presidio Management Group VI, LLC, the general partner of the USVP VI funds that are stockholder of ours. Other than the shares held by him individually and by the Kaganov Family Revocable Trust, Dr. Kaganov does not have any voting or investment power over the securities held by the USVP entities and disclaims ownership of the securities held by these entities, except as to his pecuniary interest therein.

(16) Represents 2,742,616 shares held by Essex Woodlands Health Ventures V, L.P. Mr. Sutter is a general partner of Essex Woodlands Health Ventures. Mr. Sutter disclaims beneficial ownership of these shares, except to the extent of his proportionate partnership interest.

(17) Represents 165,000 shares held by The Weinstein Living Trust. As of September 30, 2006, 5,585 shares remain subject to our repurchase right upon the termination of Dr. Weinstein' s membership on our board of directors.

(18) Represents: (a) 5,815,676 shares held by U.S. Venture Partners VI, L.P., (b) 181,349 shares held by USVP Entrepreneur Partners VI, L.P., (c) 162,589 shares held by USVP VI Affiliates Fund, L.P. and (d) 93,801 shares held by 2180 Associates Fund VI, L.P. Mr. Young is a managing member of Presidio Management Group VI, LLC, the general partner of the aforementioned limited partnerships that are stockholders of ours. Mr. Young does not have any voting or investment power over the securities held by the USVP entities and disclaims ownership of the securities held by these entities, except as to his proportionate partnership interest therein.

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DESCRIPTION OF CAPITAL STOCK

The following information describes our common stock and preferred stock, as well as options to purchase our common stock and provisions of our amended and restated certificate of incorporation and bylaws. This description is only a summary. You should also refer to our amended and restated certificate of incorporation and bylaws, which have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part.

Upon the completion of this offering, we will be authorized to issue up to 85,000,000 shares of capital stock, $0.001 par value, to be divided into two classes designated common stock and preferred stock. Of such authorized shares, 75,000,000 shares will be designated as common stock and 10,000,000 shares will be designated as preferred stock.

Common Stock

As of September 30, 2006, there were 23,382,608 shares of common stock outstanding that were held of record by 65 stockholders. These amounts assume the automatic conversion of all outstanding shares of our preferred stock into 14,492,520 shares of our common stock immediately prior to the closing of this offering. After giving effect to the sale of common stock offered in this offering, there will be shares of common stock outstanding (assuming no exercise of the underwriters' over-allotment option). As of September 30, 2006, there were outstanding options to purchase a total of 1,251,200 shares of our common stock under our Stock Incentive Plan.

The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. Subject to preferences that may be granted to any then outstanding preferred stock, holders of common stock are entitled to receive ratably only those dividends as may be declared by the board of directors out of funds legally available therefore. For more information please see "– Dividend Policy." In the event of our liquidation, dissolution or winding up, holders of common stock are entitled to share ratably in all of our assets remaining after we pay our liabilities and distribute the liquidation preference of any then outstanding preferred stock. Holders of common stock have no preemptive or other subscription or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

Upon the completion of this offering, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in our control or other corporate action. Upon completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Registration Rights

Upon completion of this offering, the holders of approximately 14,492,520 shares of our common stock will be entitled to certain rights with respect to the registration of such shares under the Securities Act. In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, these holders are entitled to notice of such registration and are entitled to include their common stock in such registration, subject to certain marketing and other limitations. Beginning six months after the completion of this offering, the holders

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of at least 50% of these securities have the right to require us, on not more than three occasions, to file a registration statement on Form S-1 under the Securities Act in order to register the resale of shares of our common stock representing at least 20% of the shares registrable under these registration rights. We may, in certain circumstances, defer such registrations and the underwriters have the right, subject to certain limitations, to limit the number of shares included in such registrations. Further, these holders may require us to register the resale of all or a portion of their shares on a Registration Statement on Form S-3, subject to certain conditions and limitations. In addition, these holders have certain "piggyback" registration rights. If we propose to register any of our equity securities under the Securities Act other than pursuant to the registration rights noted above or specified excluded registrations, which include the registration of the shares issued and issuable under our equity incentive plans and this offering, holders may require us to include all or a portion of their registrable securities in the registration and in any related underwritten offering. In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of registrable securities such holders may include. Additionally, piggyback registrations are subject to delay or termination of the registration under certain circumstances. Generally, we are required to bear all registration, selling and related expenses incurred in connection with the demand and piggyback registrations described above. If we are required to file a registration statement, we must use our reasonable best efforts to cause the registration statement to become effective.

Anti-Takeover Effects of Provisions of the Amended and Restated Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation to be effective upon completion of this offering will provide for our board of directors to be divided into three classes, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders representing a majority of the shares of common stock outstanding will be able to elect all of our directors to be elected at each annual meeting of our stockholders. Our amended and restated certificate of incorporation and bylaws to be effective upon completion of this offering will provide that all stockholder action must be effected at a duly called meeting of stockholders and not by a consent in writing, and that only our board of directors, chairman of the board, chief executive officer or president in the absence of a chief executive officer may call a special meeting of stockholders. Our amended and restated certificate of incorporation to be effective on the completion of this offering will require a $66^{2}/_{3}\%$ stockholder vote for the amendment, repeal or modification of certain provisions of our amended and restated certificate of incorporation and bylaws relating to the absence of cumulative voting, the classification of our board of directors, the requirement that stockholder actions be effected at a duly called meeting, and the designated parties entitled to call a special meeting of the stockholders.

The combination of the classification of our board of directors, the lack of cumulative voting and the $66^{2}/_{3}\%$ stockholder voting requirements will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions may have the effect of deterring hostile takeovers or delaying changes in our control or management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and in the policies they implement, and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or

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rumored takeover attempts. Such provisions may also have the effect of preventing changes in our management.

Section 203 of the General Corporation Law of the State of Delaware

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66⅔% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with or controlling or controlled by such entity or person.

NASDAQ Global Market Listing

We have applied for approval for trading and quotation of our common stock on The NASDAQ Global Market under the symbol “SFMT.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Wells Fargo Bank, N.A. Its address is 161 North Concord Exchange South St. Paul, MN 55075-1139.

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SHARES ELIGIBLE FOR FUTURE SALE

We will have shares of common stock outstanding after the completion of this offering (shares if the underwriters' over-allotment is exercised in full) based on 23,382,608 shares outstanding as of September 30, 2006. Of those shares, the shares of common stock sold in the offering (shares if the underwriters' over-allotment option is exercised in full) will be freely transferable without restriction, unless purchased by persons deemed to be our "affiliates" as that term is defined in Rule 144 under the Securities Act. Any shares purchased by an affiliate may not be resold except pursuant to an effective registration statement or an applicable exemption from registration, including an exemption under Rule 144 promulgated under the Securities Act. The remaining shares of common stock to be outstanding immediately following the completion of this offering are "restricted," which means they were originally sold in offerings that were not registered under the Securities Act. These restricted shares may only be sold through registration under the Securities Act or under an available exemption from registration, such as provided through Rule 144.

We, our officers and directors and our other stockholders have agreed that, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of each of Citigroup Global Markets Inc. and J.P. Morgan Securities Inc., dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for our common stock, subject to customary exceptions. After the 180-day lock-up period, these shares may be sold, subject to applicable securities laws. Notwithstanding the foregoing, for the purpose of allowing the underwriters to comply with NASD Rule 2711(f)(4), if:

- during the last 17 days of the initial 180-day lock-up period, we issue an earnings release or material news, or a material event relating to us occurs; or
- prior to the expiration of the initial 180-day lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the initial 180-day lock-up period,

then in each case the initial 180-day lock-up period will be extended 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, unless Citigroup Global Markets Inc. and J.P. Morgan Securities Inc. waive, in writing, such extension.

After the completion of this offering, the holders of approximately 14,492,520 shares of our common stock will be entitled to registration rights. For more information on these registration rights, see "Description of Capital Stock−Registration Rights."

In general, under Rule 144 promulgated under the Securities Act, as currently in effect, beginning 90 days after the effective date of this offering, a person (or persons whose shares are aggregated), including an affiliate, who has beneficially owned shares of our common stock for one year or more, may sell in the open market within any three-month period a number of shares that does not exceed the greater of:

- 1% of the then outstanding shares of our common stock (approximately shares immediately after the offering); or
- the average weekly trading volume in the common stock on The NASDAQ Global Market during the four calendar weeks preceding the sale.

Sales under Rule 144 promulgated under the Securities Act are also subject to certain limitations on the manner of sale, notice requirements and the availability of our current public information. A person (or persons whose shares are aggregated) who is not an affiliate at any time during the three-month period preceding a sale by him or her and who has beneficially owned his or her shares for at least two years, may sell the shares in the public market under Rule 144(k) promulgated under the Securities Act, without regard to the volume limitations, manner of sale provisions, notice requirements or the availability of current public information we refer to above.

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Any of our employees, officers, directors or consultants who purchased his or her shares before the completion of this offering or who hold options as of that date pursuant to a written compensatory plan or contract are entitled to rely on the resale provisions of Rule 701 promulgated under the Securities Act, which permits non-affiliates to sell their Rule 701 promulgated under the Securities Act, shares without having to comply with the public information, holding period, volume limitation or notice provisions of Rule 144 promulgated under the Securities Act, commencing 90 days after completion of this offering. Neither Rule 144 nor Rule 701 promulgated under the Securities Act, supersedes the contractual obligations of our security holders, including those set forth in the lock-up agreements described above and those contained in grant agreements issued under our Stock Incentive Plan and our 2006 Stock Plan.

Based on shares outstanding as of September 30, 2006 and subject to the lock-up agreements and repurchase rights under our Stock Incentive Plan and our 2006 Stock Plan, the shares of our common stock that will become eligible for sale without registration pursuant to Rule 144 or Rule 701 under the Securities Act are as follows:

160,000 shares will be immediately eligible for sale in the public market without restriction pursuant to Rule 144(k) promulgated under the Securities Act; and

47,576 shares will be eligible for sale in the public market under Rule 144 or Rule 701 promulgated under the Securities Act, beginning 90 days after the date of this prospectus, subject to volume, manner of sale, and other limitations under those rules.

Upon completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register shares of common stock reserved for issuance under our Stock Incentive Plan, 2006 Stock Plan and 2006 Employee Stock Purchase Plan, thus permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act. Such registration statement will become effective immediately upon filing.

Prior to the completion of this offering, there has been no public market for our common stock, and any sale of substantial amounts in the open market may adversely affect the market price of our common stock offered hereby.

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UNDERWRITING

Citigroup Global Markets Inc. and J.P. Morgan Securities Inc. are acting as joint bookrunning managers of the offering, and, together with Piper Jaffray & Co. and Thomas Weisel Partners LLC, are acting as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has agreed to purchase, and we have agreed to sell to that underwriter, the number of shares set forth opposite the underwriter' s name.

Underwriter	Number of Shares
Citigroup Global Markets Inc.	
J.P. Morgan Securities Inc.	
Piper Jaffray & Co.	
Thomas Weisel Partners LLC	
Total	

The underwriting agreement provides that the obligations of the underwriters to purchase the shares included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all the shares (other than those covered by the over-allotment option described below) if they purchase any of the shares.

The underwriters propose to offer some of the shares directly to the public at the public offering price set forth on the cover page of this prospectus and some of the shares to dealers at the public offering price less a concession not to exceed $ per share. The underwriters may allow, and dealers may reallow, a concession not to exceed $ per share on sales to other dealers. If all of the shares are not sold at the initial offering price, the representatives may change the public offering price and the other selling terms. The representatives have advised us that the underwriters do not intend sales to discretionary accounts to exceed percent of the total number of shares of our common stock offered by them.

We and certain selling stockholders have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional shares approximately proportionate to that underwriter' s initial purchase commitment.

We, our officers and directors and our other stockholders have agreed that, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of each of Citigroup Global Markets Inc. and J.P. Morgan Securities Inc., dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for our common stock, subject to customary exceptions. After the 180-day lock-up period, these shares may be sold, subject to applicable securities laws. Notwithstanding the foregoing, for the purpose of allowing the underwriters to comply with NASD Rule 2711(f)(4), if:

- during the last 17 days of the initial 180-day lock-up period, we issue an earnings release or material news, or a material event relating to us occurs; or
- prior to the expiration of the initial 180-day lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the initial 180-day lock-up period,

then in each case the initial 180-day lock-up period will be extended 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, unless Citigroup Global Markets Inc. and J.P. Morgan Securities Inc. waive, in writing, such extension.

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At our request, the underwriters have reserved up to % of the shares of common stock for sale at the initial public offering price to persons who are directors, officers or employees, or who are otherwise associated with us through a directed share program. The number of shares of common stock available for sale to the general public will be reduced by the number of directed shares purchased by participants in the program. Any directed shares not purchased will be offered by the underwriters to the general public on the same basis as all other shares of common stock offered. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the sales of the directed shares.

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price for the shares was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our record of operations, our current financial condition, our future prospects, our markets, the economic conditions in and future prospects for the industry in which we compete, our management, and currently prevailing general conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our company. We cannot assure you, however, that the prices at which the shares will sell in the public market after this offering will not be lower than the initial public offering price or that an active trading market in our common stock will develop and continue after this offering.

The following table shows the underwriting discounts and commissions that we and the selling stockholders are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares of common stock.

	Paid By Us		Paid By Selling Stockholders Upon Exercise
	No Exercise	Full Exercise	
Per share	$	$	
Total	$	$	

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales and syndicate covering transactions. Short sales involve syndicate sales of common stock in excess of the number of shares to be purchased by the underwriters in the offering, which creates a syndicate short position. "Covered" short sales are sales of shares made in an amount up to the number of shares represented by the underwriters' over-allotment option. In determining the source of shares to close out the covered syndicate short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the overallotment option. Transactions to close out the covered syndicate short involve either purchases of our common stock in the open market after the distribution has been completed or the exercise of the over-allotment option. The underwriters may also make "naked" short sales of shares in excess of the over-allotment option. The underwriters must close out any "naked" short position by purchasing shares of our common stock 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 shares in the open market after pricing that could adversely affect investors who purchase in the offering.

In addition, the underwriters may stabilize or maintain the price of our common stock by bidding for or purchasing shares of our common stock in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to syndicate members or other broker-dealers participating in this offering are reclaimed if shares of our common stock previously distributed in this offering are repurchased, whether in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of our common stock at a level above that which might otherwise prevail in the open market. The imposition of a penalty bid may also affect the price of our common stock to the extent that it discourages resales of our common stock. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may

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be effected on The NASDAQ Global Market or otherwise and, if commenced, may be discontinued at any time.

Any of these activities may have the effect of preventing or retarding a decline in the market price of our common stock. They may also cause the price of our common stock to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these transactions on The NASDAQ Global Market or in the over-the-counter market, or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

We estimate that our total expenses of this offering will be $.

The underwriters may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business.

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters. The representatives may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. The representatives will allocate shares to underwriters that may make Internet distributions on the same basis as other allocations. In addition, shares may be sold by the underwriters to securities dealers who resell shares to online brokerage account holders.

We and the selling stockholders have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of our common stock described in this prospectus may not be made to the public in that relevant member state prior to the publication of a prospectus in relation to our common stock that has been approved by the competent authority in that relevant member state or, where appropriate, approved in another relevant member state and notified to the competent authority in that relevant member state, all in accordance with the Prospectus Directive, except that, with effect from and including the relevant implementation date, an offer of securities may be offered to the public in that relevant member state at any time:

- to any legal entity that is 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 or
- to any legal entity that 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 or
- in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive.

Each purchaser of our common stock described in this prospectus located within a relevant member state will be deemed to have represented, acknowledged and agreed that it is a "qualified investor" within the meaning of Article 2(1)(e) of the Prospectus Directive.

For purposes of this provision, the expression an "offer to the public" 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 the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that 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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The sellers of our common stock have not authorized and do not authorize the making of any offer of our common stock through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of our common stock as contemplated in this prospectus. Accordingly, no purchaser of our common stock, other than the underwriters, is authorized to make any further offer of our common stock on behalf of the sellers or the underwriters.

Notice to Prospective Investors in the United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive ("Qualified Investors") that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in France

Neither this prospectus nor any other offering material relating to our common stock described in this prospectus has been submitted to the clearance procedures of the Autorité des Marchés Financiers or by the competent authority of another member state of the European Economic Area and notified to the Autorité des Marchés Financiers. Our common stock have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to our common stock has been or will be

- released, issued, distributed or caused to be released, issued or distributed to the public in France or
- used in connection with any offer for subscription or sale of our common stock to the public in France.

Such offers, sales and distributions will be made in France only

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d' investisseurs*), in each case investing for their own account, all as defined in, and in accordance with, Article L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code *monétaire et financier* or
- to investment services providers authorized to engage in portfolio management on behalf of third parties or
- in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code *monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the Autorité des Marchés Financiers, does not constitute a public offer (*appel public à l' épargne*).

Our common stock may be resold directly or indirectly, only in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code *monétaire et financier.*

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LEGAL MATTERS

The validity of the shares of common stock offered hereby has been passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California. Latham & Watkins LLP, Menlo Park, California, is counsel for the underwriters in connection with this offering.

EXPERTS

The financial statements as of December 31, 2004 and 2005, and for each of the three years in the period ended December 31, 2005 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the SEC for the common stock we are offering pursuant to this prospectus. This prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document. When we complete this offering, we will also be required to file annual, quarterly and special reports, proxy statements and other information with the SEC.

You can read our SEC filings, including the registration statement, over the Internet at the SEC' s web site at *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, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, NE, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. We also maintain a website at www.sfmt.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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ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
St. Francis Medical Technologies, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders' deficit and of cash flows present fairly, in all material respects, the financial position of St. Francis Medical Technologies, Inc. and its subsidiary (the "Company") at December 31, 2004 and 2005, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule appearing under Item 16(b) on page II-4 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These consolidated financial statements and financial statement schedule are the responsibility of the Company' s management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California
September 20, 2006

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ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2004	December 31, 2005	September 30, 2006	Pro Forma Stockholders' Equity September 30, 2006
			(unaudited)	
			(in thousands, except share and per share data)	
ASSETS				
Current assets:				
Cash and cash equivalents	$1,782	$1,958	$5,530	
Available-for-sale securities	3,433	–	1,180	
Accounts receivable, net	974	3,372	12,651	
Inventories, net	1,396	2,333	4,489	
Prepaid expenses and other current assets	427	709	1,291	
Note receivable from stockholder	–	827	–	
Total current assets	8,012	9,199	25,141	
Property and equipment, net	512	446	529	
Other assets	341	323	863	
Total assets	$8,865	$9,968	$26,533	
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current liabilities:				
Accounts payable	$542	$1,901	$1,750	
Accrued liabilities	327	1,057	3,439	
Current portion of liability related to early exercise of employee stock options	19	298	295	
Total current liabilities	888	3,256	5,484	
Noncurrent portion of liability related to early exercise of employee stock options	7	390	302	
Total liabilities	895	3,646	5,786	
Commitments and contingencies (Note 4)				
Redeemable convertible preferred stock: $0.001 par value;				
Authorized: 15,000,000 shares				
Issued and outstanding: 14,492,520 shares at December 31, 2004, 2005 and September 30, 2006 (unaudited), respectively and no shares at September 30, 2006 pro forma (unaudited) (Liquidation value: $27,940 at December 31, 2005 and September 30, 2006 (unaudited))	27,759	27,759	27,759	$–
Stockholders' equity (deficit):				
Common stock: $0.001 par value;				
Authorized: 30,000,000 shares;				
Issued and outstanding: 6,552,710, 8,518,042 and 8,890,088 shares at December 31, 2004, 2005 and September 30, 2006 (unaudited), respectively, and 23,382,608 shares at September 30, 2006 pro forma (unaudited)	6	8	9	23
Additional paid-in capital	356	7,341	9,163	36,908
Deferred stock-based compensation	–	(4,746)	(3,533)	(3,533)
Accumulated other comprehensive loss	(15)	(364)	(153)	(153)
Accumulated deficit	(20,136)	(23,676)	(12,498)	(12,498)
Total stockholders' equity (deficit)	(19,789)	(21,437)	(7,012)	$20,747
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$8,865	$9,968	$26,533	

The accompanying notes are an integral part of these consolidated financial statements.

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ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
	(in thousands, except share and per share data)				
Revenues	$1,017	$3,816	$10,712	$7,093	$36,525
Cost of revenues	139	573	1,664	974	3,487
Gross profit	878	3,243	9,048	6,119	33,038
Operating expenses:					
Research and development	2,161	2,827	2,531	1,893	2,958
Sales and marketing	1,641	2,830	5,589	3,558	15,461
General and administrative	1,726	2,878	4,652	3,475	3,799
Total operating expenses	5,528	8,535	12,772	8,926	22,218
Income (loss) from operations	(4,650)	(5,292)	(3,724)	(2,807)	10,820
Interest income	133	129	79	59	90
Other income (expense), net	(28)	193	105	71	268
Net income (loss)	(4,545)	(4,970)	(3,540)	(2,677)	11,178
Less: net income allocable to preferred stockholders	–	–	–	–	(7,565)
Net income (loss) allocable to common stockholders	$(4,545)	$(4,970)	$(3,540)	$(2,677)	$3,613
Net income (loss) per share allocable to common stockholders − basic	$(0.73)	$(0.77)	$(0.52)	$(0.41)	$0.47
Net income (loss) per share allocable to common stockholders − diluted	$(0.73)	$(0.77)	$(0.52)	$(0.41)	$0.40
Weighted-average shares outstanding used in calculating net income (loss) per share − basic	6,189,229	6,424,252	6,790,787	6,591,959	7,750,908
Weighted-average shares outstanding used in calculating net income (loss) per share − diluted	6,189,229	6,424,252	6,790,787	6,591,959	9,144,573
Pro forma net loss per share					
Basic (unaudited)			$(0.17)		$0.16
Diluted (unaudited)			$(0.17)		$0.15
Pro forma weighted-average shares outstanding used in calculating net income (loss) per share					
Basic (unaudited)			21,283,307		22,243,428
Diluted (unaudited)			21,283,307		23,637,093

The accompanying notes are an integral part of these consolidated financial statements.

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ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

	ShCommon St	ockount	Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
			(in thousands, except share and per share data)				
Balance at January 1, 2003	6,192,109	$ 6	$ 218	$ –	$ (22)	$ (10,621)	$ (10,419)
Exercise of common stock options	9,167	–	4	–	–	–	4
Non-employee stock compensation expense	–	–	26	–	–	–	26
Components of other comprehensive income (loss)							
Change in unrealized gain (loss) on available-for-sale securities	–	–	–	–	11	–	11
Change in cumulative translation adjustment	–	–	–	–	48	–	48
Net loss	–	–	–	–	–	(4,545)	(4,545)
Comprehensive loss							(4,486)
Balance at December 31, 2003	6,201,276	6	248	–	37	(15,166)	(14,875)
Exercise of common stock options	341,434	–	87	–	–	–	87
Exercise of common stock warrant	10,000	–	6	–	–	–	6
Non-employee stock compensation expense	–	–	15	–	–	–	15
Components of other comprehensive income (loss)							
Change in unrealized gain (loss) on available-for-sale securities	–	–	–	–	2	–	2
Change in cumulative translation adjustment	–	–	–	–	(54)	–	(54)
Net loss	–	–	–	–	–	(4,970)	(4,970)
Comprehensive loss							(5,022)
Balance at December 31, 2004	6,552,710	6	356	–	(15)	(20,136)	(19,789)
Exercise of common stock options	690,332	1	215	–	–	–	216
Issuance of notes receivable for early exercise of stock options	1,275,000	1	326	–	–	–	327
Deferred stock-based compensation	–	–	6,311	(6,311)	–	–	–
Employee stock-based employee compensation expense recorded under APB No. 25	–	–	–	1,565	–	–	1,565
Non-employee stock compensation expense	–	–	133	–	–	–	133
Components of other comprehensive income (loss)							
Change in cumulative translation adjustment	–	–	–	–	(349)	–	(349)
Net loss	–	–	–	–	–	(3,540)	(3,540)
Comprehensive loss							(3,889)
Balance at December 31, 2005	8,518,042	8	7,341	(4,746)	(364)	(23,676)	(21,437)
Exercise of common stock options (unaudited)	372,046	1	194	–	–	–	195
Vesting of common stock options early exercised in prior years (unaudited)	–	–	241	–	–	–	241
Employee stock-based employee compensation expense recorded under APB No. 25 (unaudited)	–	–	584	945	–	–	1,529
Reversal of deferred stock-based compensation for stock options forfeited (unaudited)	–	–	(268)	268	–	–	–
Non-employee stock compensation expense (unaudited)	–	–	295	–	–	–	295
Employee stock-based compensation expense recognized under SFAS 123(R) (unaudited)	–	–	776	–	–	–	776
Components of other comprehensive income (loss)							
Change in cumulative translation adjustment (unaudited)	–	–	–	–	211	–	211
Net income (unaudited)	–	–	–	–	–	11,178	11,178
Comprehensive income (unaudited)							11,389
Balance at September 30, 2006 (unaudited)	8,890,088	$ 9	$ 9,163	$ (3,533)	$ (153)	$ (12,498)	$ (7,012)

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ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
			(in thousands)	(unaudited)	
Cash flows from operating activities:					
Net income (loss)	$(4,545)	$(4,970)	$(3,540)	$(2,677)	$11,178
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:					
Depreciation	126	183	213	142	198
Loss on disposal of fixed assets	–	11	1	–	–
Interest receivable on stockholder note	–	–	26	–	–
Allowance for doubtful accounts	–	134	–	–	29
Inventory reserves	–	–	–	–	35
Stock-based compensation expense	26	15	1,698	1,360	2,600
Forgiveness of loan	–	–	60	60	60
Changes in operating assets and liabilities:					
Accounts receivable	(219)	(818)	(2,479)	(1,297)	(9,087)
Inventories	(361)	(674)	(1,138)	(1,179)	(1,949)
Prepaid expenses and other current assets	(175)	(126)	(604)	(746)	(608)
Other assets	(234)	(101)	18	17	(881)
Accounts payable	164	335	1,317	846	(173)
Accrued liabilities	121	45	1,044	556	2,475
Net cash provided by (used in) operating activities	(5,097)	(5,966)	(3,384)	(2,918)	3,877
Cash flows from investing activities:					
Purchase of property and equipment	(176)	(328)	(153)	(67)	(276)
Purchase of available-for-sale securities	(9,419)	–	–	–	(1,180)
Sales and maturities of available-for-sale securities	–	5,998	3,442	2,450	–
Net cash provided by (used in) investing activities	(9,595)	5,670	3,289	2,383	(1,456)
Cash flows from financing activities:					
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	14,984	–	–	–	–
Proceeds from exercise of common stock options	53	87	371	49	286
Proceeds from exercise of common stock warrant	–	6	–	–	–
Repayment of note receivable issued for exercise of common stock options	–	–	–	–	827
Net cash provided by financing activities	15,037	93	371	49	1,113
Effect of exchange rate changes on cash	(60)	(53)	(100)	(56)	38
Net change in cash and cash equivalents	285	(256)	176	(542)	3,572
Cash and cash equivalents at beginning of period	1,753	2,038	1,782	1,782	1,958
Cash and cash equivalents at end of period	$2,038	$1,782	$1,958	$1,240	$5,530
Supplemental disclosure of significant noncash investing and financing activities					
Note receivable issued for exercise of common stock options	$–	$–	$827	$827	$–

The accompanying notes are an integral part of these consolidated financial statements.

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ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

NOTE 1 − THE COMPANY:

Background

St. Francis Medical Technologies, Inc. (the "Company") was formed in 1996 and incorporated in the state of Nevada in January 1999 and reincorporated in the state of Delaware in January 2001. The Company is a medical device company focused on the design, development and marketing of motion-preserving technologies and procedures for orthopedic and neurological spine surgery. The Company' s first product, the X STOP Interspinous Process Decompression System, or X STOP is a less invasive implant designed to treat lumbar spinal stenosis, a condition resulting from the narrowing of neural pathways that often leads to debilitating pain in the lower back and legs. The Company sells the X STOP which received the CE Mark in June 2002 and U.S. Food and Drug Administration ("FDA") approval in November 2005.

The Company has incurred net losses during the years ended December 31, 2003, 2004 and 2005 and had an accumulated deficit of $12,498 (unaudited) at September 30, 2006. While the Company has achieved profitability during the nine month period ended September 30, 2006 (unaudited), it may not be able to sustain this profitability and may need to raise additional financing in order to pursue its business strategy. Additional financing will be required for the Company' s currently envisioned long term needs. There can be no assurance that any additional financing will be available on terms acceptable to the Company, or at all. In addition, future equity financings could result in dilution to stockholders, and future debt financings could result in certain financial and operational restrictions.

Revision to previously reported financial information (unaudited)

During the fourth quarter of fiscal 2006, the Company concluded that it is appropriate to revise previously reported unaudited financial information for the six month period ended June 30, 2006 to correct an error in its calculation of net income allocable to common stockholders and calculation of basic and diluted net income per share available to common stockholders under Emerging Issues Task Force Issue No. 03-6, *Participating Securities and the Two Class Method under FASB Statement No. 128, Earnings Per Share* and Statement of Financial Accounting Standards No. 128, *Earnings Per Share*. The revision reflects an allocation of net income to the preferential dividend rights of the preferred stockholders prior and in preference to the division of the remaining earnings on an equal amount per share to both preferred and common stock. The revision does not affect the Company' s previously reported net income (loss) or its balance sheet or statement of cash flows for any period. The impact of these adjustments is that previously reported amounts for net income allocable to common stockholders of $2,068, basic net income per share of $0.27 and diluted net income per share of $0.24 have been revised to $1,652, $0.22 and $0.19, respectively, for the six month period ended June 30, 2006 (unaudited).

NOTE 2 − SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Unaudited Interim Results

The accompanying consolidated balance sheets as of September 30, 2006, the consolidated statements of operations and of cash flows for the nine months ended September 30, 2005 and 2006, and the consolidated statements of stockholders' deficit for the nine months ended September 30, 2006 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the Company' s financial position and results of operations and cash flows for the nine months ended September 30, 2005 and 2006. Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), *Share-Based Payment*, which supersedes its previous accounting under Accounting

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Principles Board Opinion No. 25 ("APB No. 25"), *Accounting for Stock Issued to Employees.* The financial data and other information disclosed in these notes to the consolidated financial statements related to the six month periods are unaudited. The results for the nine months ended September 30, 2006 are not necessarily indicative of the results to be expected for the year ending December 31, 2006 or for any other interim period or for any future year.

Unaudited Pro Forma Stockholders' Equity Information

The unaudited pro forma stockholders' equity information as of September 30, 2006 gives effect to the conversion of all outstanding shares of the Company' s redeemable convertible preferred stock into an aggregate of 14,492,520 shares (unaudited) of common stock based on the shares of redeemable convertible preferred stock outstanding at September 30, 2006 upon the assumed completion of the Company' s initial public offering. Unaudited pro forma stockholders' equity, as adjusted for the assumed conversion of the redeemable convertible preferred stock, is set forth on the face of the Company' s consolidated balance sheet.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America.

Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, St. Francis Medical Technologies Europe B.V. All intercompany transactions and balances have been eliminated in consolidation.

Foreign Currency Translation

The foreign subsidiary' s functional currency is its local currency. The gains and losses resulting from translating the foreign subsidiary' s financial statements into U.S. dollars have been reported in other comprehensive income (loss). Revenues and expenses are translated at average exchange rates in effect during the period. Foreign currency transaction gains and losses are included in the statements of operations.

Foreign Currency Contracts

The Company utilizes certain foreign currency option contracts to manage its exposure to intercompany foreign currency exchange rate risks. These foreign currency option contracts are not designated as hedges under SFAS No. 133. *"Accounting for Derivative Instruments and Hedging Activities"* as amended. Gains or losses on foreign currency options are intended to offset losses or gains on the underlying net exposures in an effort to reduce the earnings volatility resulting from fluctuating foreign currency exchange rates. The fair value changes of these contracts, net of premium amortization, are reported in earnings as foreign exchange gain or loss, which is included in other income (expense), net in the Company' s consolidated statements of operations. Premiums are amortized over the term of the related foreign currency contracts. The Company does not utilize any other derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions.

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Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain 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 reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and short-term financial investments purchased with original maturities of three months or less at the date of purchase.

Available-for-Sale Securities

The Company classifies short-term investments in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. The Company places its investments primarily in commercial paper with maturities of over 90 days. The Company has classified such investments as available-for-sale securities which are reported at fair market value with any unrealized gains or losses recorded as a separate component of stockholders' deficit and included in other comprehensive income (loss). Realized gains and losses are calculated on the specific identification method and recorded as interest income.

Fair Value of Financial Instruments

Carrying amounts of the Company' s financial instruments including cash and cash equivalents, available-for-sale securities, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to their short maturities. The carrying amounts of the Company' s note receivable and liability related to early exercise of employee stock options approximate their fair values.

Accounts Receivable

Accounts receivable are typically unsecured and represent amounts due from customers. The Company performs ongoing credit evaluations of its customers and maintains reserves for potential credit losses. Allowance for doubtful accounts was $134, $118 and $154 (unaudited), respectively, at December 31, 2004, 2005 and September 30, 2006. Write-offs of accounts receivable have been insignificant during the years ended December 2003, 2004, 2005 and the nine-month periods ended September 30, 2005 (unaudited) and 2006 (unaudited).

Inventories

Inventories are stated at the lower of standard cost (which approximates actual cost on a first-in, first-out basis) or market. Market value is determined as the lower of replacement cost or net realizable value. Lower of cost or market is evaluated by considering obsolescence and excessive levels of inventory.

Property and Equipment

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets, which is generally three to seven years. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

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Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There have been no such impairments of long-lived assets as of December 31, 2005.

Revenue Recognition

The Company recognizes revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, *Revenue Recognition*. The Company earns revenue from the sale of its products to distributors and hospitals. Revenue is recognized when the title and risk of ownership has been transferred, provided that persuasive evidence of an arrangement exists, the price is fixed and determinable, remaining obligations are insignificant and collectibility is reasonably assured. Revenue is recorded net of customer and distributor discounts.

The Company sells its products primarily to hospitals in the United States primarily through independent sales agents and direct sales representatives. The Company sells its products in international markets to stocking distributors and to hospitals through direct sales representatives. Revenue is recorded on sales to hospitals, net of discounts, upon receipt of a valid purchase order, delivery of the product and when collection of the receivable is reasonably assured. Commissions paid to sales agents are recorded as a sales and marketing expense. Sales to stocking distributors, are recorded when title and risk of loss transfer upon shipment, provided that all other revenue recognition criteria are met. No direct sales customers or stocking distributors have price protection or stock rotation rights. All customers have a warranty for product defects in materials or workmanship but such product returns have historically been insignificant and the Company does not provide a general right of return on the sale of its products.

Shipping Costs

Shipping costs charged to customers are included in revenues and the associated expense is included in cost of revenues in the statements of operations.

Research and Development

Cost related to research, design and development of products are charged to research and development expense as incurred.

Advertising Costs

Advertising costs are included in sales and marketing expense and are expensed as incurred. Advertising costs were insignificant for the years ended December 31, 2003, 2004, 2005 and for the nine-month periods ended September 30, 2005 (unaudited) and 2006 (unaudited).

Warranty Costs

The Company offers a limited warranty on its products. Warranty expense has been insignificant for the years ended December 31, 2003, 2004, 2005 and for the nine-month periods ended September 30, 2005 (unaudited) and 2006 (unaudited).

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Concentration of Credit Risk and Other Risks and Uncertainties

The Company' s cash, cash equivalents and available-for-sale securities are maintained with financial institutions in the United States of America and Europe. Deposits may exceed the amount of insurance provided on such deposits. Management believes that these financial institutions are financially sound and accordingly, minimal credit risk exists with respect to those deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company' s accounts receivable is derived primarily from revenues earned from customers located in markets in the U.S. and Europe. There were no individual customers that accounted for more than 10% of revenues or accounts receivable for the nine-month period ended September 30, 2006 (unaudited). One customer accounted for 27% of total revenues and two customers accounted for 31% and 13% of accounts receivable for the year ended December 31, 2005. One customer accounted for 39% of total revenues and two customers accounted for 21% and 14% of accounts receivable for the year ended December 31, 2004. Two customers accounted for 40% and 11% of total revenues for the year ended December 31, 2003.

The Company is subject to risks common to companies in the medical device industry including, but not limited to, new technological innovations, dependence on key personnel, dependence on key suppliers, protection of proprietary technology, product liability and compliance with government regulations. To sustain profitable operations, the Company must successfully design, develop, manufacture and market its products. There can be no assurance that current products will continue to be accepted in the marketplace. Nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed, if at all. These factors could have a material adverse effect on the Company' s future financial results, financial position and cash flows.

The Company is wholly dependent on a sole vendor for the manufacture and supply of the X STOP product and any delay or failure to adequately supply the product by this vendor could have a material adverse impact on the Company. Additionally, the Company is dependent on a sole supplier of a material that is used in a version of the X STOP that is currently marketed in Europe. Any failure to adequately supply this material could have a material adverse impact on the Company.

Future products developed by the Company may require approvals or clearances from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company' s products will continue to meet the necessary regulatory requirements. If the Company was denied or delayed receiving such approvals or clearances, it may have a materially adverse impact on the Company.

Segment Information

The Company operates in one business segment, which encompasses the manufacturing and marketing of its X STOP device. Management uses one measurement of profitability and does not segregate its business for internal reporting. Substantially all long-lived assets are maintained in the United States.

Total revenue is attributed to geographic areas based on the country to where the product is shipped.

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The following summarizes total revenues by geographic region:

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
United States	$−	$−	$264	$−	$26,247
Germany	550	1,758	3,180	2,225	2,912
Italy	−	−	1,941	1,084	1,853
United Kingdom	186	582	1,439	1,387	1,967
Greece	−	580	295	110	176
The Netherlands	178	262	404	415	367
Rest of World	103	634	3,189	1,872	3,003
Total revenues	$1,017	$3,816	$10,712	$7,093	$36,525

Stock-Based Compensation

Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements in accordance with the provisions of APB No. 25 and related interpretations and complied with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB No. 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the Company' s stock and the exercise price. Employee stock-based compensation determined under APB No. 25 is recognized using the straight-line method for fixed awards, and the multiple option method for variable awards as prescribed by the Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Appreciation Rights and Other Variable Stock Option or Award Plans* ("FIN 28").

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

The following table illustrates the effect on net loss if the Company had accounted for its employee stock options under the fair value method of SFAS No. 123. The fair value of these options was estimated using the minimum value method at the date of grant.

	Years Ended December 31,		
	2003	2004	2005
Net loss, as reported	$(4,545)	$(4,970)	$(3,540)
Add: Employee stock-based compensation included in reported net loss	−	−	1,565
Deduct: Employee stock-based compensation determined under minimum value based method	(13)	(11)	(906)
Net loss − pro forma	$(4,558)	$(4,981)	$(2,881)
Net loss per common share − basic and diluted as reported	$(0.73)	$(0.77)	$(0.52)
Net loss per common share − basic and diluted pro forma	$(0.74)	$(0.78)	$(0.42)

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The value of each option granted is estimated on the date of grant using the minimum value method with the following weighted average assumptions:

	Years Ended December 31,		
	2003	2004	2005
Risk-free interest rate	2.75 %	2.00 %	4.03 %
Expected life (in years)	4	4	4
Dividend yield	0.0 %	0.0 %	0.0 %

Based on the above assumptions, the weighted average estimated minimum values of options granted were $0.06, $0.05, and $5.68 per share for the years ended December 31, 2003, 2004 and 2005, respectively.

Adoption of SFAS No. 123R (unaudited)

Effective January 1, 2006, the Company adopted the fair value provisions of SFAS No. 123R, *Share-Based Payment* which supersedes its previous accounting under APB No. 25. SFAS No. 123R requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. SFAS No. 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The Company adopted SFAS No. 123R using the prospective transition method, which requires that for nonpublic entities that used the minimum value method for either pro forma or financial statement recognition purposes, SFAS No. 123R shall be applied to option grants after the effective date of this standard. For options granted prior to the SFAS No. 123R effective date, which the requisite service period has not been performed as of January 1, 2006, the Company will continue to recognize compensation expense on the remaining unvested awards under the intrinsic-value method of APB No. 25. All option grants valued after January 1, 2006 will be expensed over the requisite service periods on a straight-line basis.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' deficit except those resulting from investments or contributions by stockholders. The Company' s unrealized gains and losses on available-for-sale securities and gains and losses on cumulative translation adjustments represent the only other components of comprehensive income (loss) that are excluded from the Company' s net income (loss) for the years ended December 31, 2003, 2004 and 2005 and the nine-month periods ended September 30, 2005 (unaudited) and 2006 (unaudited).

Net Income (Loss) Per Share

Basic net income (loss) per share attributed to common shareholders is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period as reduced by the weighted average unvested common shares subject to repurchase by the Company. Net income (loss) available to common stockholders is calculated using the two class method under EITF No. 03-06, *Participating Securities and the Two-Class Method Under FASB Statement No. 128*.

Diluted net income (loss) per share attributed to common stockholders is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of common and potential common shares outstanding during the period, if the effect of each class of potential common shares is dilutive. Potential common shares include common stock subject to

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repurchase rights and incremental shares of common stock issuable upon the exercise of stock options and upon conversion of preferred stock.

Historical and Pro Forma Net Loss Per Share

Upon completion of the Company' s planned initial public offering, all outstanding redeemable convertible preferred stock will be converted, on a one-to-one conversion ratio, into 14,492,520 shares of common stock. The pro forma stockholders' equity as of September 30, 2006 and the pro forma basic and diluted net (loss) income per share for the nine months ended September 30, 2006 reflect the conversion of all outstanding shares of redeemable convertible preferred stock into common stock as if the conversion had occurred on the date of issuance of the preferred stock. The pro forma stockholders' equity and pro forma basic and diluted net loss per share do not give effect to the issuance of shares in, or the receipt or use of any proceeds from, the planned initial public offering.

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A reconciliation of the numerator and denominator used in the calculation of historical basic and diluted net income (loss) per share follows:

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
Historical net income (loss) per share:					
Numerator					
Net income (loss), as reported	$(4,545)	$(4,970)	$(3,540)	$(2,677)	$11,178
Less: net income allocable to preferred stockholders	–	–	–	–	(7,565)
Net income (loss) allocable to common stockholders	$(4,545)	$(4,970)	$(3,540)	$(2,677)	$3,613
Denominator					
Weighted-average common shares outstanding	6,197,333	6,450,122	7,688,095	7,468,521	8,662,825
Less: weighted-average unvested common shares subject to repurchase	(8,104)	(25,870)	(897,308)	(876,563)	(911,917)
Denominator for basic net income (loss) per share	6,189,229	6,424,252	6,790,787	6,591,958	7,750,908
Dilutive effect of stock options	–	–	–	–	554,540
Dilutive effect of common shares subject to repurchase	–	–	–	–	839,125
Denominator for diluted net income (loss) per share	6,189,229	6,424,252	6,790,787	6,591,959	9,144,573
Basic net income (loss) per share	$(0.73)	$(0.77)	$(0.52)	$(0.41)	$0.47
Diluted net income (loss) per share	$(0.73)	$(0.77)	$(0.52)	$(0.41)	$0.40
Pro forma net income (loss) per share (unaudited)					
Numerator					
Pro forma net income (loss) allocable to common stockholders			$(3,540)		$3,613
Denominator for pro forma basic net income (loss) per share					
Shares used above			6,790,787		7,750,908
Pro forma adjustments to reflect assumed weighted-average effect of conversion of preferred stock			14,492,520		14,492,520
Denominator for pro forma basic net income (loss) per share			21,283,307		22,243,428
Dilutive effect of stock options			–		554,540
Dilutive effect of common shares subject to repurchase			–		839,125
Denominator for pro forma diluted net income (loss) per share			21,283,307		23,673,093
Pro forma basic net income (loss) per share			$(0.17)		$0.16
Pro forma diluted net income (loss) per share			$(0.17)		$0.15

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The following outstanding options, common stock subject to repurchase and redeemable convertible preferred stock were excluded from the computation of diluted net loss per common share for the periods presented because including them would have had an anti-dilutive effect:

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
Options to purchase common stock	1,254,833	2,286,000	926,313	1,003,583	−
Common stock subject to repurchase	−	18,337	1,068,744	850,000	−
Redeemable convertible preferred stock	14,492,520	14,492,520	14,492,520	14,492,520	14,492,520

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, to clarify the accounting for abnormal amounts of idle facility expense, handling costs and wasted material (spoilage). Among other provisions, the new rule requires that such items be recognized as current-period charges, regardless of whether they meet the criterion of "so abnormal" as stated in ARB No. 43. SFAS No. 151 was adopted as of January 1, 2006 and did not have a material effect on the Company' s financial statements.

In June 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections: a Replacement of Accounting Principles Board Opinion No. 20 and FASB Statement No. 3*. SFAS No. 154 requires retrospective application for voluntary changes in accounting principle unless it is impracticable to do so. Retrospective application refers to the application of a different accounting principle to previously issued financial statements as if that principle had always been used. SFAS No. 154' s retrospective application requirement replaces APB No 20' s ("Accounting Changes") requirement to recognize most voluntary changes in accounting principle by including in net income (loss) of the period of the change the cumulative effect of changing to the new accounting principle. SFAS No. 154 defines retrospective application as the application of a different accounting principle to prior accounting periods as if that principle had always been used or as the adjustment of previously issued financial statements to reflect a change in the reporting entity. SFAS No. 154 also redefines "restatement" as the revising of previously issued financial statements to reflect the correction of an error. The requirements of SFAS No. 154 are effective for accounting changes made in fiscal years beginning after December 15, 2005 and will only impact the financial statements in periods in which a change in accounting principle is made. The Company does not expect that the adoption of this standard will have an impact on its financial statements.

In November 2005, the FASB issued FASB Staff Position ("FSP") Nos. FAS 115-1 and FAS 124-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, which

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provide guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and the measurement of an impairment loss. These FSP' s also include accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. These FSP' s are required to be applied to reporting periods beginning after December 15, 2005. The adoption of these standards did not have a material impact on the Company' s financial statements.

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, *Accounting for the Uncertainty in Income Taxes − an Interpretation of FASB Statement No. 109* ("FIN No. 48"), which clarifies the accounting uncertainty in tax positions. This interpretation requires that the Company recognize in its financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN No. 48 are effective as of the beginning of its 2007 fiscal year, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is currently evaluating the impact of adopting FIN No. 48 on its financial statements.

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements,* or SAB No. 108. SAB No. 108 states that registrants should use both a balance sheet approach and an income statement approach when quantifying and evaluating the materiality of a misstatement. The interpretations in SAB No. 108 contain guidance on correcting errors under the dual approach as well as provide transition guidance for correcting errors. This interpretation does not change the requirements within SFAS No. 154 for the correction of an error on financial statements. SAB No. 108 is effective for annual financial statements covering the first fiscal year ending after November 15, 2006. The Company will be required to adopt this interpretation by December 31, 2006. The Company is currently evaluating the requirements of SAB No. 108 and the impact this interpretation may have on its financial statements (unaudited).

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements,* or SFAS No. 157. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company will be required to adopt SFAS No. 157 in the first quarter of fiscal year 2008. The Company is currently evaluating the requirements of SFAS No. 157 and has not yet determined the impact on its financial statements (unaudited).

NOTE 3 − BALANCE SHEET COMPONENTS:

Available-for-Sale Securities

	Amortized Cost	Unrealized Gain (Loss)	Estimated Fair Market Value
At December 31, 2004:			
Corporate securities (all maturing within one year)	$3,442	$(9)	$3,433
At September 30, 2006:			
Corporate securities (all maturing within one year)	$1,180	$−	$1,180

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At December 31, 2005, the Company did not have any available-for-sale securities.

Inventories

Inventories consist of the following:

	December 31,		September 30,
	2004	2005	2006
			(unaudited)
Raw materials	$61	$68	$54
Work-in-process	549	1,204	993
Finished goods	786	1,061	3,442
	$1,396	$2,333	$4,489

Property and Equipment, net

Property and equipment, net consist of the following:

	December 31,		September 30,
	2004	2005	2006
			(unaudited)
Machinery and equipment	$296	$343	$371
Computer equipment	376	351	554
Office furniture and fixtures	341	440	490
	1,013	1,134	1,415
Less: Accumulated depreciation	(501)	(688)	(886)
	$512	$446	$529

Depreciation expense related to property and equipment was $126, $183 and $213 for the years ended December 31, 2003, 2004 and 2005, respectively. Depreciation expense related to property and equipment was $142 and $198 for the nine-month periods ended September 30, 2005 and 2006, respectively (unaudited).

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,		September 30,
	2004	2005	2006
			(unaudited)
Sales agent commissions	$–	$–	$1,111
Employee compensation and related	97	314	753
Professional services	89	74	1,069
Foreign sales taxes payable	103	397	443
Other	38	272	63
	$327	$1,057	$3,439

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NOTE 4 − COMMITMENTS AND CONTINGENCIES:

Operating Lease Commitments

The Company leases office space under noncancelable operating leases that expire in February and March 2009. Rent expense was $73, $204 and $291 for the years ended December 31, 2003, 2004 and 2005, respectively. Rent expense was $205 (unaudited) and $208 (unaudited) for the nine-month periods ended September 30, 2005 and 2006, respectively.

Future minimum lease payments under the leases at December 31, 2005 are as follows:

Year Ending December 31,	
2006	$286
2007	293
2008	300
2009	65
Total minimum lease payments	$944

In July 2006, the Company entered into a new operating lease for office space (see Note 11).

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company is not currently subject to any material legal proceedings.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company' s exposure under these agreements is unknown because it involves future claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company' s request in such capacity. There have been no claims to date and the Company has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future claims.

NOTE 5 − CONVERTIBLE PREFERRED STOCK:

Under the Company' s Amended and Restated Certificate of Incorporation, as amended, the Company is authorized to issue 15,000,000 shares of convertible preferred stock, of which 2,318,970 shares are designated as Series A convertible preferred stock ("Series A preferred stock"), 5,808,573 shares are designated as Series B convertible preferred stock ("Series B preferred stock") and 6,500,000 shares are designated as Series C convertible preferred stock ("Series C preferred stock").

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Convertible preferred stock at December 31, 2004, 2005 and September 30, 2006 (unaudited) consists of the following:

	Shares Outstanding	Carrying Amount	Liquidation Value
Series A preferred stock	2,318,970	$2,647	$2,690
Series B preferred stock	5,808,573	10,128	10,165
Series C preferred stock	6,364,977	14,984	15,085
	14,492,520	$27,759	$27,940

The holders of the convertible preferred stock have various rights and preferences as follows:

Dividends

The holders of Series A preferred stock, Series B preferred stock and Series C preferred stock are entitled to receive noncumulative dividends at the per annum rate of $0.0928, $0.14 and $0.1896 per share, respectively. Such dividends, which are in preference to any dividends on common stock, are payable quarterly when, and if declared by the Board of Directors. No dividends have been declared to date.

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series A preferred stock, Series B preferred stock and Series C preferred stock are entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock or other junior security, an amount equal to the respective preferred stock issuance price of $1.16, $1.75 and $2.37 per share, respectively, and an amount equal to all declared but unpaid dividends on each such share. If the assets and funds available for distribution are insufficient to cover the liquidation preference, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of preferred stock in proportion to the amounts each holder would receive if the Company had sufficient funds to pay the liquidation preference.

After payment of the full liquidation preference, any remaining assets of the Company available for distribution to stockholders shall be distributed among the holders of convertible preferred stock and common stock pro rata based on the number of shares of common stock held by each, assuming conversion of all such preferred stock into common stock. The maximum distributions to holders of Series A preferred stock on liquidation is $4.64 per share, after which the remaining assets of the Company shall be distributed among the holders of the Series B preferred stock and Series C preferred stock on an as-converted basis. The maximum distributions to holders of Series B preferred stock and Series C preferred stock on liquidation is $7.00 per share, after which the remaining assets of the Company shall be distributed among the holders of the common stock.

Any merger, consolidation or other reorganization of the Company into or with any other corporation resulting in the transfer of more than 50% of the voting power of the Company, and/or a sale, conveyance or other distribution or encumbrance of all or substantially all of the assets of the Company, is deemed a liquidation event.

Conversion

Each share of convertible preferred stock is convertible at the option of the holder, into a number of fully paid and nonassessable shares of common stock as is determined by dividing the preferred stock

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issue price by the conversion price in effect at the time of conversion. The conversion price of Series A, Series B, and Series C preferred stock is $1.16, $1.75 and $2.37 per share, respectively, subject to adjustments pursuant to the Company' s Amended and Restated Certificate of Incorporation. Conversion is automatic immediately upon the closing of a firm commitment underwritten public offering in which the public offering price equals or exceeds $5.25 per share (adjusted to reflect subsequent stock dividends, stock splits or recapitalization) and the aggregate gross proceeds raised are at least $20,000, or the date specified by written consent or agreement of at least a majority of the holders of the then outstanding shares of convertible preferred stock, voting together as a single class.

Voting Rights

The holder of each share of Series A, Series B and Series C preferred stock shall have full voting rights and powers equal to the voting rights and powers of the holders of common stock and shall be entitled to the number of votes equal to the number of shares of common stock into which each share of convertible preferred stock could be converted.

Registration Rights

The holders of the Company' s common stock issuable upon the conversion of the Company' s Series A, Series B and Series C preferred stock are entitled to certain registration rights. These registration rights are subject to certain conditions and limitations, including the right of the underwriters of an offering to limit the number of shares included in any such registration under certain circumstances. The Company is generally required to pay all expenses incurred in connection with registrations effected in connection with such rights, excluding underwriting discounts and commissions. The Company is not required to pay penalties associated with such registration rights.

NOTE 6 − STOCKHOLDERS' EQUITY (DEFICIT):

Common Stock

Under the Company' s Amended and Restated Certificate of Incorporation, as amended in June 2004, the Company is authorized to issue 30,000,000 shares of common stock. Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when, and if declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared or paid as of December 31, 2005.

Warrant to Purchase Common Stock

In February 2004, the Company issued warrants to purchase 10,000 shares of the Company' s common stock at $0.55 per share to a service provider. The warrants were valued using the Black-Scholes option pricing model, assuming 75% volatility, 3.10% risk-free interest rate, a contractual life of five years and fair value of the Company' s common stock at the time of issuance of $0.55 per share. The value ascribed to the warrants of $3 was recognized as general and administrative expense during the year ended December 31, 2004. The warrants were exercised during the year ended December 31, 2004.

NOTE 7 − STOCK OPTION PLAN:

In January 1999, the Company adopted the 1999 Stock Option Plan, as amended and restated, in April 1999, and in July 1999 adopted the Stock Incentive Plan, as amended and restated in April 2003 (together the "Plans"). Options granted under the Plans may be incentive stock options ("ISO") or non-qualified stock options. Incentive stock options may only be granted to employees (including officers

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and directors who are also employees). Options under the Plans may be granted for periods up to ten years and at prices no less than 85% of the estimated fair value of the shares on the date of the grant as determined by the Board of Directors provided, however, that (i) the exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant and (ii) the term of the options is no longer than five years and the exercise price is at least 110% of the estimated fair market value for incentive options for which the grantee owns greater than 10% of the voting power of all classes of stock. The options generally vest over four years. The Company has reserved 4,585,000 shares of common stock for issuance under the Plans.

Activity under the Plans is as follows:

		Outstanding Options			
	Shares Available for Grant	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)	Aggregate Intrinsic Value
Balances, January 1, 2003	255,891	887,000	$0.29		
Additional shares reserved	1,000,000	–	–		
Options granted	(407,000)	407,000	0.50		
Options exercised	–	(9,167)	0.40		
Options canceled	30,000	(30,000)	0.40		
Balances, December 31, 2003	878,891	1,254,833	0.36		
Additional shares reserved	1,250,000	–	–		
Options granted	(1,558,000)	1,558,000	0.64		
Options exercised	–	(341,434)	0.26		
Options canceled	185,399	(185,399)	0.44		
Balances, December 31, 2004	756,290	2,286,000	0.56		
Additional shares reserved	1,000,000	–	–		
Options granted	(923,500)	923,500	0.71		
Options exercised	–	(1,965,332)	0.61		
Options canceled	317,855	(317,855)	0.54		
Balances, December 31, 2005	1,150,645	926,313	0.61		
Options granted (unaudited)	(782,900)	782,900	1.43		
Options exercised (unaudited)	–	(372,046)	0.77		
Options forfeited/canceled (unaudited)	85,967	(85,967)	0.60		
Balances, September 30, 2006 (unaudited)	453,712	1,251,200	$1.08	9.05	$18,921
Options vested and expected to vest at September 30, 2006 (unaudited)		1,174,636	$1.06	8.22	$17,780
Options vested at September 30, 2006 (unaudited)		254,349	$0.64	7.88	$3,959

The aggregate intrinsic value amounts disclosed in the above table have been computed based on the difference between the original exercise price of the options and the fair value of the Company' s common stock, as determined by management, of $16.20 per share at September 30, 2006 (unaudited).

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During the nine months ended September 30, 2006, the Company granted stock options to purchase an aggregate of 782,900 shares (unaudited) of common stock with an estimated weighted-average grant-date fair value of $11.81 per share (unaudited). The total fair value of options accounted for under SFAS No. 123R that vested during the nine months ended September 30, 2006 was $0 (unaudited). The total intrinsic value of options exercised during the nine months ended September 30, 2006 was $2,401 (unaudited). Net cash proceeds from the exercise of stock options was $286 (unaudited) for the nine months ended September 30, 2006.

Options outstanding and exercisable and vested by exercise price at December 31, 2005 are as follows:

	Options Outstanding and Exercisable		Options Vested	
Exercise Price	Number of Options	Weighted Average Remaining Contractual Life (Years)	Number of Options	Weighted Average Exercise Price
$0.12	27,000	3.85	27,000	$0.12
0.25	15,000	5.09	15,000	0.25
0.40	112,162	6.15	108,514	0.40
0.44	50,000	5.60	50,000	0.44
0.55	71,000	7.66	41,556	0.55
0.65	556,151	9.65	87,970	0.65
1.00	95,000	9.94	20,103	1.00
	926,313	8.64	350,143	$0.49

Options outstanding and exercisable and vested by exercise price at September 30, 2006 (unaudited) are as follows:

	Options Outstanding and Exercisable		Options Vested	
Exercise Price	Number of Options	Weighted Average Remaining Contractual Life (Years)	Number of Options	Weighted Average Exercise Price
$ 0.12	20,000	3.17	20,000	$0.12
0.40	20,000	4.85	20,000	0.40
0.55	53,000	6.90	41,065	0.55
0.65	461,500	8.96	129,824	0.65
1.00	286,000	9.28	43,043	1.00
1.14	247,000	9.65	–	1.14
2.20	157,200	9.90	417	2.20
14.63	6,500	10.00	–	14.63
	1,251,200	9.05	254,349	$0.64

At December 31, 2004, there were 703,854 options vested at a weighted average exercise price of $0.43 per share.

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Early Exercise of Employee Options

Stock options granted under the Company' s stock option plans provide employee option holders the right to elect to exercise unvested options in exchange for restricted common stock. Unvested shares which amounted to 18,337 and 1,068,744 at December 31, 2004 and 2005, respectively, and 831,064 (unaudited) at September 30, 2006, were subject to a repurchase right held by the Company at the original issuance price in the event the optionees' employment is terminated either voluntarily or involuntarily. These repurchase terms are considered to be a forfeiture provision and do not result in variable accounting. In accordance with EITF No. 00-23, *Issues Related to the Accounting for Stock Compensation under APB No. 25*, the shares purchased by the employees pursuant to the early exercise of stock options are not deemed to be outstanding until those shares vest. In addition, cash received from employees for exercise of unvested options is treated as a liability. Amounts so recorded are transferred into common stock and additional paid-in capital as the shares vest.

The activity of nonvested shares for the nine months ended September 30, 2006 (unaudited) as a result of early exercise of options granted to employees is as follows:

Nonvested Shares	Shares
Balance as of December 31, 2005	1,068,774
Early exercise of options (unaudited)	130,000
Vested (unaudited)	(367,710)
Balances as of September 30, 2006 (unaudited)	831,064

As of December 31, 2004, a liability of $26 has been recorded in the accompanying balance sheets for the shares subject to repurchase of which $7 is classified as a long-term liability and $19 as a short-term liability. As of December 31, 2005, a liability of $688 has been recorded in the accompanying balance sheets for the shares subject to repurchase of which $390 is classified as a long-term liability, and $298 is classified as a short-term liability. As of September 30, 2006, a liability of $597 (unaudited) has been recorded in the accompanying balance sheets for the shares subject to repurchase of which $302 (unaudited) is classified as a long-term liability and $295 (unaudited) is classified as a short-term liability.

Stock-based Compensation Associated with Awards to Employees

During the year ended December 31, 2005 and the nine-month period ended September 30, 2006, the Company issued stock options to certain employees with exercise prices below the fair market value of the Company' s common stock at the date of grant, determined with hindsight. The Company retrospectively estimated the fair value of its common stock based upon several factors, including its operating and financial performance and progress attained in its business, past sales of its convertible preferred stock, and the expected valuation that the Company would obtain in an initial public offering. The Company has reviewed these key factors and events between each date and has determined that the fair value of its common stock is appropriately reflected using a progression from $0.65 per share of common stock at January 1, 2005, to $16.20 per share (unaudited) at September 30, 2006. In accordance with the requirements of APB No. 25, the Company has recorded deferred stock-based compensation, for the difference between the exercise price of the stock options granted during the year ended December 31, 2005 and the fair value of the Company' s stock at the date of grant, determined with hindsight. During the year ended December 31, 2005, the Company recorded deferred stock-based compensation related to these options of $6,311 and amortized $1,565 and $1,286 (unaudited) and $945 (unaudited) of stock-based compensation in the year ended December 31, 2005 and nine-month periods ended September 30, 2005 and 2006, respectively. In addition, the Company granted 90,000 options to an employee during the year ended December 31, 2005 which have vesting provisions based on certain performance conditions related to revenue milestones and recognized $0

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and $584 (unaudited) of stock-based compensation associated with this grant during the year ended December 31, 2005 and nine month period ended September 30, 2006.

The Company granted stock options to employees with exercise prices below estimated fair market value, determined with hindsight, on the date of grant as follows (unaudited):

Grants Made During Quarter Ended	Number of Options Granted	Weighted-Average Exercise Price per Share	Weighted-Average Fair Value per Share	Weighted-Average Intrinsic Value per Share
March 31, 2005	250,000	$0.65	$0.81	$0.16
June 30, 2005	−	$0.65	$3.92	$3.27
September 30, 2005	155,000	$0.65	$7.20	$6.55
December 31, 2005	516,000	$0.83	$8.63	$7.80
March 31, 2006	290,000	$1.11	$11.31	$10.20
June 30, 2006	318,000	$1.14	$14.05	$12.91
September 30, 2006	159,900	$2.61	$15.84	$13.22

Note Receivable from Stockholder

In June 2004, the Company granted 1,275,000 options to its Chief Executive Officer to purchase common stock at an exercise price of $0.65 per share. Under the terms of the grant award, the holder was entitled to exercise the options in exchange for a full recourse note.

In March 2005, the Chief Executive Officer exercised all the 1,275,000 options in exchange for a full recourse note of $827 and cash of $1. Under EITF No. 85-1 *Classifying Notes Received for Capital Stock*, the Company has recorded the note as a current asset as the note was repaid on September 20, 2006 (see Note 11). The note bears interest at 3.76% per annum which the Company considered to be below the market rate on the issuance date. The balance with accrued and unpaid interest was due and payable in March 2009 (four years from the date of the agreement). The repayment terms will accelerate and the whole unpaid balance of principal and interest shall be immediately due and payable upon the earliest to occur of (i) immediately prior to and conditioned upon the filing of the Company' s initial registration statement filed under the Securities Exchange Act of 1933, (ii) failure on the part of the borrower to make any payment under the note when due (iii) the termination of the officer' s employment with the Company for any or no reason (iv) failure on the part of the borrower to observe any obligation under the security agreement or any other security instrument which secures this note, (v) if the officer admits in writing his inability to pay his debts as they are due or if the officer seeks any reorganization or similar release under any state or federal law regarding bankruptcy or insolvency, or (vi) if the officer seeks any action to transfer or otherwise dispose of any shares of capital stock which the officer has pledged pursuant to the security agreement without the prior consent of the lender. Accrued interest on the note as of December 31, 2005 was $26.

In accordance with EITF No. 00-23, Issue 33(b), the unvested portion of the amount received in consideration for the early exercise of options is included as a liability in the accompanying balance sheet. Amounts of $501 and $345 (unaudited) were included in liabilities as of December 31, 2005 and September 30, 2006, respectively, in connection with the unvested portion subject to repurchase of the 1,275,000 options exercised by the Chief Executive Officer in March 2005.

In accordance with FASB Interpretation No. 44 ("FIN 44"), *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25*, the exercise price of the award was not fixed and, therefore, variable accounting was applied to the award from the date of

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grant to the date the options were exercised. Stock-based compensation for the period from the date of grant to the date of exercise was recorded under FIN No. 28. The Company recorded deferred stock-based compensation of $2,091 based on the intrinsic value of the stock options and amortized $1,336 and $234 during the year ended December 31, 2005 and nine-month period ended September 30, 2006 (unaudited), respectively. The remaining unamortized deferred stock-based compensation upon exercise of the stock option is amortized on a straight-line basis over the remaining vesting period.

Stock-based Compensation Associated with Awards to Nonemployees

The Company granted 125,000, 30,000 and 2,500 options during the years ended December 31, 2003, 2004 and 2005, respectively and 2,500 (unaudited) and 15,000 (unaudited) options during the nine month periods ended September 30, 2005 and 2006 to nonemployees in exchange for services. Stock-based compensation expense related to stock options granted to nonemployees is recognized as the stock options are earned. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered. The fair value of the stock options granted to nonemployees is calculated at each reporting date using the Black-Scholes option pricing model using the following assumptions:

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
Risk-free interest rate	4.60%	2.00%	4.03%	3.63 %	4.68 %
Contractual term (in years)	10	10	10	10	10
Dividend yield	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %
Expected volatility	75 %	75 %	75 %	75 %	60 %

The stock-based compensation expense will fluctuate as the estimated fair value of the common stock fluctuates. In connection with the grant of stock options to nonemployees, the resulting compensation expense was $26, $15 and $133 for the years ended December 31, 2003, 2004 and 2005, respectively, and $74 (unaudited) and $295 (unaudited) for the nine month periods ended September 30, 2005 and 2006 (unaudited), respectively.

Adoption of SFAS No. 123R (Unaudited)

Effective January 1, 2006, the Company adopted SFAS No. 123R, *Share-Based Payment*, using the prospective transition method, which requires the measurement and recognition of compensation expense for all employee share-based payment awards granted and modified after January 1, 2006.

The expected term of options gave consideration to historical exercises, the vesting term of the Company' s options, the cancellation history of the Company' s options and the options' contractual term of ten years. The expected stock price volatility assumptions for the Company' s stock options for the six months ended June 30, 2006 were determined by the examining historical volatilities for industry peers, as the Company did not have any trading history for the Company' s common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company' s common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury constant maturity rate as of the date of grant. The expected divided assumption is based on the Company' s history and expectation of dividend payouts.

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The assumptions used to value options granted during the nine months ended September 30, 2006 were as follows:

	Nine Months Ended September 30, 2006 (unaudited)	
Risk-free interest rate	4.68	%
Expected term (in years)	4	
Dividend yield	0.00	%
Expected volatility	60	%

Employee stock-based compensation expense under SFAS No. 123R recognized in the nine months ended September 30, 2006 was $776 (unaudited) and was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

At September 30, 2006, the Company had $7,199 (unaudited) of total unrecognized compensation expense under SFAS 123R, net of estimated forfeitures, related to stock option plans that will be recognized over a weighted-average period of 3.63 years.

Stock-based compensation expense recorded under APB No. 25, SFAS No. 123R and EITF No. 96-18 related to options granted to employees and nonemployees was allocated to cost of revenues, research and development, sales and marketing and general and administrative expense as follows:

	Years Ended December 31,			Nine Months Ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
Cost of revenues	$−	$−	$3	$−	$29
Research and development	26	15	57	−	452
Sales and marketing	−	−	278	102	1,678
General and administrative	−	−	1,360	1,258	441
	$26	$15	$1,698	$1,360	$2,600

NOTE 8 − RELATED PARTY TRANSACTIONS:

In July 2004, the Company entered into a loan agreement with the Company' s Chief Executive Officer for relocation expenses in the amount of $120 at an interest rate of 5% per annum. The terms of the agreement provided that 50% of the principal and all accrued interest of the loan would be forgiven if the Chief Executive Officer remained an employee as of June 30, 2005, and that all of the principal and interest would be forgiven if he remained an employee as of June 30, 2006. As of September 30, 2006 (unaudited), all principal and interest relating to this loan agreement was forgiven.

In March 2005, the Company entered into a full recourse note with the Chief Executive Officer that was repaid in September 2006. (see Note 7.)

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NOTE 9 − INCOME TAXES:

Temporary differences which give rise to significant components of the net deferred tax assets are as follows:

	December 31,	
	2004	2005
Deferred tax assets:		
Net operating loss carryforwards	$6,626	$6,642
Foreign net operating losses	257	129
Research credits	688	899
Accruals and reserves	16	612
Depreciation	18	18
Other	229	75
	7,834	8,375
Less: Valuation allowance	(7,834)	(8,375)
Net deferred tax assets	$−	$−

The differences between the U.S. federal statutory income tax rate and the Company' s effective tax rate are as follows:

	Years Ended December 31,		
	2003	2004	2005
Tax at federal statutory rate	34.0 %	34.0 %	34.0 %
State, net of federal benefit	2.9 %	2.2 %	2.2 %
Deferred stock-based compensation	−	−	(19.1)%
Benefit for research and development credit	1.6 %	4.3 %	2.8 %
Other	0.5 %	(2.8)%	(4.7)%
Change in valuation allowance	(39.0)%	(37.7)%	(15.2)%
Provision for taxes	0.0 %	0.0 %	0.0 %

Based on the available objective evidence, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2004 and 2005. The valuation allowance increased by $1,774, $2,131 and $541 during the years ended December 31, 2003, 2004 and 2005.

As of December 31, 2005, the Company has net operating loss carryforwards of approximately $18,867 for federal and $10,455 for state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2019 for federal and 2008 for state tax purposes.

As of December 31, 2005 the Company has research credit carryforwards of approximately $417 and $462 for federal and state income tax purposes, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2019. The state credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In the event the Company has had a change in ownership, utilization of the carryforwards could be restricted.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS − (Continued)
(in thousands, except share and per share data)

Management evaluates on a periodic basis the recoverability of deferred tax assets. At such time as it is determined that is more likely than not that deferred tax assets are realizable, the valuation allowance will be reduced.

NOTE 10 − EMPLOYEE BENEFIT PLAN:

In May 1999, the Company adopted the St. Francis Medical Technologies 401(k) Profit Sharing Plan and Trust (the "401(k) Plan") which covers its U.S.-based employees. Eligible employees may make pre-tax salary deferral contributions up to a specified maximum. The Company may make matching contributions at its discretion for 100% of an employee' s contributions to the 401(k) Plan, up to a maximum amount equal to 4% of such employee' s base salary. The Company made no contributions during the years ended December 31, 2003, 2004 and 2005, respectively, and $0 (unaudited) and $46 (unaudited) for the nine-month periods ended September 30, 2005 and 2006, respectively.

NOTE 11 − OTHER EVENTS:

Initial Public Offering

On September 14, 2006, the Board of Directors approved the filing of a registration statement with the Securities and Exchange Commission for an initial public offering of the Company' s common stock.

2006 Equity Incentive Plan

On September 14, 2006, the Board of Directors adopted the 2006 Stock Plan. A total of 1,500,000 shares of common stock were reserved for issuance pursuant to the 2006 Stock Plan. In addition, the shares reserved for issuance under the 2006 Equity Incentive Plan included shares reserved but unissued under the Company' s existing stock option plan as the result of termination of options or the repurchase of shares. The 2006 Stock Plan provides for annual increases in the number of shares available for issuance on the first day of each fiscal year, equal to the least of:

5% of the outstanding shares of common stock;

2,500,000 shares; or

such other lesser amounts as determined by the Board of Directors.

2006 Employee Stock Purchase Plan

On September 14, 2006, the Board of Directors adopted the 2006 Employee Stock Purchase Plan subject to stockholder approval. A total of 300,000 shares of common stock were reserved for issuance pursuant to the 2006 Employee Stock Purchase Plan. The 2006 Employee Stock Purchase Plan will become effective upon the closing of the Company' s initial public offering. The 2006 Employee Stock Purchase Plan provides for annual increases in the number of shares available for issuance under the plan on the first day of each fiscal year, equal to the least of:

1.5% of the outstanding shares of common stock;

1,000,000 shares; or

such other lesser amounts as determined by the Board of Directors.

Repayment of Note Receivable

On September 20, 2006 the Chief Executive Officer repaid the full recourse loan of $827 and accrued interest of $48.

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ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS − (Continued)
(in thousands, except share and per share data)

Operating Lease

In July 2006, the Company entered into a new lease agreement with a five year term with its landlord to lease a larger facility within the same business park as its current facility and concurrently was released from the earlier lease that was due to expire in February 2009. The Company is expected to pay its proportional share of the utilities, property taxes and other operating expenses allocated to the building.

Future minimum lease payments under the new lease are as follows:

Year Ended December 31,	
2006 (remainder of year)	$127
2007	763
2008	786
2009	809
2010	835
2011	712
Total minimum lease payments	$4,032

Line of Credit

In April 2006, the Company entered into a one year line of credit agreement with a financial institution that provides for borrowings of $2,000 subject to an adequate borrowing base and compliance with certain financial covenants. The line of credit is collateralized against substantially all of the Company' s assets. No amounts have been drawn down from the line of credit. A member of the Company' s Board of Directors is also a member of the Board of Directors of the parent company of this financial institution.

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Shares

ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

Common Stock

PROSPECTUS

Until , 2006 all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Citigroup **JPMorgan**

Piper Jaffray **Thomas Weisel Partners LLC**

, 2006

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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, other than underwriting discounts and commissions, payable by St. Francis Medical Technologies, Inc. in connection with the sale of the common stock being registered hereby. All amounts are estimates except the SEC Registration Fee and the NASD filing fee.

	Amount to be Paid
SEC registration fee	$9,229
NASD filing fee	9,125
NASDAQ Global Market listing fee	100,000*
Blue Sky fees and expenses	*
Printing and Engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer Agent and Registrar fees	*
Miscellaneous	*
Total	$*

* To be completed by amendment.

ITEM 14. Indemnification of Directors and Officers.

On completion of this offering, our amended and restated certificate of incorporation will contain provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, the personal liability of directors and executive officers for monetary damages for breach of their fiduciary duties as a director or officer. Our amended and restated certificate of incorporation and bylaws will provide that we shall indemnify our directors and executive officers and may indemnify our employees and other agents to the fullest extent permitted by the General Corporation Law of the State of Delaware.

Sections 145 and 102(b)(7) of the General Corporation Law of the State of Delaware provide that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, executive officer, employee or agent of the corporation or is or was serving at the request of the corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation.

We have entered into indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and bylaws, and intend to enter into indemnification agreements with any new directors and executive officers in the future.

We have purchased and intend to maintain insurance on behalf of any person who is or was a director or officer of our company against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

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The Purchase Agreement (Exhibit 1.1 hereto) provides for indemnification by the underwriters of us and our executive officers and directors, and by us of the underwriters, for certain liabilities, including liabilities arising under the Securities Act.

See also the undertakings set out in response to Item 17 herein.

ITEM 15. Recent Sales of Unregistered Securities.

Since September 30, 2003, we have sold and issued the following securities:

Common Stock

In July 2004, we issued 10,000 shares of our common stock to two consultants upon exercise of warrants to purchase shares of common stock for an aggregate exercise price of $5,500.

The sales of the above securities were deemed to be exempt from registration in reliance on Section 4(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving any public offering. The recipients were either accredited or sophisticated investors, as those terms are defined in the Securities Act and the regulations promulgated thereunder. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and other instruments issued in such transactions. The recipients either received adequate information about us or had access, through employment or other relationships, to such information.

Stock Options and Stock Purchase Rights

(1) From September 30, 2003 through September 30, 2006, we granted stock options and stock purchase rights to acquire an aggregate of 3,479,000 shares of our common stock at prices ranging from $0.12 to $14.63 per share to employees, consultants and directors pursuant to the our Stock Incentive Plan, as amended.

(2) From September 30, 2003 through September 30, 2006, we issued an aggregate of 2,517,979 shares of our common stock to employees, consultants and directors pursuant to the exercise of stock options and stock purchase rights under our Stock Incentive Plan, as amended, for aggregate consideration of $1,542,859.

(3) From September 30, 2003 through September 30, 2006, we issued an aggregate of 205,000 shares of our common stock to employees, consultants and directors pursuant to the exercise of stock options and stock purchase rights under our Amended and Restated 1999 Stock Option Plan, for aggregate consideration of $24,600.

The sales of the above securities were deemed to be exempt from registration in reliance on Rule 701 promulgated under Section 3(b) under the Securities Act as transactions pursuant to a compensatory benefit plan or a written contract relating to compensation.

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ITEM 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

EXHIBIT INDEX

Exhibit Number	Description
1 .1*	Form of Underwriting Agreement.
3 .1**	Amended and Restated Certificate of Incorporation of the Registrant.
3 .2**	Amended and Restated Certificate of Incorporation of the Registrant to be effective upon closing of the offering to which this Registration Statement relates.
3 .3**	Bylaws of the Registrant.
3 .4**	Amended and Restated Bylaws of the Registrant to be effective upon closing of the offering to which this Registration Statement relates.
4 .1*	Specimen Common Stock certificate of the Registrant.
4 .2**	Amended and Restated Investors' Rights Agreement, dated April 16, 2003, by and among the Registrant and certain stockholders.
5 .1*	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
10.1**	Form of Indemnification Agreement for directors, chief executive officer and chief financial officer.
10.2**	Amended and Restated 1999 Stock Option Plan.
10.3**	Stock Incentive Plan.
10.4	2006 Stock Plan.
10.5**	2006 Employee Stock Purchase Plan.
10.6**	Industrial Gross Lease, dated November 15, 2003, by and between the Registrant and Alameda Real Estate Investments.
10.7**	Lease, dated July 26, 2006, by and between the Registrant and Legacy Partners I Alameda, LLC.
10.8†**	Supply and Inventory Agreement, dated July 16, 2004, by and between the Registrant and RMS Company.
10.9†**	Agreement for the Supply of Polyaryletheretherketone, dated October 21, 2002, by and between the Registrant and Invibio, Inc.
10.10**	Form of Sales Representative Agreement for U.S. representatives.
10.11**	Form of Sales Representative Agreement for non-U.S. representatives.
10.12**	Kevin Sidow Promissory Note, dated March 22, 2005.
10.13**	Kevin Sidow Offer Letter, dated May 12, 2004.
10.14**	Pledge and Security Agreement, dated March 22, 2005, by and between Kevin Sidow and the Registrant.
10.15**	Loan and Security Agreement, dated April 24, 2006, by and between the Registrant and Silicon Valley Bank.

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21.1**	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2*	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (See Exhibit 5.1).
24.1**	Power of Attorney (see page II-5 of the original filing).

* To be filed by amendment.

** Previously filed.

† Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

(b) Financial Statement Schedules

Schedules not listed are omitted because they are not required, are not applicable or the information is included in the consolidated financial statements or notes thereto.

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Schedule II

Valuation and Qualifying Accounts

The change in the allowance for doubtful accounts for the years ended December 31, 2003, 2004 and 2005, respectively, is summarized in the following table:

	Years Ended December 31,		
	2003	2004	2005
		(in thousands)	
Balance at beginning of year	$ 0	$38	$134
Additions charged to general and administrative expense	38	91	–
Write-offs	–	–	–
Foreign currency translation adjustments	–	5	(16)
Balance at end of year	$ 38	$134	$118

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 by the registrant for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described in Item 14 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 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 reference 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.

(2) For the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser to 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

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registrant will be a seller to the purchasers 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.

(3) For purposes of determining any liability under the Securities Act of 1933, 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 of 1933, shall be deemed to be part of this registration statement as of the time it was declared effective.

(4) For the purpose of determining any liability under the Securities Act of 1933, 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 this offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Alameda, state of California, on the 22nd day of November, 2006.

St. Francis Medical Technologies, Inc.

By: /s/ Kevin K. Sidow

Kevin K. Sidow
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Kevin K. Sidow Kevin K. Sidow	President and Chief Executive Officer, Director (principal executive officer)	November 22, 2006
/s/ Michael A. Bates Michael A. Bates	Chief Financial Officer (principal financial officer and principal accounting officer)	November 22, 2006
/s/ David M. Clapper* David M. Clapper	Director	November 22, 2006
/s/ Joseph R. Cutts* Joseph R. Cutts	Director	November 22, 2006
/s/ Ross A. Jaffe* Ross A. Jaffe	Director	November 22, 2006
/s/ Alan L. Kaganov* Alan L. Kaganov	Director	November 22, 2006
Martin P. Sutter	Director	
Allan M. Weinstein	Director	
/s/ Philip M. Young* Philip M. Young	Director	November 22, 2006
* /s/ Kevin K. Sidow Kevin K. Sidow *Attorney-in-Fact*		

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21.1**	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.

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23.2*	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (See Exhibit 5.1).
24.1**	Power of Attorney (see page II-5 of the original filing).

* To be filed by amendment.

** Previously filed.

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Exhibit 10.4

ST. FRANCIS MEDICAL TECHNOLOGIES, INC.

2006 STOCK PLAN

1. Purposes of the Plan. The purposes of this Plan are:

to attract and retain the best available personnel for positions of substantial responsibility,

to provide additional incentive to Employees, Directors and Consultants, and

to promote the success of the Company' s business.

The Plan permits the grant of Incentive Stock Options, Nonstatutory Stock Options, Restricted Stock, Restricted Stock Units, Stock Appreciation Rights, Performance Units and Performance Shares.

2. Definitions. As used herein, the following definitions will apply:

(a) "Administrator" means the Board or any of its Committees as will be administering the Plan, in accordance with Section 4 of the Plan.

(b) "Applicable Laws" means the requirements relating to the administration of equity-based awards under U.S. state corporate laws, U.S. federal and state securities laws, the Code, any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws of any foreign country or jurisdiction where Awards are, or will be, granted under the Plan.

(c) "Award" means, individually or collectively, a grant under the Plan of Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Performance Units or Performance Shares.

(d) "Award Agreement" means the written or electronic agreement setting forth the terms and provisions applicable to each Award granted under the Plan. The Award Agreement is subject to the terms and conditions of the Plan.

(e) "Board" means the Board of Directors of the Company.

(f) "Change in Control" means the occurrence of any of the following events:

(i) Any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the total voting power represented by the Company' s then outstanding voting securities;

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(ii) The consummation of the sale or disposition by the Company of all or substantially all of the Company' s assets;

(iii) A change in the composition of the Board occurring within a two (2)-year period, as a result of which fewer than a majority of the directors are Incumbent Directors. "Incumbent Directors" means directors who either (A) are Directors as of the effective date of the Plan, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company); or

(iv) The consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation.

(g) "Code" means the Internal Revenue Code of 1986, as amended. Any reference to a section of the Code herein will be a reference to any successor or amended section of the Code.

(h) "Committee" means a committee of Directors or of other individuals satisfying Applicable Laws appointed by the Board in accordance with Section 4 hereof.

(i) "Common Stock" means the common stock of the Company.

(j) "Company" means St. Francis Medical Technologies, Inc., a Delaware corporation, or any successor thereto.

(k) "Consultant" means any person, including an advisor, engaged by the Company or a Parent or Subsidiary to render services to such entity.

(l) "Director" means a member of the Board.

(m) "Disability" means total and permanent disability as defined in Section 22(e)(3) of the Code, provided that in the case of Awards other than Incentive Stock Options, the Administrator in its discretion may determine whether a permanent and total disability exists in accordance with uniform and non-discriminatory standards adopted by the Administrator from time to time.

(n) "Employee" means any person, including Officers and Directors, employed by the Company or any Parent or Subsidiary of the Company. Neither service as a Director nor payment of a director' s fee by the Company will be sufficient to constitute "employment" by the Company.

(o) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

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(p) "Exchange Program" means a program under which (i) outstanding Awards are surrendered or cancelled in exchange for Awards of the same type (which may have lower exercise prices and different terms), Awards of a different type, and/or cash, (ii) Participants would have the opportunity to transfer any outstanding Awards to a financial institution or other person or entity selected by the Administrator, and/or (iii) the exercise price of an outstanding Award is reduced. The Administrator will determine the terms and conditions of any Exchange Program in its sole discretion.

(q) "Fair Market Value" means, as of any date, the value of Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or a national market system, including without limitation the Nasdaq National Market or The Nasdaq SmallCap Market of The Nasdaq Stock Market, its Fair Market Value will be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or system on the day of determination, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable;

(ii) If the Common Stock is regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value of a Share will be the mean between the high bid and low asked prices for the Common Stock on the day of determination, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable;

(iii) For purposes of any Awards granted on the Registration Date, the Fair Market Value will be the initial price to the public as set forth in the final prospectus included within the registration statement in Form S-1 filed with the Securities and Exchange Commission for the initial public offering of the Company' s Common Stock; or

(iv) In the absence of an established market for the Common Stock, the Fair Market Value will be determined in good faith by the Administrator.

(r) "Fiscal Year" means the fiscal year of the Company.

(s) "Incentive Stock Option" means an Option intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

(t) "Inside Director" means a Director who is an Employee.

(u) "Nonstatutory Stock Option" means an Option that by its terms does not qualify or is not intended to qualify as an Incentive Stock Option.

(v) "Officer" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(w) "Option" means a stock option granted pursuant to the Plan.

(x) "Outside Director" means a Director who is not an Employee.

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(y) "Parent" means a "parent corporation," whether now or hereafter existing, as defined in Section 424(e) of the Code.

(z) "Participant" means the holder of an outstanding Award.

(aa) "Performance Share" means an Award denominated in Shares which may be earned in whole or in part upon attainment of performance goals or other vesting criteria as the Administrator may determine pursuant to Section 10.

(bb) "Performance Unit" means an Award which may be earned in whole or in part upon attainment of performance goals or other vesting criteria as the Administrator may determine and which may be settled for cash, Shares or other securities or a combination of the foregoing pursuant to Section 10.

(cc) "Period of Restriction" means the period during which the transfer of Shares of Restricted Stock are subject to restrictions and therefore, the Shares are subject to a substantial risk of forfeiture. Such restrictions may be based on the passage of time, the achievement of target levels of performance, or the occurrence of other events as determined by the Administrator.

(dd) "Plan" means this 2006 Stock Plan.

(ee) "Registration Date" means the effective date of the first registration statement that is filed by the Company and declared effective pursuant to Section 12(g) of the Exchange Act, with respect to any class of the Company' s securities.

(ff) "Restricted Stock" means Shares issued pursuant to a Restricted Stock award under Section 7 of the Plan, or issued pursuant to the early exercise of an Option.

(gg) "Restricted Stock Unit" means a bookkeeping entry representing an amount equal to the Fair Market Value of one Share, granted pursuant to Section 8. Each Restricted Stock Unit represents an unfunded and unsecured obligation of the Company.

(hh) "Rule 16b-3" means Rule 16b-3 of the Exchange Act or any successor to Rule 16b-3, as in effect when discretion is being exercised with respect to the Plan.

(ii) "Section 16(b)" means Section 16(b) of the Exchange Act.

(jj) "Service Provider" means an Employee, Director or Consultant.

(kk) "Share" means a share of the Common Stock, as adjusted in accordance with Section 14 of the Plan.

(ll) "Stock Appreciation Right" means an Award, granted alone or in connection with an Option, that pursuant to Section 9 is designated as a Stock Appreciation Right.

(mm) "Subsidiary" means a "subsidiary corporation", whether now or hereafter existing, as defined in Section 424(f) of the Code.

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3. Stock Subject to the Plan.

(a) Stock Subject to the Plan. Subject to the provisions of Section 14 of the Plan, the maximum aggregate number of Shares that may be issued under the Plan is 1,500,000 Shares, plus (i) any Shares that, as of the Registration Date, have been reserved but not issued pursuant to any awards granted under the St. Francis Medical Technologies Stock Incentive Plan (the "Old Plan") and are not subject to any awards granted thereunder, and (ii) any Shares subject to stock options or similar awards granted under the Old Plan that expire or otherwise terminate without having been exercised in full and Shares issued pursuant to awards granted under the Old Plan that are forfeited to or repurchased by the Company, with the maximum number of Shares to be added to the Plan pursuant to clauses (i) and (ii) equal to 460,000 Shares. The Shares may be authorized, but unissued, or reacquired Common Stock.

(b) Automatic Share Reserve Increase. The number of Shares available for issuance under the Plan shall be increased on the first day of each Fiscal Year beginning with the 2008 Fiscal Year, in an amount equal to the least of (A) 2,500,000 Shares, (B) five percent (5%) of the outstanding Shares on the last day of the immediately preceding Fiscal Year or (C) such number of Shares determined by the Board.

(c) Lapsed Awards. If an Award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an Exchange Program, or, with respect to Restricted Stock, Restricted Stock Units, Performance Units or Performance Shares, is forfeited to or repurchased by the Company due to failure to vest, the unpurchased Shares (or for Awards other than Options or Stock Appreciation Rights the forfeited or repurchased Shares) which were subject thereto will become available for future grant or sale under the Plan (unless the Plan has terminated). With respect to Stock Appreciation Rights, only Shares actually issued pursuant to a Stock Appreciation Right will cease to be available under the Plan; all remaining Shares under Stock Appreciation Rights will remain available for future grant or sale under the Plan (unless the Plan has terminated). Shares that have actually been issued under the Plan under any Award will not be returned to the Plan and will not become available for future distribution under the Plan; provided, however, that if Shares issued pursuant to Awards of Restricted Stock, Restricted Stock Units, Performance Shares or Performance Units are repurchased by the Company or are forfeited to the Company, such Shares will become available for future grant under the Plan. Shares used to pay the exercise price of an Award or to satisfy the tax withholding obligations related to an Award will become available for future grant or sale under the Plan. To the extent an Award under the Plan is paid out in cash rather than Shares, such cash payment will not result in reducing the number of Shares available for issuance under the Plan. Notwithstanding the foregoing and, subject to adjustment as provided in Section 14, the maximum number of Shares that may be issued upon the exercise of Incentive Stock Options shall equal the aggregate Share number stated in Section 3(a), plus, to the extent allowable under Section 422 of the Code and the Treasury Regulations promulgated thereunder, any Shares that become available for issuance under the Plan pursuant to Section 3(c).

(d) Share Reserve. The Company, during the term of this Plan, will at all times reserve and keep available such number of Shares as will be sufficient to satisfy the requirements of the Plan.

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4. Administration of the Plan.

(a) Procedure.

(i) Multiple Administrative Bodies. Different Committees with respect to different groups of Service Providers may administer the Plan.

(ii) Section 162(m). To the extent that the Administrator determines it to be desirable to qualify Options granted hereunder as "performance-based compensation" within the meaning of Section 162(m) of the Code, the Plan will be administered by a Committee of two (2) or more "outside directors" within the meaning of Section 162(m) of the Code.

(iii) Rule 16b-3. To the extent desirable to qualify transactions hereunder as exempt under Rule 16b-3, the transactions contemplated hereunder will be structured to satisfy the requirements for exemption under Rule 16b-3.

(iv) Other Administration. Other than as provided above, the Plan will be administered by (A) the Board or (B) a Committee, which committee will be constituted to satisfy Applicable Laws.

(b) Powers of the Administrator. Subject to the provisions of the Plan, and in the case of a Committee, subject to the specific duties delegated by the Board to such Committee, the Administrator will have the authority, in its discretion:

(i) to determine the Fair Market Value;

(ii) to select the Service Providers to whom Awards may be granted hereunder;

(iii) to determine the number of Shares to be covered by each Award granted hereunder;

(iv) to approve forms of Award Agreements for use under the Plan;

(v) to determine the terms and conditions, not inconsistent with the terms of the Plan, of any Award granted hereunder. Such terms and conditions include, but are not limited to, the exercise price, the time or times when Awards may be exercised (which may be based on performance criteria), any vesting acceleration or waiver of forfeiture restrictions, and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Administrator will determine;

(vi) to determine the terms and conditions of any, and to institute any Exchange Program;

(vii) to construe and interpret the terms of the Plan and Awards granted pursuant to the Plan;

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(viii) to prescribe, amend and rescind rules and regulations relating to the Plan, including rules and regulations relating to sub-plans established for the purpose of satisfying applicable foreign laws;

(ix) to modify or amend each Award (subject to Section 19(c) of the Plan), including the discretionary authority to extend the post-termination exercisability period of Awards;

(x) to allow Participants to satisfy withholding tax obligations in such manner as prescribed in Section 15;

(xi) to authorize any person to execute on behalf of the Company any instrument required to effect the grant of an Award previously granted by the Administrator;

(xii) to allow a Participant to defer the receipt of the payment of cash or the delivery of Shares that would otherwise be due to such Participant under an Award

(xiii) to make all other determinations deemed necessary or advisable for administering the Plan.

(c) Effect of Administrator' s Decision. The Administrator' s decisions, determinations and interpretations will be final and binding on all Participants and any other holders of Awards.

5. Eligibility. Nonstatutory Stock Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Performance Shares and Performance Units may be granted to Service Providers. Incentive Stock Options may be granted only to Employees.

6. Stock Options.

(a) Limitations. Each Option will be designated in the Award Agreement as either an Incentive Stock Option or a Nonstatutory Stock Option. However, notwithstanding such designation, to the extent that the aggregate Fair Market Value of the Shares with respect to which Incentive Stock Options are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Parent or Subsidiary) exceeds one hundred thousand dollars ($100,000), such Options will be treated as Nonstatutory Stock Options. For purposes of this Section 6(a), Incentive Stock Options will be taken into account in the order in which they were granted. The Fair Market Value of the Shares will be determined as of the time the Option with respect to such Shares is granted.

(b) Term of Option. The term of each Option will be stated in the Award Agreement. In the case of an Incentive Stock Option, the term will be ten (10) years from the date of grant or such shorter term as may be provided in the Award Agreement. Moreover, in the case of an Incentive Stock Option granted to a Participant who, at the time the Incentive Stock Option is granted, owns stock representing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Parent or Subsidiary, the term of the Incentive Stock Option will be five (5) years from the date of grant or such shorter term as may be provided in the Award Agreement.

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(c) Option Exercise Price and Consideration.

(i) Exercise Price. The per share exercise price for the Shares to be issued pursuant to exercise of an Option will be determined by the Administrator, subject to the following:

(1) In the case of an Incentive Stock Option

a) granted to an Employee who, at the time the Incentive Stock Option is granted, owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the per Share exercise price will be no less than one hundred ten percent (110%) of the Fair Market Value per Share on the date of grant.

b) granted to any Employee other than an Employee described in paragraph (A) immediately above, the per Share exercise price will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(2) In the case of a Nonstatutory Stock Option, the per Share exercise price will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(3) Notwithstanding the foregoing, Options may be granted with a per Share exercise price of less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code.

(ii) Waiting Period and Exercise Dates. At the time an Option is granted, the Administrator will fix the period within which the Option may be exercised and will determine any conditions that must be satisfied before the Option may be exercised.

(iii) Form of Consideration. The Administrator will determine the acceptable form of consideration for exercising an Option, including the method of payment. In the case of an Incentive Stock Option, the Administrator will determine the acceptable form of consideration at the time of grant. Such consideration may consist entirely of: (1) cash; (2) check; (3) promissory note, (4) other Shares, provided Shares acquired directly or indirectly from the Company, (A) have been owned by the Participant and not subject to substantial risk of forfeiture for more than six months on the date of surrender, and (B) have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which said Option will be exercised; (5) consideration received by the Company under a broker-assisted (or other) cashless exercise program implemented by the Company in connection with the Plan; (6) any combination of the foregoing methods of payment; or (7) such other consideration and method of payment for the issuance of Shares to the extent permitted by Applicable Laws.

(d) Exercise of Option.

(i) Procedure for Exercise; Rights as a Stockholder. Any Option granted hereunder will be exercisable according to the terms of the Plan and at such times and under such

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conditions as determined by the Administrator and set forth in the Award Agreement. An Option may not be exercised for a fraction of a Share.

An Option will be deemed exercised when the Company receives: (i) notice of exercise (in such form as the Administrator specify from time to time) from the person entitled to exercise the Option, and (ii) full payment for the Shares with respect to which the Option is exercised (together with applicable withholding taxes). Full payment may consist of any consideration and method of payment authorized by the Administrator and permitted by the Award Agreement and the Plan. Shares issued upon exercise of an Option will be issued in the name of the Participant or, if requested by the Participant, in the name of the Participant and his or her spouse. Until the Shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to an Option, notwithstanding the exercise of the Option. The Company will issue (or cause to be issued) such Shares promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 14 of the Plan.

Exercising an Option in any manner will decrease the number of Shares thereafter available, both for purposes of the Plan and for sale under the Option, by the number of Shares as to which the Option is exercised.

(ii) Termination of Relationship as a Service Provider. If a Participant ceases to be a Service Provider, other than upon the Participant' s death or Disability, the Participant may exercise his or her Option within such period of time as is specified in the Award Agreement to the extent that the Option is vested on the date of termination (but in no event later than the expiration of the term of such Option as set forth in the Award Agreement). In the absence of a specified time in the Award Agreement, the Option will remain exercisable for three (3) months following the Participant' s termination. Unless otherwise provided by the Administrator, if on the date of termination the Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will revert to the Plan. If after termination the Participant does not exercise his or her Option within the time specified by the Administrator, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

(iii) Disability of Participant. If a Participant ceases to be a Service Provider as a result of the Participant' s Disability, the Participant may exercise his or her Option within such period of time as is specified in the Award Agreement to the extent the Option is vested on the date of termination (but in no event later than the expiration of the term of such Option as set forth in the Award Agreement). In the absence of a specified time in the Award Agreement, the Option will remain exercisable for twelve (12) months following the Participant' s termination. Unless otherwise provided by the Administrator, if on the date of termination the Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will revert to the Plan. If after termination the Participant does not exercise his or her Option within the time specified herein, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

(iv) Death of Participant. If a Participant dies while a Service Provider, the Option may be exercised following the Participant' s death within such period of time as is specified

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in the Award Agreement to the extent that the Option is vested on the date of death (but in no event may the option be exercised later than the expiration of the term of such Option as set forth in the Award Agreement), by the Participant' s designated beneficiary, provided such beneficiary has been designated prior to Participant' s death in a form acceptable to the Administrator. If no such beneficiary has been designated by the Participant, then such Option may be exercised by the personal representative of the Participant' s estate or by the person(s) to whom the Option is transferred pursuant to the Participant' s will or in accordance with the laws of descent and distribution. In the absence of a specified time in the Award Agreement, the Option will remain exercisable for twelve (12) months following Participant' s death. Unless otherwise provided by the Administrator, if at the time of death Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will immediately revert to the Plan. If the Option is not so exercised within the time specified herein, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

7. Restricted Stock.

(a) Grant of Restricted Stock. Subject to the terms and provisions of the Plan, the Administrator, at any time and from time to time, may grant Shares of Restricted Stock to Service Providers in such amounts as the Administrator, in its sole discretion, will determine.

(b) Restricted Stock Agreement. Each Award of Restricted Stock will be evidenced by an Award Agreement that will specify the Period of Restriction, the number of Shares granted, and such other terms and conditions as the Administrator, in its sole discretion, will determine. Unless the Administrator determines otherwise, the Company as escrow agent will hold Shares of Restricted Stock until the restrictions on such Shares have lapsed.

(c) Transferability. Except as provided in this Section 7, Shares of Restricted Stock may not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated until the end of the applicable Period of Restriction.

(d) Other Restrictions. The Administrator, in its sole discretion, may impose such other restrictions on Shares of Restricted Stock as it may deem advisable or appropriate.

(e) Removal of Restrictions. Except as otherwise provided in this Section 7, Shares of Restricted Stock covered by each Restricted Stock grant made under the Plan will be released from escrow as soon as practicable after the last day of the Period of Restriction or at such other time as the Administrator may determine. The Administrator, in its discretion, may accelerate the time at which any restrictions will lapse or be removed.

(f) Voting Rights. During the Period of Restriction, Service Providers holding Shares of Restricted Stock granted hereunder may exercise full voting rights with respect to those Shares, unless the Administrator determines otherwise.

(g) Dividends and Other Distributions. During the Period of Restriction, Service Providers holding Shares of Restricted Stock will be entitled to receive all dividends and other distributions paid with respect to such Shares, unless the Administrator provides otherwise. If any such dividends or distributions are paid in Shares, the Shares will be subject to the same restrictions

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on transferability and forfeitability as the Shares of Restricted Stock with respect to which they were paid.

(h) Return of Restricted Stock to Company. On the date set forth in the Award Agreement, the Restricted Stock for which restrictions have not lapsed will revert to the Company and again will become available for grant under the Plan.

8. Restricted Stock Units.

(a) Grant. Restricted Stock Units may be granted at any time and from time to time as determined by the Administrator. After the Administrator determines that it will grant Restricted Stock Units under the Plan, it shall advise the Participant in an Award Agreement of the terms, conditions, and restrictions related to the grant, including the number of Restricted Stock Units.

(b) Vesting Criteria and Other Terms. The Administrator shall set vesting criteria in its discretion, which, depending on the extent to which the criteria are met, will determine the number of Restricted Stock Units that will be paid out to the Participant. The Administrator may set vesting criteria based upon the achievement of Company-wide, business unit, or individual goals (including, but not limited to, continued employment), or any other basis determined by the Administrator in its discretion.

(c) Earning Restricted Stock Units. Upon meeting the applicable vesting criteria, the Participant shall be entitled to receive a payout as determined by the Administrator. Notwithstanding the foregoing, at any time after the grant of Restricted Stock Units, the Administrator, in its sole discretion, may reduce or waive any vesting criteria that must be met to receive a payout.

(d) Form and Timing of Payment. Payment of earned Restricted Stock Units shall be made as soon as practicable after the date(s) determined by the Administrator and set forth in the Award Agreement. The Administrator, in its sole discretion, may only settle earned Restricted Stock Units in cash, Shares, or a combination of both.

(e) Cancellation. On the date set forth in the Award Agreement, all unearned Restricted Stock Units shall be forfeited to the Company.

9. Stock Appreciation Rights.

(a) Grant of Stock Appreciation Rights. Subject to the terms and conditions of the Plan, a Stock Appreciation Right may be granted to Service Providers at any time and from time to time as will be determined by the Administrator, in its sole discretion.

(b) Number of Shares. The Administrator will have complete discretion to determine the number of Stock Appreciation Rights granted to any Service Provider.

(c) Exercise Price and Other Terms. The per share exercise price for the Shares to be issued pursuant to exercise of an Stock Appreciation Right shall be determined by the Administrator and shall be no less than one hundred percent (100%) of the Fair Market Value per

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share on the date of grant. Otherwise, subject to Section 6(a) of the Plan, the Administrator, subject to the provisions of the Plan, shall have complete discretion to determine the terms and conditions of Stock Appreciation Rights granted under the Plan.

(d) Stock Appreciation Right Agreement. Each Stock Appreciation Right grant will be evidenced by an Award Agreement that will specify the exercise price, the term of the Stock Appreciation Right, the conditions of exercise, and such other terms and conditions as the Administrator, in its sole discretion, will determine.

(e) Expiration of Stock Appreciation Rights. An Stock Appreciation Right granted under the Plan will expire upon the date determined by the Administrator, in its sole discretion, and set forth in the Award Agreement. Notwithstanding the foregoing, the rules of Section 6(d) also will apply to Stock Appreciation Rights.

(f) Payment of Stock Appreciation Right Amount. Upon exercise of an Stock Appreciation Right, a Participant will be entitled to receive payment from the Company in an amount determined by multiplying:

(i) The difference between the Fair Market Value of a Share on the date of exercise over the exercise price; times

(ii) The number of Shares with respect to which the Stock Appreciation Right is exercised.

At the discretion of the Administrator, the payment upon Stock Appreciation Right exercise may be in cash, in Shares of equivalent value, or in some combination thereof.

10. Performance Units and Performance Shares.

(a) Grant of Performance Units/Shares. Performance Units and Performance Shares may be granted to Service Providers at any time and from time to time, as will be determined by the Administrator, in its sole discretion. The Administrator will have complete discretion in determining the number of Performance Units and Performance Shares granted to each Participant.

(b) Value of Performance Units/Shares. Each Performance Unit will have an initial value that is established by the Administrator on or before the date of grant. Each Performance Share will have an initial value equal to the Fair Market Value of a Share on the date of grant.

(c) Performance Objectives and Other Terms. The Administrator will set performance objectives or other vesting provisions (including, without limitation, continued status as a Service Provider) in its discretion which, depending on the extent to which they are met, will determine the number or value of Performance Units/Shares that will be paid out to the Service Providers. The time period during which the performance objectives or other vesting provisions must be met will be called the "Performance Period." Each Award of Performance Units/ Shares will be evidenced by an Award Agreement that will specify the Performance Period, and such other terms and conditions as the Administrator, in its sole discretion, will determine. The Administrator may set performance objectives based upon the achievement of Company-wide, divisional, or

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individual goals, applicable federal or state securities laws, or any other basis determined by the Administrator in its discretion.

(d) Earning of Performance Units/Shares. After the applicable Performance Period has ended, the holder of Performance Units/Shares will be entitled to receive a payout of the number of Performance Units/Shares earned by the Participant over the Performance Period, to be determined as a function of the extent to which the corresponding performance objectives or other vesting provisions have been achieved. After the grant of a Performance Unit/Share, the Administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such Performance Unit/Share.

(e) Form and Timing of Payment of Performance Units/Shares. Payment of earned Performance Units/Shares will be made as soon as practicable after the expiration of the applicable Performance Period. The Administrator, in its sole discretion, may pay earned Performance Units/Shares in the form of cash, in Shares (which have an aggregate Fair Market Value equal to the value of the earned Performance Units/Shares at the close of the applicable Performance Period) or in a combination thereof.

(f) Cancellation of Performance Units/Shares. On the date set forth in the Award Agreement, all unearned or unvested Performance Units/Shares will be forfeited to the Company, and again will be available for grant under the Plan.

11. Formula Awards to Outside Directors.

(a) General. Outside Directors will be entitled to receive all types of Awards (except Incentive Stock Options) under this Plan, including discretionary Awards not covered under this Section 11. All grants of Awards to Outside Directors pursuant to this Section will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

(b) Type of Option. If Options are granted pursuant to this Section they will be Nonstatutory Stock Options and, except as otherwise provided herein, will be subject to the other terms and conditions of the Plan.

(c) No Discretion. No person will have any discretion to select which Outside Directors will be granted Awards under this Section or to determine the number of Shares to be covered by such Awards (except as provided in Sections 11(g) and 14).

(d) Initial Award. Each person who first becomes an Outside Director following the Registration Date will be automatically granted an Option to purchase 30,000 Shares (the "Initial Award") on or about the date on which such person first becomes an Outside Director, whether through election by the stockholders of the Company or appointment by the Board to fill a vacancy; provided, however, that an Inside Director who ceases to be an Inside Director, but who remains a Director, will not receive an Initial Award.

(e) Annual Award. Each Outside Director will be automatically granted an Option to purchase 7,500 Shares (an "Annual Award") on each date of the annual meeting of the

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stockholders of the Company beginning in 2008, if as of such date, he or she will have served on the Board for at least the preceding twelve (12) months.

(f) Terms. The terms of each Award granted pursuant to this Section will be as follows:

(i) The term of the Award will be ten (10) years.

(ii) The exercise price for Shares subject to Awards will be one hundred percent (100%) of the Fair Market Value on the grant date.

(iii) Subject to Section 14, the Initial Award will vest and become exercisable ratably as to a number of Shares subject to the Initial Award each month following its grant date, so that the Initial Award will be fully vested and exercisable on the third anniversary of its date of grant, provided that the Participant continues to serve as a Director through such dates.

(iv) Subject to Section 14, the Annual Award will vest and become exercisable ratably as to a number of Shares subject to the Annual Award each month following its grant date, so that the Annual Award will be fully vested and exercisable on the first anniversary of its date of grant, provided that the Participant continues to serve as a Director through such date.

(g) Adjustments. The Administrator in its discretion may change and otherwise revise the terms of Awards granted under this Section 11, including, without limitation, the number of Shares and exercise prices thereof, for Awards granted on or after the date the Administrator determines to make any such change or revision.

12. Leaves of Absence/Transfer Between Locations. Unless the Administrator provides otherwise, vesting of Awards granted hereunder will be suspended during any unpaid leave of absence. A Service Provider will not cease to be an Employee in the case of (i) any leave of absence approved by the Company or (ii) transfers between locations of the Company or between the Company, its Parent, or any Subsidiary. For purposes of Incentive Stock Options, no such leave may exceed ninety (90) days, unless reemployment upon expiration of such leave is guaranteed by statute or contract. If reemployment upon expiration of a leave of absence approved by the Company is not so guaranteed, then three (3) months following the ninety-first (91st) day of such leave any Incentive Stock Option held by the Participant will cease to be treated as an Incentive Stock Option and will be treated for tax purposes as a Nonstatutory Stock Option.

13. Transferability of Awards. Unless determined otherwise by the Administrator, an Award may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the Participant, only by the Participant. If the Administrator makes an Award transferable, such Award will contain such additional terms and conditions as the Administrator deems appropriate.

14. Adjustments; Dissolution or Liquidation; Merger or Change in Control.

(a) Adjustments. In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or

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exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the Plan, shall adjust the number and class of Shares that may be delivered under the Plan and/or the number, class, and price of Shares covered by each outstanding Award, the numerical Share limits in Section 3 of the Plan and the number of Shares issuable pursuant to Awards to be granted under Section 11.

(b) Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, the Administrator will notify each Participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it has not been previously exercised, an Award will terminate immediately prior to the consummation of such proposed action.

(c) Change in Control. In the event of a merger or Change in Control, each outstanding Award will be treated as the Administrator determines, including, without limitation, that each Award be assumed or an equivalent option or right substituted by the successor corporation or a Parent or Subsidiary of the successor corporation. The Administrator shall not be required to treat all Awards similarly in the transaction.

In the event that the successor corporation does not assume or substitute for the Award, the Participant will fully vest in and have the right to exercise all of his or her outstanding Options and Stock Appreciation Rights, including Shares as to which such Awards would not otherwise be vested or exercisable, all restrictions on Restricted Stock and Restricted Stock Units will lapse, and, with respect to Awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met. In addition, if an Option or Stock Appreciation Right is not assumed or substituted in the event of a Change in Control, the Administrator will notify the Participant in writing or electronically that the Option or Stock Appreciation Right will be exercisable for a period of time determined by the Administrator in its sole discretion, and the Option or Stock Appreciation Right will terminate upon the expiration of such period.

For the purposes of this subsection (c), an Award will be considered assumed if, following the Change in Control, the Award confers the right to purchase or receive, for each Share subject to the Award immediately prior to the Change in Control, the consideration (whether stock, cash, or other securities or property) received in the Change in Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the Change in Control is not solely common stock of the successor corporation or its Parent, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of an Option or Stock Appreciation Right or upon the payout of a Restricted Stock Unit, Performance Unit or Performance Share, for each Share subject to such Award, to be solely common stock of the successor corporation or its Parent equal in fair market value to the per share consideration received by holders of Common Stock in the Change in Control.

Notwithstanding anything in this Section 14(c) to the contrary, an Award that vests, is earned or paid-out upon the satisfaction of one or more performance goals will not be considered assumed if the Company or its successor modifies any of such performance goals without the

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Participant' s consent; provided, however, a modification to such performance goals only to reflect the successor corporation' s post-Change in Control corporate structure will not be deemed to invalidate an otherwise valid Award assumption.

(d) Outside Director Awards. With respect to Awards granted to an Outside Director that are assumed or substituted for, if on the date of or following such assumption or substitution the Participant' s status as a Director or a director of the successor corporation, as applicable, is terminated other than upon a voluntary resignation by the Participant (unless such resignation is at the request of the acquirer), then the Participant will fully vest in and have the right to exercise Options and/or Stock Appreciation Rights as to all of the Shares underlying such Award, including those Shares which would not otherwise be vested or exercisable, all restrictions on Restricted Stock and Restricted Stock Units will lapse, and, with respect to Performance Units and Performance Shares, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met.

15. Tax Withholding.

(a) Withholding Requirements. Prior to the delivery of any Shares or cash pursuant to an Award (or exercise thereof), the Company will have the power and the right to deduct or withhold, or require a Participant to remit to the Company, an amount sufficient to satisfy federal, state, local, foreign or other taxes (including the Participant' s FICA obligation) required to be withheld with respect to such Award (or exercise thereof).

(b) Withholding Arrangements. The Administrator, in its sole discretion and pursuant to such procedures as it may specify from time to time, may permit a Participant to satisfy such tax withholding obligation, in whole or in part by (without limitation) (a) paying cash, (b) electing to have the Company withhold otherwise deliverable cash or Shares having a Fair Market Value equal to the minimum statutory amount required to be withheld, or (c) delivering to the Company already-owned Shares having a Fair Market Value equal to the minimum statutory amount required to be withheld. The Fair Market Value of the Shares to be withheld or delivered will be determined as of the date that the taxes are required to be withheld.

16. No Effect on Employment or Service. Neither the Plan nor any Award will confer upon a Participant any right with respect to continuing the Participant' s relationship as a Service Provider with the Company, nor will they interfere in any way with the Participant' s right or the Company' s right to terminate such relationship at any time, with or without cause, to the extent permitted by Applicable Laws.

17. Date of Grant. The date of grant of an Award will be, for all purposes, the date on which the Administrator makes the determination granting such Award, or such other later date as is determined by the Administrator. Notice of the determination will be provided to each Participant within a reasonable time after the date of such grant.

18. Term of Plan. Subject to Section 22 of the Plan, the Plan will become effective upon its adoption by the Board. It will continue in effect for a term of ten (10) years from the date adopted by the Board, unless terminated earlier under Section 19 of the Plan.

19. Amendment and Termination of the Plan.

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(a) Amendment and Termination. The Board may at any time amend, alter, suspend or terminate the Plan.

(b) Stockholder Approval. The Company will obtain stockholder approval of any Plan amendment to the extent necessary and desirable to comply with Applicable Laws.

(c) Effect of Amendment or Termination. No amendment, alteration, suspension or termination of the Plan will impair the rights of any Participant, unless mutually agreed otherwise between the Participant and the Administrator, which agreement must be in writing and signed by the Participant and the Company. Termination of the Plan will not affect the Administrator' s ability to exercise the powers granted to it hereunder with respect to Awards granted under the Plan prior to the date of such termination.

20. Conditions Upon Issuance of Shares.

(a) Legal Compliance. Shares will not be issued pursuant to the exercise of an Award unless the exercise of such Award and the issuance and delivery of such Shares will comply with Applicable Laws and will be further subject to the approval of counsel for the Company with respect to such compliance.

(b) Investment Representations. As a condition to the exercise of an Award, the Company may require the person exercising such Award to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required.

21. Inability to Obtain Authority. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company' s counsel to be necessary to the lawful issuance and sale of any Shares hereunder, will relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority will not have been obtained.

22. Stockholder Approval. The Plan will be subject to approval by the stockholders of the Company within twelve (12) months after the date the Plan is adopted by the Board. Such stockholder approval will be obtained in the manner and to the degree required under Applicable Laws.

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 1 to the Registration Statement on Form S-1 of our report dated September 20, 2006 relating to the consolidated financial statements and financial statement schedule of St. Francis Medical Technologies, Inc., which appears in such Amendment No. 1 to the Registration Statement. We also consent to the reference to us under the heading "Experts" in such Amendment No. 1 to the Registration Statement.

/s/ PricewaterhouseCoopers LLP
San Jose, California
November 21, 2006

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