UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

(Mark One)

[X] **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2006 or

[ ] **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
Commission File Number 000-49804

Kyphon Inc.

(Exact name of registrant as specified in its charter)

Delaware	**77-0366069**
(State of incorporation)	(I.R.S. Employer Identification No.)

1221 Crossman Avenue
Sunnyvale, California 94089
(Address of principal executive offices, including Zip Code)

(408) 548-6500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
Common Stock, $0.001 par value	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
Not applicable

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES [X] NO [ ]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES [ ] NO [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such requirements for the past 90 days. YES [X] NO [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by a check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.
Large accelerated filer [X] Accelerated filer [ ] Non-accelerated filer [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
YES [ ] NO [X]

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2006 (which is the last business day of registrant's most recently completed second fiscal quarter), as reported on the NASDAQ Stock Market was approximately $983.3 million. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 15, 2007, the registrant had 45,362,409 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report.

KYPHON INC.
FISCAL YEAR 2006 ANNUAL REPORT ON FORM 10-K
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PART 1

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning our intentions, beliefs and expectations regarding our future growth, levels of expenses and operating results; developments in Medicare and third-party payor coverage and reimbursement of our products; the timing and success of our clinical trials and regulatory submissions; our belief that our cash and cash equivalents will be sufficient to satisfy our anticipated cash requirements; our expectations regarding our revenues and customers; our distributors and territorial expansion efforts; our planned or proposed acquisitions of technologies or businesses; and our plans to pursue research, development and commercialization of additional spine products developed internally or arising from acquisitions. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in Item 1A of this Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.

ITEM 1. BUSINESS

Overview

Kyphon Inc., a Delaware corporation founded in 1994 and headquartered in Sunnyvale, California, is a global medical device company specializing in the design, manufacture and marketing of medical devices to treat and restore spinal anatomy and diagnose the source of low back pain using minimally invasive technology.

With the acquisition of InnoSpine, Inc. in early 2006, and St. Francis Medical Technologies, Inc. in early 2007, and the proposed acquisitions of certain assets of Disc-O-Tech Medical Technologies, Ltd. and its U.S. subsidiary (which we refer to as Disc-O-Tech) (assuming we obtain regulatory approval and we complete the acquisitions), we will have three product platforms: Spinal Fracture Management and Repair, Disc Disease Diagnosis and Therapies and Spinal Motion Preservation. All three product families will be sold and supported through our existing sales organizations in North America and Europe, in addition to distributors in selected areas outside the U.S.

We define these three product platforms as follows:

- ***Spinal Fracture Management and Repair***: Our focus in this area is to treat spinal fractures, including vertebral compression fractures due to osteoporosis, cancer and trauma with minimally invasive technology. Our goals in developing products for Spinal Fracture Management and Repair are to provide clinicians with highly effective, minimally invasive devices to treat their patients, in order to relieve the patients' pain, restore mobility and recreate the natural anatomic structure. We consider this to be our core business based upon our history in balloon kyphoplasty, and we are continually seeking to expand the range of products we offer to clinicians in this area.

- ***Disc Disease Diagnosis and Therapies***: Our product franchise in this area is intended to assist clinicians in diagnosis and treatment of degenerative disc disease. Our goal in this product area is two-fold: to develop improved diagnostic tools to assist the clinician in identifying the source of a patient's pain, and to develop minimally invasive devices for treatment of degenerative disc disease. Our acquisition of InnoSpine, Inc. provides us with a diagnostic platform in this area, and we are committed to developing or acquiring additional technologies to provide minimally invasive approaches to treating the degenerated disc. Our proposed acquisition of the non-vertebroplasty assets of Disc-O-Tech Medical Technologies, Ltd. (assuming we obtain regulatory approval and complete the acquisition) will provide us with an initial platform for minimally invasive spinal fusion.

- ***Spinal Motion Preservation***: We seek to provide physicians with minimally invasive approaches to treat lumbar spinal stenosis (LSS). Our acquisition of St. Francis Medical Technologies, Inc. provides us with the first FDA-approved minimally invasive device for the treatment of neurogenic intermittent claudication in mild to moderate LSS patients. In Europe, we are in the initial stages of launching the *Aperius*™ PercLID™ device, our internally developed product for the treatment of LSS.

As of December 31, 2006, we believe we have trained approximately 10,400 physicians in North America, Europe and Asia-Pacific on the balloon kyphoplasty technique, and these physicians had used our instruments to treat approximately 285,000 patients and 335,000 spinal fractures. To support these physicians, we have built a large and growing worldwide direct sales organization that numbered approximately 480 field-based sales professionals as of December 31, 2006. Balloon kyphoplasty treatment of spinal compression fractures has been shown to result in significant patient benefits, including reduction of spinal deformity, increased mobility and improved quality of life. The risks of procedures using our instruments include the same risks common to performing surgery using anaesthesia and to performing surgery on older patients. In addition, like other spine surgeries, procedures using our instruments may result in serious complications, including embolization, cardiac arrest, cerebrovascular accident, myocardial infraction, nerve injury, paralysis and death. However, balloon kyphoplasty has been demonstrated to have a low complication rate.

In February 2003, we acquired Sanatis GmbH, a privately held developer and manufacturer of orthopaedic biomaterials based in Rosbach, Germany. This acquisition provided us with a core competency in biomaterials and represented a strategic response to surgeons' expressed desire to use materials that resorb or remodel into bone in traumatic fracture patients rather than using more traditional bone filler materials. We obtained a CE Mark (a mark that allows us to market a product throughout the European Union) for our first product from the acquisition of Sanatis, our *KyphOs*™ calcium phosphate cement, in December 2003, and we are now authorized to sell this material in Europe.

In January 2006, we acquired InnoSpine, Inc., or InnoSpine, a company focused on developing and marketing its proprietary technology platform for the diagnosis and potential treatment of axial low back pain due to disc degeneration. InnoSpine's initial technology, which was cleared for marketing by the Food and Drug Administration (FDA) in April 2005, was developed with the aim of improving the results available from existing discography techniques through a novel diagnostic method known as the *Functional Anaesthetic Discography*™ (F.A.D.) procedure, which involves a single-use disposable device with no capital equipment requirements. In contrast to traditional provocative discography which relies on delivery of fluid under pressure to provoke pain in a disc while the patient is prone, the F.A.D. procedure is a unique, minimally invasive procedure that utilizes a catheter-based system anchored in the disc space to deliver mild anaesthetic to a candidate disc while the patient loads his or her spine in positions that cause pain. If the pain sensations from normal loading are relieved by anaesthetic delivery to the degenerated disc, then the disc can be identified for further treatment. We began a limited commercial launch in the U.S. of our *Discyphor*™ system for practicing the F.A.D. procedure in the third quarter of 2006.

In January 2007, we acquired St. Francis Medical Technologies, Inc., or St. Francis, a company that manufactures the *X-STOP* Interspinous Process Decompression (*IPD*®) System, the first FDA-approved interspinous process device for treating lumbar spinal stenosis (LSS), for $525.0 million in cash, plus additional revenue-based contingent payments of up to $200.0 million payable in either cash or a combination of cash and stock, at our election in 2008. The *X-STOP IPD* System received a CE mark in Europe in 2001 and has been commercially available since December 2002. We closed our acquisition of St. Francis in January 2007. The *X-STOP* technology is complementary to our own extension limiting technology for the treatment of LSS, our next-generation, percutaneous *Aperius* PercLID device, which we commercially launched in a very limited manner in late 2006 in Europe, for the purpose of conducting physician preference testing.

In December 2006, we agreed to acquire the non-vertebroplasty, spine-related product assets and associated intellectual property rights of Disc-O-Tech Medical Technologies, Ltd., a privately held Israeli company, and its U.S. subsidiary (which we refer to together as Disc-O-Tech), and made cash payments of $100.0

million as purchase consideration. We also agreed to acquire all of Disc-O-Tech's vertebroplasty assets and related intellectual property rights for a total of another $120.0 million, payable in three equal annual installments beginning January 2008. An additional $20.0 million in contingent payments, plus royalties, may also be paid based on the development of further technologies following closing of the second agreement. Completion of the transactions is subject to various conditions, including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, or HSR Act. The Federal Trade Commission has issued second requests for information with respect to its review of our acquisition of the non-vertebroplasty assets and our acquisition of the vertebroplasty assets. The purchase price under both agreements is payable even if regulatory approvals are delayed or not obtained. There can be no assurance that the Federal Trade Commission will not block our purchase of all or any of the assets under either purchase agreement, or that we will otherwise complete all or part of the acquisitions. We may have to divest or license to third parties some or all of the assets proposed to be acquired, which may be detrimental to our business and our ability to recoup our material investment in the assets subject to this agreement.

Completion of the non-vertebroplasty transaction, if and when that occurs, will enable us to further broaden our focus in minimally invasive spine by adding the *B-Twin*™ Expandable Spinal System technology for minimally invasive fusion in patients with degenerative disc disease in the lumbar and cervical spine. This technology is CE marked and available in Europe, but not presently available in the United States. Back pain affects four out of five persons in the United States at some point in their lives, with more than 150,000 lumbar and nearly 200,000 cervical spinal fusions performed each year to treat common spinal conditions such as degenerative disc disease and spondylolisthesis (misaligned vertebrae). The non-vertebroplasty assets also include Disc-O-Tech's SKy™ Bone Expander System, which is available only outside the U.S. for use in the treatment of vertebral compression fractures. The vertebroplasty assets include Disc-O-Tech's Confidence™ Cement System, which will be another treatment option complementary to our existing *KyphX* technology for vertebral compression fractures depending on a patient's individual needs and a clinician's goals for his or her patients. The Confidence System incorporates a delivery mechanism that is designed to provide controlled injection of putty-like cement, reduce clinician radiation exposure and streamline cement preparation. Our ability to offer such additional minimally invasive diagnostic and therapeutic tools to our customers is a natural next step in broadening our product offerings.

We intend to pursue the research, development and commercialization of spine products arising from these acquisitions, and we may also choose to do so based on our licenses to various portfolios of patents we have acquired, including from Bonutti Research in August 2002, Dr. J. Lee Berger in April 2005, and Dr. Harvinder Sandhu in November 2005, as well as other product initiatives, to complement our existing *KyphX* and *Discyphor* instruments and to leverage our experienced sales force and expertise in spinal fracture treatments. The full commercialization of products from these acquisitions will require additional research, development, and regulatory approvals and/or clearances, and may require clinical studies prior to market launch in the U.S. and/or abroad. In addition, we may pursue additional acquisitions, including acquisitions of non-spinal fracture treatment technologies or biologics as well as technologies having application elsewhere in the spine, as appropriate and consistent with our long-term vision for Kyphon.

Spinal Fracture Management and Repair

Anatomy and Prevalence of Vertebral Compression Fractures

The spinal column contains 24 bones called vertebrae. Each vertebra consists of a large block of bone, called the vertebral body, which helps maintain upright posture. The vertebral body consists of soft inner, or cancellous, bone surrounded by a thin outer shell of hard, or cortical, bone. The soft tissue between each vertebral body is generally referred to as the intervertebral (spinal) disc. Each vertebra also has bone segments that extend out from the vertebral body, called the posterior elements, which surround and protect the spinal cord. Balloon kyphoplasty and vertebroplasty treat compression fractures of the vertebral body, known as vertebral compression fractures.

We believe there are approximately 700,000 clinically-diagnosed vertebral compression fractures in

approximately 550,000 patients each year due to osteoporosis in North America, Europe and Japan. Osteoporosis is a disease that primarily affects women and men over the age of 50, and is characterized by bone deterioration that leads to an increased susceptibility to such fractures. These fractures can result in significant pain, reduced physical function and diminished quality of life. They can also result in a forward curvature of the spine, kyphosis, which can decrease lung function and is associated with an increased risk of death. We also estimate that each year in North America, Europe and Japan, 150,000 fractures occur in 50,000 cancer patients due to the cancer or its treatments, also with debilitating consequences. Multiple myeloma, a cancer of blood cells that affects bone, and the spread of various cancers into bone, are the most common causes of spinal fracture due to cancer. Additionally, we estimate that there are 100,000 patients per year in North America, Europe and Japan that suffer traumatic vertebral compression fractures which may be treatable with minimally invasive techniques similar to the treatments for fractures caused by osteoporosis and cancer.

Consequences of Vertebral Compression Fractures

When the spine is structurally weakened, routine downward pressure can cause a vertebral body to collapse and fracture. These fractures are referred to as vertebral compression fractures. Fractures of the vertebral body, located at the front of the spinal column, can cause the spine to tilt forward. Over time, these fractures can result in a curved deformity of the spine and a forward-stooped posture called kyphosis. Vertebral compression fractures are caused primarily by deterioration of the inner cancellous bone due to osteoporosis. Other causes of spinal fractures include trauma, cancerous and benign tumors and infection.

Unrepaired spinal fractures can result in serious physical and emotional consequences, including:

- *Increased Risk of Mortality*. In a 2000 study of 6,459 women with osteoporosis followed for 3.8 years, those women who sustained a spinal fracture during the study were 8.7 times more likely to die during the time period of the study than those women who did not experience a fracture.

- *Acute and Chronic Pain*. Acute back pain is common to patients suffering from spinal fractures whether caused by osteoporosis, trauma or cancer. In addition, the spine deformity caused by these fractures can change the position of muscles and ligaments, leading to chronic pain. In a 1998 study of 7,223 women over the age of 65, those who had a single unrepaired spinal fracture that had set in its collapsed position were two times more likely to suffer back pain than equivalently-aged women without spine deformity.

- *Health Effects Resulting from Organ Compression.* Fractured and collapsed vertebrae shorten and curve the spine, moving the ribs down toward the pelvis and compressing the chest and stomach. Compression of the lungs can create new, or worsen already existing, respiratory disorders, including lung disease and pneumonia. A German and a Canadian study published in the 1990s, involving a total of 108 participants, demonstrated that patients with spinal fractures showed a statistically significant decrease in lung capacity that correlated with spine deformity. In addition, kyphosis can lead to compression of the stomach and a resultant reduced appetite and weight loss.

- *Functional Limitation*. Spinal fractures can cause prolonged or permanent disability, reducing mobility and impairing other physical functions. Patients with spinal fractures can require significant assistance, including the use of walkers or other aids, during normal physical activities. In a 2001 study of 1,395 post-menopausal women, patients with one or more unrepaired spinal fractures scored significantly lower on a standardized test for physical function than those who had no fractures. The loss in quality of life increased with additional fractures. Multiple fractures are common in patients from cancers such as multiple myeloma.

- *Increased Risk of Additional Fractures.* The change in alignment of the spine can shift a patient's center of balance, increasing the risk of falls and additional fractures, particularly of the spine and hip. In a 1991 study of 1,098 post-menopausal women followed for 4.7 years, the presence of one spinal fracture increased the risk of subsequent spinal fractures by five times compared to the risk of someone suffering a first fracture. The presence of two or more spinal fractures increased the

risk of additional spinal fractures by 12 times in the same timeframe. In addition, a 2001 study prospectively following 6,788 women over the age of 50 for the incidence of osteoporotic fractures found that one or more spinal fractures increased the risk of hip fracture by 4.5 times, while the presence of two or more spinal fractures increased the risk of hip fracture by 7.2 times.

- *Emotional Effects*. Studies have demonstrated that the physical deformity caused by spinal fractures, and the resulting fear of falling, can create patient anxiety and clinical depression, leading to a reduction in normal daily and social activities.

Alternative Treatments of Spinal Fractures

When treating a patient with a spinal fracture, an orthopaedic surgeon's primary objective, as with any fracture, is to reduce the fracture, that is, to return the bone toward its pre-fracture position. While surgeons can use conventional orthopaedic surgical techniques to reduce and otherwise repair spinal fractures, such as traumatic fractures in younger patients, these procedures are highly invasive and especially risky for elderly patients. As a result, before the development of less invasive alternatives, physicians rarely referred their patients with osteoporosis and cancer for surgical procedures to repair spinal fractures, but instead prescribed therapies and treatments designed to simply manage the pain.

Patients suffering from spinal fractures caused by osteoporosis are subject to heightened risks during the performance of traditional spine surgery due to their advanced age and poor bone quality. Similar to patients with fractures due to osteoporosis, patients with fractures due to cancer are often poor surgical candidates and have been typically treated with pain management regimens only. Of the patients in our addressable traumatic fracture market, we believe that some are treated surgically today using more invasive open fracture reduction techniques and others are treated conservatively with non-surgical interventions.

The primary alternative treatment methods for vertebral compression fractures are as follows:

Non-Surgical Management. Due to the limitations of conventional surgery for patients with spinal fractures, the majority of these patients are treated with conservative physical rehabilitation and pain management therapies. These methods do not involve surgical intervention and do not repair the fractured spine. These conservative therapies can comprise many techniques, alone or in combination, including:

- bed rest, in the hospital or at home;
- prescription and over-the-counter pain medication;
- back braces;
- home healthcare;
- physical therapy;
- exercise;
- chiropractic care; and
- radiation in cancer patients.

Pain Management Therapies. These therapies are designed to provide pain relief while the fractured vertebra slowly sets in its collapsed position. Treatment periods can be lengthy, resulting in expensive hospital stays and follow-up care. These therapies can also worsen the underlying problem. For example, bed rest is known to cause bone and muscle loss, making recovery more difficult in elderly patients, and potentially leading to additional fractures. In addition, doctors report that patient compliance with these therapies is low because of the:

- prolonged nature of treatment;
- patients' reluctance to wear back braces;
- difficulty and pain associated with exercise and physical therapy; and
- inadequate pain reduction.

Vertebroplasty. Alternatively, physicians may opt to stabilize the fractured area with a treatment that has become known as vertebroplasty. Vertebroplasty does not restore the spinal anatomy, but is aimed simply at reducing the pain associated with the fracture. Because vertebroplasty freezes the vertebral body in its collapsed position, patients may continue to suffer the physical, emotional and quality of life problems associated with the unrepaired spinal fractures.

Conventional Spine Surgery. Spine surgery is complex and risky given the proximity of the surgical site to the spinal cord and major organs. Conventional spine surgery can repair fractured vertebrae and restore height, but is highly invasive and involves significant risks. These surgeries involve making long incisions in the patient's chest or back so that stainless steel instruments can move the fractured bones back into their normal position. However, the instruments used in these surgeries are not optimally designed to manipulate deteriorated osteoporotic bone. The fractured bones are then held in place by metal implants, which, in the case of elderly patients with osteoporosis, can fail to hold due to the softness of the inner cancellous bone to which they are attached. As a result, this surgery is performed in very limited circumstances to treat osteoporosis-related vertebral compression fractures. The invasiveness of conventional spine surgery may lead to death, additional spinal cord injury, extensive post-operative hospital stays and prolonged bed rest for recovery. Additional complications may include bowel, lung and nerve damage, pain, embolization, infection and blood clots. Due to these risks, among others, conventional spine surgery is rarely performed to treat osteoporosis and cancer-related fractures, and is used to treat only a portion of the trauma-related fractures.

The Kyphon Solution for Treatment of Vertebral Compression Fractures

Kyphon provides surgeons with procedural solutions for repairing fractures during minimally invasive spine surgery known as balloon kyphoplasty. Our instruments have also been used in open surgical procedures. We generally refer to our instruments as the *KyphX* instruments.

Minimally invasive spinal fracture surgeries using our *KyphX* instruments typically involve the insertion of two of our disposable proprietary balloon devices into the fractured bone. The spine specialist inflates our balloons to compact and move the deteriorated bone. As a result of the inflation of the balloons, some or all of the collapse caused by the fracture may be reversed. This reversal can be more difficult if the bone has already begun healing in its fractured position. However, we have also developed products that facilitate treatment of chronic fractures that may have partially healed. After the bone has been moved, the balloons are removed, and the newly-created cavities are stabilized by filling them with the spine specialist's choice of bone filler material, typically a relatively viscous, plastic polymer bone cement that is introduced under low pressure and then hardens in place. We sell a proprietary bone cement known as *KyphX® HV-R™* bone cement for this purpose, which is both CE-Marked in Europe and cleared by the FDA in the U.S. for balloon kyphoplasty.

We have trained approximately 10,400 physicians, including 4,400 overseas in the use of our *KyphX* instruments. We believe these physicians have used our instruments to treat approximately 285,000 patients and 335,000 spinal fractures worldwide.

Balloon kyphoplasty has been reported to result in significant improved patient outcomes, including:

- vertebral body height restoration;
- angular deformity correction;
- vertebral body volume increase;
- significant reduction in back pain;
- significant reduction in the number of days per month that the patient remains in bed;
- significant improvement in the patient's quality of life;
- significant improvement in the patient's ability to perform the activities of daily living;
- high rates of patient satisfaction with the procedure;

- significant improvement in pain and mobility; and
- a low complication rate.

Currently, our FDA clearance permits us to promote in the United States our line of *KyphX*® Inflatable Bone Tamps, devices used to move and compact bone, for use as conventional bone tamps for the reduction of fractures and/or the creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with *KyphX HV-R* bone cement), hand, tibia (a leg bone), radius (an arm bone) and calcaneus (the heel bone).

KyphX HV-R bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

Recently, we concluded an extensive review of the published clinical literature describing the results for 1,947 patients treated with balloon kyphoplasty and 6,808 patients treated with vertebroplasty. The data in the published literature demonstrate that balloon kyphoplasty is associated with a statistically significantly lower procedure-related complication rate and a statistically significantly lower procedure-related bone cement complication rate, as compared to vertebroplasty, although bone cement leakage may still occur with balloon kyphoplasty. As a result, we have now introduced the corresponding comparative claims into our educational and marketing materials.

Our Products and Their Use During Minimally Invasive Balloon Kyphoplasty Spine Fracture Procedures

Spinal fracture procedures using our *KyphX* instruments are minimally invasive and are generally performed by spine-focused orthopaedic surgeons and neurosurgeons, as well as interventional radiologists and interventional neuroradiologists. A spine specialist first creates a working channel through the patient's back into the fractured vertebral body using one of our *KyphX* Bone Access Systems.

The physician then inserts one of our proprietary disposable *KyphX* Inflatable Bone Tamps into the fractured bone and carefully inflates it with fluid using X-ray images to monitor the procedure. The surgeon most often chooses to create a second access channel into the same vertebra being treated and inserts a second balloon into the other side of the vertebra. Surgeons can control inflation volume and pressure using our *KyphX* Inflation Syringe. Inflation of the balloons compacts the soft inner bone creating a cavity inside. When possible, this inflation also pushes the hard outer bone up toward its natural position, reducing the fracture.

The *KyphX* Inflatable Bone Tamps are then removed, and the surgeon chooses a bone filler material to insert into the void, typically our proprietary *KyphX HV-R* Bone Cement. Using the *KyphX* Bone Filler Device, the surgeon delivers the chosen bone filler material into the void under manual control and low pressure in an attempt to minimize the risk of leakage of the bone filler material into the spinal canal or the surrounding tissue.

Once the procedure is complete, the incisions are closed, typically with a small number of stitches. These procedures are usually performed in the operating room, but may also be performed in radiology suites or in ambulatory surgical centers. Surgeons choose local or general anesthesia based on the patient's health and preference and the number of fractures to be treated. The entire surgical procedure is usually performed in about one hour per fracture treated. Because the patients are often older, they are usually admitted for observation in an overnight hospital stay although the procedure may also be performed on an out-patient basis.

In December 2006, we signed two definitive agreements to acquire certain product assets and associated intellectual property rights of Disc-O-Tech. One of the transactions relates to, among other technologies and rights, the SKy Bone Expander System, which is available only outside the U.S. for use in the treatment of vertebral compression fractures.

Under the other agreement, we have agreed to acquire Disc-O-Tech's Confidence System and all related assets. We have not completed either of these acquisitions, and both are still subject to regulatory approval.

Our Spinal Fracture Management and Repair Products

We currently sell the following instruments, as well as our proprietary brands of bone filler materials which are used in spinal fracture procedures:

Product Category	**Description**	**Function**
KyphX Bone Access Systems (several varieties)	• Set of small disposable tools	• Create a working channel into fractured bone
KyphX Inflatable Bone Tamps (several varieties)	• Disposable balloon catheter	• Compact soft inner bone and move hard outer bone
KyphX Xpander Inflation Syringe	• Disposable syringe with rotating handle and pressure gauge	• Inflate the *KyphX* Inflatable Bone Tamps
KyphX Bone Filler Device	• Disposable stainless steel nozzle with inner rod and plastic handle	• Deliver bone filler materials into bone cavity
KyphX Bone Biopsy Device	• Disposable stainless steel tube and rod	• Take a sample of bone for evaluation purposes
KyphX Curettes (several varieties)	• Disposable stainless steel device with articulating tip	• Scrape or score bone in the spine
KyphX HV-R polymethylmethacrylate bone cement and *KyphOs* calcium phosphate	• Bone filler materials	• Bone filler materials used in balloon kyphoplasty procedures

If and when we are able to complete our acquisition of certain assets of Disc-O-Tech (which is still subject to regulatory approval), we will add the following instruments to our product line:

Product Category	**Description**	**Function**
SKy Bone Expander System	• Disposable, expandable polymer device	• Deploy within the soft inner bone of a vertebra
Confidence System	• Disposable cement injection system, including a PMMA bone filler material	• Inject thick cement into vertebral compression fractures where height restoration may not be desired or viewed by the treating physician as feasible

KyphX Bone Access Systems. Our *KyphX* Bone Access Systems are sterile sets of small disposable surgical tools used to access and create a working channel into the fractured bone. Our bone access systems are available in several varieties, including our *KyphX* Introducer Tool Kit, *Osteo Introducer* System and Advanced *Osteo Introducer* System. One version contains a long guide pin, an instrument used to separate tissue, and a small hand drill. In addition, it contains two small tubes through which other

tools are passed and a proprietary handle that can be used with multiple *KyphX* instruments. A second version combines the instrument used to separate tissue, the small tube through which other tools are passed and the proprietary handle into one tool. Alternative versions of this one tool can either be pushed or twisted into and through bone. All versions of the Bone Access System contain a sterile needle used to penetrate hard bone.

KyphX Inflatable Bone Tamps. Our proprietary *KyphX Xpander, Elevate, Exact* and *Express* Inflatable Bone Tamps are disposable sterile devices that combine the functionality of a metal bone tamp with the engineering principles of medical balloon technologies. Unlike other medical balloons, however, our balloons are specially designed to be used in bone. Other currently available medical balloons are not used in bone because they are not appropriate in size, shape or durability, or are not designed to provide lifting force.

Conventional bone tamps are rigid stainless steel instruments that move fractured hard bone and compact soft bone using indirect mechanical force. While it is the goal of orthopaedic surgeons to move a fractured area all at once, conventional bone tamps are not used to do this without a large incision and without significant tissue and bone disruption. Unlike other bone tamps, the *KyphX* Inflatable Bone Tamps contain a balloon that can be placed inside a fractured bone through a narrow working channel and expanded to move fractured bone all at once. Once inside, the balloon portion of the *KyphX* Inflatable Bone Tamp is carefully inflated under X-ray monitoring. This inflation applies direct lifting force to compact the soft inner bone and move the broken hard outer bone back towards its prefracture position.

KyphX Xpander Inflation Syringe. Our *KyphX Xpander* Inflation Syringe is a disposable sterile device with a rotating handle and a built-in pressure gauge that precisely controls the inflation of our *KyphX* Inflatable Bone Tamps. The rotating handle allows the surgeon to deliver a measured volume of the fluid that inflates the balloon.

KyphX Bone Filler Device. The *KyphX* Bone Filler Device is a disposable stainless steel nozzle with an inner rod and a plastic handle. *KyphX HV-R* bone cement can be loaded into the nozzle and pushed into the void with the inner rod under low pressure and fine manual control.

KyphX Bone Biopsy Device. Our *KyphX* Bone Biopsy Device is a disposable, stainless steel tube and rod that can be used to take biopsy samples of bone for further evaluation.

KyphX Curettes. Our *KyphX* Curettes are disposable, stainless steel devices with articulating tips that are used to scrape or score bone in the spine. Our *KyphX* Curettes are sold in various tip configurations and lengths.

KyphX Bone Filler Materials. We have developed our own *KyphX HV-R* polymethylmethacrylate (PMMA) bone cement with the appropriate handling characteristics for minimally invasive use in balloon kyphoplasty procedures in the spine. We obtained a CE Mark for our *KyphX HV-R* bone cement in October 2002 and began selling it in Europe to spine surgeons who use our *KyphX* instruments. We obtained FDA clearance for use of our *KyphX HV-R* bone cement as a bone filler material for balloon kyphoplasty in April 2004 and began immediate commercialization in the U.S.

We obtained a CE Mark for our first product from our acquisition of Sanatis GmbH, our *KyphOs* calcium phosphate cement, in December 2003, and started selling this bone filler material in Europe during 2004. In 2006, we obtained a CE Mark on *KyphOs-FS*, a new calcium phosphate cement, with shorter setting times and *KyphOs-FSR*, also a calcium phosphate cement, with a barium sulfate additive for increased radiopacity.

SKy Bone Expander System. The SKy Bone Expander is an expandable polymer device, intended for use in the treatment of thoracic and lumbar spine vertebral body compression fractures. The SKy Bone Expander is inserted into the collapsed vertebra in a reduced device configuration of 4 mm in diameter, and is then expanded to up to 14 mm or 16 mm in height. The SKy Bone Expander is removed and bone void filler is injected into the vertebral body. The SKy Bone Expander is currently available outside of the

United States, primarily through distributor sales organizations. Kyphon is evaluating plans to bring the product into current distribution channels, as well as to bring the core technology in the SKy Bone Expander System to the U.S. There are no defined plans to incorporate the product into Kyphon's current business in the U.S. and our proposed acquisition of Disc-O-Tech's SKy Bone Expander remains subject to regulatory clearance.

Confidence System. The Confidence System allows for the injection of highly viscous cement into a vertebral compression fracture. The Confidence System is placed into the fracture, and then highly viscous cement is injected into the vertebral compression fracture. Similar to balloon kyphoplasty procedures, the procedure is minimally invasive and can typically be performed in less than an hour. Because a balloon is not used in the typical Confidence System procedure, height restoration is not typically attained. The ability to inject high viscosity cement, and to do so while the surgeons hands are outside of the fluoroscopic field, are unique advantages of this product. We intend to incorporate these features into other products, in addition to marketing the Confidence System. Our proposed acquisition of Disc-O-Tech's Confidence System remains subject to regulatory clearance.

Our Strategy in Spinal Fracture Management Repair

Our mission is to become the recognized global leader in restoring spinal function through minimally invasive therapies. In particular, the key elements of our strategy in spinal fracture repair are to:

- *Establish Minimally Invasive Balloon Kyphoplasty Surgery Using Our KyphX Instruments as the Standard of Care for Spinal Fracture Repair*. We intend to support clinical trial efforts to establish that treating spinal fractures with balloon kyphoplasty using our *KyphX* instruments provides significantly improved patient outcomes versus the pain management therapies typically prescribed by physicians today.

- *Continue to Penetrate the Market for the Treatment of Spinal Fractures with Our Experienced Direct Sales Force*. Our instruments are sold in North America directly to hospitals by our experienced sales team. By leveraging their extensive medical device experience, our sales people are able to identify key physicians within these hospitals and provide effective customer assistance to continue the market adoption of our instruments. In Europe, our products are sold by our direct sales force located in the major countries of Europe as well as through agents or distributors. As of December 31, 2006, our direct field based spine sales organization included over 480 individuals in North America and Europe. We also sell our products in various other countries of the world through agents or distributors.

- *Educate Primary Care Physicians*. Patients with spinal fractures often are not referred to spine surgeons for treatment, but instead are prescribed pain management therapies by primary care physicians. Our objective is to educate primary care physicians and other medical advisers on the balloon kyphoplasty procedure as an alternative to conventional spinal fracture treatment and conservative pain management therapies. We have initiated various marketing programs aimed at raising the awareness about the clinical outcomes of balloon kyphoplasty in the primary care physician community, including direct advertising, attendance at medical meetings, and peer-to-peer educational forums.

- *Expand Marketing Claims*. We currently promote the use of our products and our bone cement for use in balloon kyphoplasty procedures, as well as the short- and long-term outcomes associated with the use of our products in balloon kyphoplasty. In Europe, we are conducting a post-marketing clinical study comparing balloon kyphoplasty to conventional treatments of bed rest, pain medication and bracing. The primary purpose for conducting the European study is to gather clinical data to support our sales and marketing efforts, as well as to support reimbursement for performing the balloon kyphoplasty procedure. Patient enrollment in this study was completed in December 2005, and we will continue to monitor these patients for two years of follow-up evaluations. We expect additional data may be available from this trial sometime during 2007. In addition, we have initiated, or plan to initiate, several additional U.S.-based, post-marketing

clinical studies to collect information on various other benefits and clinical applications of our *KyphX* instruments and our bone cement. We believe the results of these and other studies, if successful, may allow us to expand our marketing and third-party reimbursement efforts.

- *Develop and Introduce New Products to Address Different Indications.* Develop, obtain regulatory approval and introduce new tools, balloon and procedural kits to address different spinal fracture morphologies and indications including recalcitrant fractures and sacral insufficiency fractures.

- *Support Appropriate Levels of Facility and Physician Coverage and Reimbursement in the United States*. In all 50 states and in the District of Columbia, Medicare reimburses both facilities and physicians at varying payment levels for their services when they perform procedures using our *KyphX* instruments and our bone cement. We intend to use peer-reviewed physician journal articles, data from our European and U.S. trials and support from leading physicians who are familiar with the *KyphX* instruments to continue to support further appropriate levels of facility and physician coverage and reimbursement.

- *Expand our Global Commercial Reach*. Our *KyphX* instruments are currently available in North America, and in many European and Asia-Pacific countries. We are pursuing clinical, regulatory and reimbursement initiatives intended to facilitate the use of our *KyphX* instruments in additional countries throughout the world. Two important programs in this regard are to garner national reimbursement in major European counties such as France and the United Kingdom, as well as to gain regulatory and reimbursement approvals for our products in Japan. In Japan, we believe that over 500,000 spinal fractures occur each year due to osteoporosis, cancer and trauma and are treatable using our *KyphX* instruments during balloon kyphoplasty procedures. We will invest significant resources in our efforts to enter the Japanese market, including completing an 81-patient single-arm study currently underway to gain approval to market our products in that country, as well as hiring a direct sales organization to lead our programs.

Disc Disease Diagnosis and Therapies

Anatomy and Presence of Degenerative Disc Disease

We estimate that between 70% and 80% of the U.S. population experiences debilitating low back pain due to degenerative disc disease at least once in their lifetime. Discogenic pain, or pain originating in the intervertebral disc, in the lumbar spine is one of major contributors to low back pain. There are several reasons for this pain, including compression of the disc due to age or obesity, or herniation of the disc, where a small portion of the nucleus pulposus (biological material inside the disc) leaks out of the disc and irritates the spinal cord. Spine surgery, including spinal fusion and total disc arthroplasty, and other intradiscal interventions are increasingly being used to treat degenerative disc disease. We believe that, in the U.S. alone, over 200,000 lumbar spine interventions are performed annually to treat discogenic pain of the lumbar spine. However, outcomes from surgical interventions for this disease are unpredictable, with clinical success rates averaging between 50% and 70% in the published literature. We believe that incomplete diagnosis is one contributor to the poor success rates of lumbar spine interventions for degenerative disc disease.

Consequences of Degenerative Disc Disease

Degenerative disc disease is a term used to describe changes in intervertebral discs over time. Intervertebral discs are soft, compressible tissue that separates the vertebrae in the spine. The discs act as shock absorbers within the spine, allowing it to flex, bend, and twist. As people age, intervertebral discs break down, or degenerate. Although this deterioration of the discs, known as degenerative disc disease, can take place throughout the spine, it most often occurs in the discs in the lower back (lumbar region) and the lower part of the neck (cervical region). Typical consequences of disc degeneration include:

- *Loss of Fluid in the Affected Disc.* This results in making the disc less flexible and thereby reducing the ability of the disc to act as a shock absorber. Loss of fluid results in a narrowing of the disc, reducing the distance between adjacent vertebrae. Degenerative disc disease often results in microtears or fissures in the outer layers of the disc, or annulus. The jellylike material inside the disc, the nucleus pulposus, may be forced out through these microtears or fissures in the annulus, causing the disc to bulge or herniate. An acute injury may also begin the process of degenerative disc disease.

- *Discogenic Pain.* In some patients, degenerative disc disease results in pain originating from the disc, known as discogenic pain. Discogenic pain presents as persistent aching or stiffness in the spine, localized pain in the neck, upper back, or lower back, or chronic pain in the lower back, especially after sitting or standing for extended periods, or prolonged activity.

- *Reduction in Activity*. As with any chronic pain condition, patients are typically forced to adjust their lifestyle, and reduce their daily activities. Simple chores and tasks that were routine become difficult, and the patient may end up relying more and more upon caregivers and members of their family to help them with these formerly routine tasks.

Initial treatment regimens for discogenic low back pain typically involve non-operative therapies, including bed rest, pain medication, exercise, and physical therapy for a period of three to six months. If conservative care is not effective in addressing the symptoms, many patients receive injections of anesthetics and/or steroids to manage the pain non-operatively.

If these methods fail, many patients are offered spinal surgery. For patients suffering from chronic back pain caused by degenerative disc disease, spine fusion is the most common surgical treatment option recommended. Spine fusion involves the fusing of adjoining vertebrae in cases where the patient has advanced disc degeneration. The procedure involves a surgical incision in the patient's back or abdomen, removal of the affected disc and the insertion of bone graft, metal implants and/or a spine fusion cage to join the two adjacent vertebrae. This procedure is designed to stabilize the spinal segment, thereby relieving the pain associated with the affected disc. The risks of spinal fusion surgery include blood loss and infection, as well as an extended recovery time for most patients.

Alternative Means of Diagnosing Discogenic Pain

Typical means of diagnosis of discogenic back pain include imaging studies and/or provocative discography:

Imaging Studies. The vast majority of physicians who diagnose patients suspected of suffering from discogenic low back pain utilize Magnetic Resonance Imaging (MRI) as the initial diagnostic study. Use of MRI in these patients indicates which intervertebral discs are degenerated, resulting in a condition known as degenerative disc disease. However, the clinical literature indicates that many patients with degenerative disc disease do not suffer from low back pain, and conversely, intervertebral discs that are painful do not always appear to be degenerated in MRI.

Provocative Discography. Many patients also undergo an interventional diagnostic procedure known as provocative discography (or discogram) to determine which, if any, discs are causing the patient's low back pain. Provocative discography involves the injection of a radiopaque contrast agent, under pressure, into the suspected discs with the aid of fluoroscopic imaging. The primary goal of provocative discography is to reproduce the patient's usual pain by pressurizing the suspected discs individually. This pressurization is thought to mimic the pressure created on the disc when the patient performs the activities that cause pain for the patient. The pain caused during the discography is described as similar (concordant) or dissimilar (discordant) to the pain the patient typically experiences. If the pain is similar, the disc at that level is often determined to be positive for discogenic pain, and if the pain is dissimilar, the test is often determined to be negative. If no pain is generated during the injection, the test is determined to be negative.

Additionally, the radiopaque contrast agent allows the clinician to image the anatomy of the disc by observing the flow and distribution of contrast as it is injected into the disc space.

Recent publications suggest that provocative discography can be positive in patients without low back pain and also in patients who have back pain that is known to be non-discogenic. As a result, we believe that an additional diagnostic procedure may be useful in diagnosing discogenic low back pain.

The Kyphon Solution for Diagnosis of Discogenic Back Pain: Discyphor™ Catheter for Functional Anaesthetic Discography™

Kyphon acquired the *Discyphor* product line from InnoSpine in January 2006. These products are used in a procedure known as Functional Anaesthetic Discography™ (F.A.D.), which is a diagnostic procedure designed to determine if an intervertebral disc is a source of low back pain in adults. The core balloon catheter technology was cleared by the FDA in April 2005 pursuant to a 510(k) submission for delivery of local anaesthetic, radiopaque contrast or saline solution to the intradiscal space.

The F.A.D. Procedure involves the placement of *Discyphor* Catheter(s) into one or more intervertebral discs suspected to be potential pain generators. Provocative discography may be performed at each suspected level prior to the F.A.D. procedure at these levels.

Our Products and Their Use for the Diagnosis of Discogenic Back Pain

To begin a functional anaesthetic discogram, the patient is first asked to perform activities that exacerbate his/her typical low back pain. Anaesthetic is then injected into one suspected intervertebral disc at a time. If the patient experiences pain relief following anaesthetic injection while performing the activities that are typically painful, the injected disc(s) are concluded to be pain generators. If a patient does not experience pain relief following anaesthetic injection while performing the pain-eliciting activities, the injected disc(s) are not considered to be pain generators. To date, over 650 F.A.D. procedures have been performed by over 100 clinicians, including pain management physicians, interventional radiologists, and spine surgeons.

We currently sell the following instruments used in disc disease diagnosis:

Product Category	**Description**	**Function**
Discyphor Catheter System	Disposable balloon catheter and related access and inflation products	Create access to an intervertebral disc for injection of anaesthetic/saline
Discyphor Introducer Needle	Custom disposable spinal access needle	Create access to an intervertebral disc
Discyphor Spinal Needle	Disposable spinal needle	Perform provocative discography and facilitate placement of *Discyphor* Catheter

Our Strategy for Building our Discogenic Back Pain Diagnosis Business

Our goal is to make the ***Discyphor*™ Functional Anaesthetic Discography™ (F.A.D.) procedure** the standard interventional diagnostic procedure for diagnosing the source of low back pain. The specific elements of our strategy for F.A.D. include the following:

- *Grow our base of users of the Discyphor Catheter System*. Over 100 clinicians, including pain management physicians, interventional radiologists, and spine surgeons, utilized the Discyphor product line to perform F.A.D. procedures during 2006. We intend to expand the number of

clinicians who are performing F.A.D. procedures by additional dedicated sales efforts in high-potential geographic areas.

- *Initiate Clinical Trials to Support Expanded Indications for Discyphor Products*. We intend to conduct clinical trials that support expanded marketing claims surrounding F.A.D. procedures, including:
  - ❖ comparative diagnostic claims with provocative discography, and
  - ❖ claims surrounding predictive value of F.A.D. on surgical interventional outcomes for discogenic pain.

  During 2007, we plan to initiate a prospective trial designed to document the diagnostic outcomes of F.A.D. and provocative discography when performed on the same intervertebral level. Outcomes from this study will be considered when designing a randomized study to compare the value of F.A.D compared to provocative discography in predicting surgical outcomes for patients with low back pain.

- *Establish Specific Reimbursement Guidelines for F.A.D.* F.A.D. procedures are currently reimbursed under existing unlisted codes. We intend to use forthcoming peer reviewed clinical publications on F.A.D., in conjunction with the results from Kyphon-sponsored clinical studies, to support establishment of specific reimbursement guidelines from Medicare and third party payers to appropriately compensate physicians and facilities for performing F.A.D. procedures.

- *Develop Next Generation Discyphor Product Lines*. We believe that potential exists for improving the procedural speed and reducing the risk of complication of the *Discyphor* products acquired from InnoSpine. We intend to develop next-generation products that meet established user needs and enable increased utilization of our *Discyphor* Catheter System by the physician group currently performing interventional diagnostic procedures.

Market Opportunity for Minimally Invasive Lumbar Spinal Fusion

Spinal fusion is the most common surgical procedure for the treatment of painful degenerative disc disease (DDD) resulting in chronic low back pain. Kyphon estimates that the U.S. spinal fusion market included over 300,000 procedures in 2006, comprised of 200,000 lumbar procedures and 100,000 cervical procedures. Current spinal fusion products require implantation through open back and abdomen surgery, which results in high levels of blood loss and infection risk, as well as extended patient recovery time. We believe that a percutaneous solution can provide potential advantages such as less blood loss, reduced tissue and muscle trauma, lowered risk of neurological damage and infection, and shorter procedure and recovery time. In addition, a percutaneous fusion procedure may enable spine specialists to treat those patients who ordinarily may not be good candidates for a traditional open and invasive fusion procedure.

The Kyphon Solution for Minimally Invasive Lumbar Spinal Fusion

Our proposed acquisition of Disc-O-Tech's percutaneous *B-Twin* Expandable Spinal fusion technology (which has not yet been completed and remains subject to regulatory approval) will provide us with a minimally invasive product line for lumbar spinal fusion, a procedure undertaken for patients with severe degenerative disc disease and spondylolisthesis. Although a CE mark for the *B-Twin* Expandable Spinal fusion technology was obtained in August 2001, this technology is not currently available in the United States. The minimally invasive fusion procedure is intended to result in less trauma to the patient than alternative surgical procedures. In addition, the *B-Twin* procedure is believed to be simpler and more straightforward for the spine surgeon to perform than other surgical alternatives. The *B-Twin* System is a minimally invasive titanium device for use in percutaneous spinal fusion procedures for treatment of painful degenerative disc disease in the lumbar spine (lower back) and cervical spine (neck). The system is the only percutaneous interbody cage on the market, and has been used in percutaneous spinal fusion procedures, as well as mini open posterior, lumbar interbody fusion (PLIF) procedures.

The Use of the B-Twin Expandable Spinal System During Minimally Invasive Spinal Fusion

The *B-Twin* Expandable Spinal System is used in conjunction with bone graft or other suitable materials as a stand-alone implant for spinal stabilization during lumbar spinal fusion surgery, as well as in conjunction with additional traditional or minimally invasive spinal implants. The non-expanded *B-Twin* implant is preloaded on a single use Delivery System. Following discectomy (disc removal), endplate preparation (scratching) and bone graft insertion, the *B-Twin* implant is introduced into the intervertebral space using the Delivery System. Once in position, it is expanded and then released from the Delivery System. Using the same procedure, a second equal-size *B-Twin* implant is introduced into the contralateral side of the same intervertebral space. The *B-Twin* Expandable Spinal System is implanted using an open posterior, open anterior or posterior-lateral percutaneous surgical approach. The *B-Twin* Expandable Spinal System is introduced into the intervertebral space, following discectomy, in a narrow configuration of 5 mm in diameter. It can then be expanded to a size range of 7.5 to 15 mm in diameter, depending upon the size chosen by the physician.

The Cervical *B-Twin* Expandable Spinal System utilizes similar technology to the lumbar product, and is intended for use in cervical interbody fusion procedures, with bone graft, in skeletally mature patients with degenerative disc disease of the cervical spine, at one or two levels. The implantation procedure is performed via a percutaneous approach through a 4.3 mm cannula (working sleeve). Following placement of bone graft, the Cervical *B-Twin* Expandable Spinal System is introduced into the intervertebral space in its reduced diameter of 3.3 mm, and is then gradually expanded in a controlled manner to 8 mm. Following its expansion, the Cervical *B-Twin* is released from its Delivery System. Using the same procedure, a second device may be introduced.

The *B-Twin* technology offers certain potential advantages over existing spinal fusion products.

- *Percutaneous Procedure.* The *B-Twin* expandable technology allows physicians to insert the lumbar and cervical products percutaneously, in an anterior, posterior or posterior lateral approach, as opposed to current spinal cages which require open back, abdomen or neck surgery. This difference reduces surgery time and patient recovery time, risk of infection, and blood loss.

- *Minimizes Bone Dissection.* The low profile of the *B-Twin* System in the contracted state allows the device to be inserted into the space between two vertebral bodies without disrupting the bone and tissue surrounding the vertebrae, reducing trauma to surrounding muscle, tissue and ligament encasing the spinal column.

- *Ease of Use.* The *B-Twin* System includes a preloaded implant in the single-use delivery instrument ready for percutaneous spine surgery, without requiring open back or abdomen surgery.

- *Most Procedures Can Now be Performed Posteriorly.* A significant challenge often facing spine surgeons and their patients is the access route to the patient's disc. Often, the disc is approached anteriorly (from the front), requiring a large incision in the patient's abdomen and a surgical procedure in the front part of the patient's disc. When this is completed, the surgical wound in the patient's abdomen is sutured, and the patient is then placed on his/her stomach, for the placement of pedicle screws and rod in the spine. With the *B-Twin*, the vast majority of patients can avoid the anterior access, and have the entire procedure performed through the posterior access route.

Our Strategy for Entering the Fusion Market

The following describes our strategy for entering the fusion market when and if we complete the acquisition of these assets from Disc-o-Tech:

- *Continue Penetration of International Markets.* The *B-Twin* product line is currently available in 30 countries outside of the U.S. though a network of distributors. These distributors have supported over 13,000 *B-Twin* implantations since product introduction in 2001. Upon completion of our acquisition of the *B-Twin* product line (subject to regulatory approval), Kyphon plans to continue to support these distributors as part of the existing

distributor relationships. Over time, we intend to offer this product platform through our direct sales channel in Europe.

- *Introduce the B-Twin Technology to U.S. Markets*. The *B-Twin* products are currently not available in the U.S. We are evaluating our regulatory and clinical strategy for introducing the technology to the U.S., including initiation of clinical trials, upon completion of our proposed acquisition of the *B-Twin* product line. At this time, the FDA is evaluating the down-classification of interbody cages from Class III to Class II devices. If this occurs, we intend to work with the FDA to understand the regulatory pathway for bringing the *B-Twin* technology to the U.S. market.

- *Develop a Minimally Invasive Fusion Product Line.* The *B-Twin* device represents only one category of devices that is utilized in fusion surgery. In most cases, the placement of a *B-Twin* device has also required the use of posterior stabilization devices such as pedicle screws and rods. Kyphon does not currently market a posterior stabilization product line, and we are therefore, dependent upon the physician selecting these products from other vendors. Our goal is to develop a product solution that is entirely minimally invasive but this may be in conjunction with other vendors or entirely a Kyphon solution.

Spinal Motion Preservation

Our recent acquisition of St. Francis provides us with the *X-STOP* Interspinous Process Decompression (*IPD*) System, the first FDA-approved product in the U.S. for the treatment of mild to moderate lumbar spinal stenosis, a narrowing of the space surrounding the spinal cord. This procedure is intended to provide the patient with less trauma and greater relief than alternative surgical procedures or conservative therapies can provide. In addition, the *X-STOP* procedure is believed to be simpler and more straightforward for the spine surgeon to perform than other surgical alternatives.

Anatomy and Prevalence of Lumbar Spinal Stenosis

With the acquisition of St. Francis we have entered the market for the treatment of lumbar spinal stenosis (LSS). 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 United States population as well as increases in the prevalence of obesity are expected to contribute to growth in the incidence of LSS.

Consequences of Lumbar Spinal Stenosis

Consequences of LSS are typical of a slowly progressing, chronic, painful disease state. Individuals suffering from this progressive disease typically enter into a cascade of decline in their quality of life. This cascade often progresses as follows:

- *Pain During Activity*: As LSS progresses, patients suffering from this disease begin to experience discomfort and pain in the lower extremities, during their everyday activity. Treated with analgesics, this early stage of the disease is often managed by the patient, and the pain ascribed simply to the effects of aging.

- *Reduction in Activity Due to Pain and Discomfort*: As the disease progresses, patients begin to reduce the overall activity in their lives due to the constant pain in the lower extremities. Still dismissed as the inevitable, untreatable effect of aging, it is common for people to suffer for years without treatment.

- *Restriction of Day to Day Activity*: As the disease takes its toll, sufferers are forced to restrict their daily activities even further, even eliminating simple daily tasks. It is not uncommon to see these individuals leaning forward for relief. A typical example would be a person leaning over a shopping cart and finding relief in the forward flexion of the spine. This is, in fact, a well established indication of lumbar spinal stenosis. At this point, many patients find the pain and discomfort intolerable and unmanageable through over the counter medications, and seek medical help from their physician.

Alternative Treatments for Lumbar Spinal Stenosis

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 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%.

We believe that the traditional treatment paradigm for LSS leaves 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.

The Kyphon Solution for Treatment of Lumbar Spinal Stenosis

Kyphon provides surgeons with a procedural solution to moderate LSS. The *X-STOP* Interspinous Process Decompression (IPD) System, 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* device 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* device 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 current Indication for Use of the *X-STOP IPD* System is as follows:

> *The X-STOP Interspinous Process Decompression (IPD) System ("X-STOP") is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with X-ray, MRI, and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing). The X-STOP is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/ groin pain, with or without back pain, and have undergone a regimen of at least 6 months of non-operative treatment. The X-STOP may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.*

We believe that the principal benefits of our *X-STOP* System are:

- *Efficacious, Motion-Preserving Therapy*. In a 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* device 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* device in the clinical study mentioned above 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 IPD* patients reported symptom relief and overall satisfaction with the *X-STOP* procedure that were similar to those reported by the laminectomy patients in the other study.

- *Less Invasive, Cost-Effective Procedure.* The *X-STOP* device 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* device can typically return home from the procedure

more quickly than patients undergoing a laminectomy. We believe the less invasive nature of the procedure, coupled with the shorter post-procedure recovery time relative to laminectomy, makes the *X-STOP IPD* 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.

- *May Enable Patients to Resume More Active Lifestyle*. The symptom relief provided by the *X-STOP IPD* 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* device 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* device is separated from the spinal cord by bone, which substantially reduces the risk of intraoperative injury to nerves or the spinal cord. During the 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 IPD* enables physicians to treat elderly patients or seriously ill patients who may have other co-morbidities that make more invasive surgery inadvisable or impossible.

The Use of the X-STOP System During Minimally Invasive Spine Surgery

Spinal surgery using our *X-STOP IPD* instruments is minimally invasive and generally performed by spine-focused orthopaedic surgeons and neurosurgeons. The procedure may be performed under local or general anesthesia as chosen by the surgeon based on the patient's health and preference. The procedure is usually performed 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 Implant 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 less than 90 minutes.

Our Products for Spinal Motion Preservation

X-STOP System: This system is the first less invasive, non-fusion motion-preserving device to receive FDA premarket approval for the treatment of lumbar spinal stenosis (LSS). We believe the *X-STOP* Interspinous Process Device represents a significant advancement in LSS treatment. The *X-STOP* IPD is a spinal implant designed to fit within the interspinous space. The *X-STOP* IPD 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* device enables it to be inserted without removing bone or ligaments, resulting in a procedure that can be performed under local anesthesia. The *X-STOP* device 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.

The *X-STOP* device 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* device is currently made either entirely from titanium or with titanium wings and a PEEK spacer. Our initial FDA premarket approval for the *X-STOP IPD* received in November 2005 was for a titanium device. We received FDA approval for the PEEK device in August 2006. Both versions of the *X-STOP IPD* are commercially available in Europe.

In addition to the *X-STOP* implant, there are a range of surgical instruments for use by the surgeon in implanting the *X-STOP* device. These surgical instruments include tissue dilators, a sizing distractor for determining the appropriate size of the *X-STOP* device 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 loaner basis or may be purchased directly by the hospital. The principal *X-STOP* surgical instruments include, small dilator, large dilator, sizing distractor, spacer insertion tool, wing insertion tool and hex driver for adjustable wing attachment.

Aperius PercLID System: The *Aperius* product represents the next generation in the treatment of Lumbar Spinal Stenosis. Developed internally by a team of Kyphon engineers, our *Aperius* technology is intended to further simplify the treatment of LSS, while providing the same benefits and mechanism of action as the *X-STOP* device. An expandable device, the *Aperius* implant is percutaneously placed between the spinous processes, and then expanded in place, to end in a position similar to the *X-STOP* device. In its expanded state, the *Aperius* implant is designed to stay in place, and not to migrate.

Similar to the *X-STOP* device, our *Aperius* product requires a specifically designed set of instrumentation for its placement. However, unlike the *X-STOP* device, the instrumentation to deliver the *Aperius* implant is not re-usable, and is discarded after each placement of the device. This single-use design enables the hospital to avoid the management and continuous processing and sterilization of a set of instruments, and simplifies the case preparation for the operating room staff and physicians.

Limited physician testing of our *Aperius* technology began in Europe in November 2006. We are carefully monitoring the initial clinical experience, and have had satisfactory results to date. We intend to continue to gather this clinical information, and to begin to aggressively market the *Aperius* technology in Europe in the first half of 2007. We have not yet formulated a regulatory strategy for our *Aperius* technology in the United States. While the final position in the body and likely indication of our *Aperius* and the *X-STOP* technologies are similar, we believe that a separate regulatory approval will be necessary for the *Aperius* product, which will require additional clinical studies.

Our Strategy for our Spinal Motion Preservation Business

The *X-STOP IPD* System allows us 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 in this area are as follows:

- *Establish Kyphon products as the Standard of Care for the Treatment of Moderate LSS in the U.S.* We believe that the advantages of the *X-STOP* system in clinical efficacy, procedure reversibility, 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* system 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 under-diagnosed and under treated, and we intend to educate physicians to raise awareness of LSS and available treatment alternatives, including the *X-STOP IPD*. As the U.S. population ages, we believe that this group will continue to pursue an active lifestyle 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 Indications for the X-STOP IPD System into New Markets.* Pre-clinical testing regarding the motion-preserving biomechanical properties of the *X-STOP IPD* System showed a significant reduction of facet loads and disc pressures. We believe that these characteristics may make the *X-STOP IPD* System a suitable treatment for low back pain and other degenerative spinal disorders.

- *Continue to Penetrate the Market for the Treatment of LSS with Our Experienced Direct Sales Force.* Our products are sold in the United States directly to hospitals by our experienced sales team. By leveraging their extensive medical device experience, our sales people are able to identify key physicians within these hospitals and provide effective customer assistance to continue the market adoption of our product. In Europe, our products are sold by our direct sales force located in the major countries of Europe as well as through agents or distributors. We also sell our products in various other countries of the world through agents or distributors.

- *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. 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.

- *Establish our Aperius Technology as the Next-Generation Product for the Treatment of Lumbar Spinal Stenosis.* We believe the *Aperius* product represents an attractive next generation product

for the treatment of LSS. With percutaneous placement, patient trauma and tissue disruption is minimized. In addition, procedural time is greatly reduced, reducing the length of time the patient is under general anaesthesia. The single-use nature of the instruments used to implant the *Aperius* device simplifies the procedural set-up for the hospital, and enables the hospital to avoid management of the instruments required to place the device.

- *Support Appropriate Levels of Facility and Physician Coverage and Reimbursement in the United States.* We intend to use peer-reviewed physician journal articles, data from our European and U.S. trials and support from leading physicians who are familiar with the *X-STOP* System to continue to support further appropriate levels of facility and physician coverage and reimbursement.

- *Expand our Global Commercial Reach.* Our *X-STOP* System is currently available in North America, and in many European and Asia-Pacific countries. We are pursuing clinical, regulatory and reimbursement initiatives intended to facilitate the use of the *X-STOP* System in additional countries throughout the world. Our *Aperius* product is in the initial stages of a limited launch in several countries in Europe. We intend to launch the *Aperius* device in a large number of countries outside the U.S. during 2007 and 2008. We also intend to formulate our U.S. strategy for our *Aperius* technology during 2007. Between these two products, we believe we have the most compelling motion-preserving technologies in the market, and a significant lead in the U.S. market.

Sales and Marketing of All of Our Products

We market and sell our Spinal Fracture Management and Repair, Disc Disease Diagnosis and Therapies, and Spinal Motion Preservation products through our direct sales force in the United States and Europe, which numbers approximately 480 field-based sales professionals as of December 31, 2006. In addition, for certain markets outside the United States, we market some or all of our products through sales agents or distributors who are not employees of the company. Our target customer base includes the approximately 21,000 physicians who perform spine surgery, including orthopaedic spine surgeons, neurosurgeons, interventional radiologists and interventional neuroradiologists in the U.S., Europe and other selected countries. No customer accounted for more than 10% of total net sales in 2006, 2005 or 2004.

Our U.S. sales organization is comprised of spine consultants who act as the primary customer contact. These spine consultants have extensive experience selling medical devices, generally focusing on emerging technologies. We expect we will need to continue to increase the size of our sales organization in order to increase sales and market penetration and to provide the significant, ongoing level of customer support required by our sales strategy. We have trained approximately 10,400 physicians in the U.S., Europe and Asia-Pacific to perform the balloon kyphoplasty procedure with our *KyphX* instruments. Approximately 1,400 physicians in the U.S. have been trained to perform the *X-STOP* procedure. We anticipate that physician training on the *X-STOP IPD* System will be a significant part of our strategy in 2007. Finally, approximately 100 physicians in the U.S. have been trained on the use of our *Discyphor* Catheter System for Functional Anaesthetic Discography.

We have operated mainly in the United States, and 79%, 84% and 88% of our sales were to customers located within the United States in 2006, 2005 and 2004, respectively. The majority of our international sales are derived from European Union countries. Our European operations are presently headquartered in Belgium with direct sales organizations in the major European countries. We anticipate continuing to build direct sales organizations in the major European countries while establishing distributor or agency arrangements in the smaller ones. We intend to follow a similar model in Europe to the one established in the United States, working with internationally recognized physicians initially as we expand our training, reimbursement and selling activities. We are also establishing an operational presence in Switzerland including manufacturing, distribution and certain research and development activities, to support the growth of our international business. In 2006, we initiated the construction of new office and warehouse space in Neuchâtel, Switzerland to replace the adjacent temporary facilities currently in use. We expect this to serve as the operational center of our international business, and expect it to be completed in the first

half of 2008.

We are still in the early stages of initiating the sales process in selected Asia-Pacific markets. We have initially trained surgeons and sold products in South Korea and China. In 2004, we formed our Japanese subsidiary, Kyphon Nippon KK, and have formulated and begun to execute on our clinical and regulatory plans for Japan. In addition, we have sold our products in Canada through a direct sales force, and in Brazil, Puerto Rico, Argentina, Chile and Mexico through distributors, and we have established a presence in certain additional Asian countries, South Africa and Australia. Overall, we now sell our products in over 40 countries around the world.

Other Business Initiatives

With our acquisitions of InnoSpine and St. Francis and our proposed acquisitions of certain spine-related assets of Disc-O-Tech (which have not yet been completed and remain subject to regulatory approval), we have moved beyond our original sole focus of Spinal Fracture Management and Repair, to also now include Disc Disease Diagnosis and Therapies and Spinal Motion Preservation. We have a variety of internal resources dedicated to supporting research and development in each of these areas, as well as potential business development opportunities. We also continue to examine additional areas in the minimally invasive treatment of spine diseases, such as cancer therapy aimed at addressing the actual cancerous conditions that affect the spine rather than merely the effects of those cancerous conditions. We believe all of these business initiatives provide further opportunity to grow our company in the area of minimally invasive spine.

We are committed to becoming the recognized global leader in restoring spinal function through minimally invasive therapies. With three leading product franchises in diagnosing and treating diseases of the spine, all of which are based upon minimally invasive approaches, we believe we are positioned as the leader in the minimally invasive spine field. To continue this leadership, we expect further organic development and business development opportunities will be required, and we are prepared to execute upon these opportunities as appropriate.

Reimbursement Overview

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 technology and related procedures are obtained from third-party payors. These third-party payors, and in particular managed care organizations, are increasingly challenging the prices charged for medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. These cost containment measures, if instituted in a manner affecting the coverage or payment for our technology, could adversely affect our business and our financial condition.

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 prove that our technology improves health outcomes, such as functional ability, and does so in a cost-effective manner.

Reimbursement for the Balloon Kyphoplasty Procedure

Approximately 90% of patients in the U.S. with spinal fractures caused by osteoporosis are insured under Medicare, while the rest are insured primarily by private payors. Most patients with spinal fractures caused by cancer and trauma are insured by private payors. Medicare and private payors have provided coverage and reimbursement for procedures in which our technology is used. Private payors often follow the coverage and payment policies of Medicare. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our technology 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). For both inpatient and outpatient spinal fracture reduction procedures, Medicare reimburses the facilities in which the procedures are performed based upon prospectively determined amounts. As to hospital inpatient stays, a 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 (DRG).

For procedures using our technology performed in hospital outpatient departments, payment is based on the Ambulatory Payment Classification (APC) under which the procedure is categorized. The Centers for Medicare & Medicaid Services (CMS), the Federal agency responsible for administering the Medicare program, assigns procedures that are comparable, both clinically and in terms of the resources required, to the same APCs. Hospitals 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.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services under the national Medicare Physician Fee Schedule. In all 50 states and in the District of Columbia, Medicare reimburses physicians for their professional services when they perform procedures using our *KyphX* instruments, and reimburses them the same amount regardless of whether the procedure is inpatient or outpatient. As of January 1, 2006, there were three Category I CPT codes, or reimbursement codes, established describing procedures in which our products are used: CPT codes 22523, 22524 and 22525.

In Europe, kyphoplasty has been assigned a code in the recently implemented German OPS system. In other European countries, we continue to focus efforts on obtaining reimbursement coverage for the procedure, although no assurances can be provided that such efforts will result in favorable outcomes for us. We are aware that in the past, one or more competitors have attempted to adversely affect our ability to acquire timely and appropriate levels of reimbursement in several foreign countries by seeking much lower levels of reimbursement for their own competitive products that may not support the pricing or anticipated pricing of our products in those markets.

Reimbursement for the *X-STOP* Procedure

We believe the majority of the patients suffering from lumbar stenosis that may be appropriate candidates for the *X-STOP* procedure are insured in the U.S. under Medicare, while the rest are insured primarily by private payors. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our technology 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) for interspinous decompression procedures. Medicare reimburses the facilities in which the procedures are performed based upon prospectively determined amounts. As to hospital inpatient stays, a prospective payment is determined by the patient's condition and other patient data and procedures performed during the inpatient stay, using the DRG classification system. Hospitals performing inpatient procedures using our products are paid the applicable DRG payment rate for the inpatient stay, regardless of the actual cost for such treatment. In addition to the DRG payment hospitals may receive a new technology payment from CMS. Hospitals may receive an add-on payment of up to a maximum of $4,400 for the *X-STOP* device implanted in the hospital inpatient setting for Medicare patients for up to three years. This is in addition to the DRG payment amount that the hospital may receive. The actual total amount of payment will be different for each hospital and each case depending on the hospital specific cost-charge ratio.

As to procedures using our technology performed in hospital outpatient departments, payment is based on the APC under which the procedure is categorized. CMS, the Federal agency responsible for administering

the Medicare program, assigns procedures that are comparable, both clinically and in terms of the resources required, to the same APCs. Both the new technology add-on payment and the pass through payment are in effect for no less than two years and no more than three years.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services under the national Medicare Physician Fee Schedule. Effective January 1, 2007, there are two Category III CPT codes, or reimbursement codes, describing procedures in which our products are used: CPT "T" codes 0171T and 0172T. These codes are considered "tracking codes" and do not have a preset level of reimbursement so reimbursement decisions are made in the local CMS offices. As the codes became effective January 1, 2007, it is too early to know the impact the codes will have on our business.

Manufacturing

We believe our manufacturing operations are in compliance with regulations mandated by the FDA and the European Union. We have been a FDA-registered and California-licensed medical device manufacturer since 1998 and have had our EC Certificate since February 2000. We are subject to unannounced inspections by the FDA, TÜV, our notified body, and the Food and Drug Branch of the California Department of Health Services, or CDHS, and these inspections may include the manufacturing facilities of our subcontractors. The FDA inspected our Sunnyvale, California manufacturing facility during 2006 and all observations raised have been adequately addressed. We have also been inspected by the CDHS and European auditors and there have been no material audit findings as a result of these inspections.

We inspect, assemble, test, package and sterilize components that we manufacture, as well as components manufactured to our specifications by outside contractors. We inspect each lot of components and finished instruments to determine compliance with our specifications.

The purchased components for our instruments are generally available from more than one supplier. There are no contractual obligations by suppliers to continue to supply to us, nor are we contractually obligated to purchase from a particular supplier. We have identified and qualified alternate suppliers for materials in our *KyphX* Inflatable Bone Tamps and most of our other *KyphX* instruments. Although additional suppliers have been identified for certain, presently sole-sourced items, including our inflation syringe and our proprietary bone cement, none has been qualified at this time.

We are currently increasing our manufacturing capabilities as we increase commercialization efforts. We may experience difficulties in scaling-up production, including problems with production yields and quality control and assurance, which may adversely affect our business and growth.

Research and Development

Our research and development group focuses on developing new products to address unmet patient and market needs, and product line expansion with respect to our existing products with the concomitant goal of enhancing revenue. A major focus of the group is to explore new technologies primarily for use in minimally invasive spinal procedures in the following product platforms, including but not necessarily limited to:

- ***Spinal Fracture Management and Repair***: Our focus in this area is to treat vertebral compression fractures due to osteoporosis, cancer and trauma with minimally invasive technology. Our goals in developing products for Spinal Fracture Management and Repair are to provide clinicians with highly effective, minimally invasive devices to treat their patients, in order to relieve the patients' pain, restore mobility and recreate the natural anatomic structure. We consider this to be our core business based upon our history in balloon kyphoplasty, and we are continually seeking to expand the range of products we offer to clinicians in this area.

- ***Disc Disease Diagnosis and Therapies***: Our product franchise in this area is intended to assist clinicians in diagnosis and treatment of degenerative disc disease. Our goal in this product area is

two-fold: to develop improved diagnostic tools to assist the clinician in identifying the source of a patient's pain, and to develop minimally invasive devices for treatment of degenerative disc disease. Our acquisition of InnoSpine provides us with a diagnostic platform in this area, and we are committed to developing or acquiring additional technologies to provide minimally invasive approaches to treating the degenerated disc. Our proposed acquisitions of certain spine-related assets of Disc-O-Tech (if and when those transactions are granted regulatory approval and completed) will provide us with a platform in minimally invasive spinal fusion with the *B-Twin* product, and we intend to further develop this product into additional offerings in this area.

- ***Spinal Motion Preservation***: We seek to provide physicians minimally invasive approaches to treat lumbar spinal stenosis. Our acquisition of St. Francis provides us with the first FDA-approved minimally invasive device for the treatment of neurogenic intermittent claudication in mild to moderate stenosis patients. We have developed the *Aperius* product internally, and additional iterations of this product are being considered for further development.

In conjunction with these platforms, we intend to develop the following:

- additional instruments to facilitate the use of our products in fractures that are particularly difficult to repair;
- Kyphon-branded biomaterials for use as bone void fillers;
- instruments and implants for the treatment of degenerative spinal disorders, such as lumbar spinal stenosis;
- instruments and biomaterials for the diagnosis and treatment of spinal disc disease; and
- minimally invasive instruments for spinal fusion.

Our expenditure for research and development totaled $40.0 million, $46.4 million and $22.2 million in 2006, 2005, and 2004, respectively. Research and development expense in 2005 included a $20.0 million one time expense associated with the acquisition of an exclusive license to Dr. Harvinder Sandhu's early invention rights concerning a directional bone tamp for treating vertebral compression fractures and a $1.0 million one time expense associated with the acquisition of an exclusive license to Dr. Lee Berger's patent portfolio relating to expandable cavity-creation devices.

Unless an exemption is available, we will need approval or clearance from the FDA to promote or market any of these products in the United States. We cannot be certain that we will be able to obtain approval or clearance for these products.

Competition

In our Spinal Fracture Management and Repair product platform, we compete with providers of non-surgical treatments, drugs to reduce pain, drugs to prevent osteoporosis, open surgical procedures and instruments for vertebroplasty. Our products compete with conventional spine instrumentation in the market for traumatic spinal fracture treatments. We also are beginning to see introductions into the marketplace of instruments designed to create voids in vertebral bodies without any attempt at fracture reduction, which are marketed as a safer alternative to vertebroplasty and a less expensive alternative to balloon kyphoplasty. Competition is likely to increase the awareness and frequency of alternative procedures to balloon kyphoplasty. We are also beginning to see introduction by competitors of instruments designed to achieve either or both void creation and fracture reduction, including copies of our products in some Asia-Pacific countries. These products are initially being marketed in the U.S., Europe and Asia as equally effective and less expensive than our *KyphX* products. Numerous companies are developing and marketing materials, including biomaterials, which may be used as bone filler materials. Given the early stage of many of these competitive marketing efforts, it is premature to determine what, if any, impact these products may have on our sales growth.

Osteoporosis drugs marketed and in development today may, under some limited circumstances, reduce the risk of fracture by up to 70%. These drugs are made by large pharmaceutical companies such as Merck, Eli

Lilly, Wyeth, Procter & Gamble, Novartis AG and Aventis Pharmaceuticals. These drugs and future drugs may further reduce the incidence of spinal fractures over time.

Our products for the diagnosis of low back pain compete against other methods for the diagnosis of degenerative disc disease, such as imaging studies and provocative discography. We believe that products specifically designed and used in the diagnosis of degenerative disc disease are not a meaningful percentage of any company's revenue.

Our products for lumbar spinal stenosis compete primarily with conservative, non-surgical therapies in the United States, including pain killers and other pain medications. No other spinal device implants are approved for lumbar spinal stenosis in the United States. In the United States, we know of at least four clinical trials that have been initiated by competitors seeking to gain approval to market and sell their products in the Untied Sates with an indication that includes the treatment of lumbar spinal stenosis. These trials are long and complex, and we do not know if, or when, they may result in competitive entry into the United States market.

Outside of the United States, and in Europe in particular, several competitors are marketing products that compete directly with our *X-STOP IPD* System and *Aperius* products. These competitors include both large and small spine companies. We believe our products to be superior in performance, but do not have extensive clinical data to definitely prove this point of view. As a result, physicians in these non-U.S. markets utilize several different factors in their usage decisions, including price and relationships with the vendor or the vendor's representative. While we believe we have a leading share position in several countries, there are several other markets we do not have a leading share position, due either to the success of another competitor in that market, or our lack of presence in that market.

Our products for the performance of cervical and spinal fusion compete against a wide variety of products marketed by several competitors around the world. The largest companies in the spine medical device industry all have significant revenues derived from products designed for use in spinal fusion, including Medtronic, Johnson and Johnson and Synthes. However, as these products have matured and less differentiation is seen by customers, several new companies have been formed to produce, market and sell products similar to the products marketed by the large spine companies. Several of these companies are relatively small, and rely upon their distributors and customers as investors. As a result, traditional pedicle screw and rod products used in these procedures are rapidly commoditizing. Our strategy in this market is not to market similar devices to these various companies, but rather, to bring to market innovative devices that enable the physician to perform spinal fusion procedures in a much less invasive fashion. Such innovative products may require changes in physician technique, and may only be applicable to a proportion of the spinal fusion procedures currently done in the market today. However, less invasive products that are as effective as the traditional fusion products, less traumatic for the patient, simpler to use for the physician and lower cost for both the hospital and the overall healthcare system are widely desired in the marketplace. It is these types of products that we intend to develop.

Any products that we commercialize will be subject to intense competition. Overall, we believe the primary competitive factors that affect our instruments are the cost of our products and the cost of procedures performed with our products, third-party payor coverage and reimbursement status, effectiveness and safety. Many of our competitors and potential competitors in these markets have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that may be more effective than ours or that would render our instruments obsolete or noncompetitive. In addition, these competitors often have significantly greater experience and brand recognition than we do in their respective fields. These competitors may also be willing to conduct their business in ways that are not beneficial to our ability to continue to provide our products as we now do, such as by substantially undercutting our prices or by seeking very low levels of third-party payor reimbursement in various geographic markets in order to penetrate those markets quickly. Our ability to compete successfully will depend on our ability to develop innovative products that reach the market in a timely manner through our direct sales channel, receive adequate third-party payor coverage and reimbursement and are safer, less invasive and less expensive than alternatives available for the same condition. Because of the size of the potential market, we anticipate that companies will dedicate

significant resources to developing competing products and procedures. Our technologies and instruments may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. We may also be forced to protect our market space through enforcement of our intellectual property rights, which would be expensive to do and likely would constitute a significant distraction to our executive team and which efforts ultimately may not succeed.

Patents and Proprietary Technology

We believe that in order to have a competitive advantage, we must develop, maintain and protect the proprietary aspects of our technologies. We rely on a combination of patents, trademarks, trade secrets, non-disclosure and other contractual agreements and technical measures to protect our intellectual property rights. Kyphon®, *KyphX*®, *KyphX HV-R*™ and *KyphOs*™ are some of our trademarks. We have trademark rights in these and others of our marks in the United States and have registrations issued and pending in the United States and other countries for these and others of our trademarks. As of December 31, 2006, we had over 50 issued U.S. patents, 60 issued foreign patents, 130 pending U.S. patent applications, and 160 pending foreign applications. Our patent portfolio also includes 26 U.S. patents that we exclusively licensed from Bonutti Research in August 2002, and 5 U.S. patents that we licensed from Dr. J. Lee Berger in April 2005.

Under the terms of our agreement with Bonutti Research, we acquired the exclusive right to develop minimally invasive balloons and related products for use within joints, ligaments, tendons, or cartilage in the spine and the co-exclusive right to develop minimally invasive balloons and related products for use in orthopaedic applications in joints, ligaments, cartilage, nerves or tendons outside of the spine.

Under the terms of our agreement with Dr. Berger, we acquired exclusive rights to certain technology including, among other things, technology relating to expandable cavity-creation devices.

In February 2003, we acquired Sanatis GmbH, a privately-held developer and manufacturer of orthopaedic biomaterials based in Rosbach, Germany. Sanatis has filed four patent applications covering inventions relating to calcium cement formulations and a cement delivery technology.

In November 2005, Kyphon and Dr. Harvinder Sandhu, a well-respected orthopaedic surgeon, entered into an agreement for Kyphon to acquire an exclusive license to Dr. Sandhu's early invention rights concerning a directional bone tamp for treating vertebral compression fractures. As a result of our exclusive license agreement with Dr. Sandhu, we recorded a one-time charge of $20.0 million in our financial statements for the period ending December 31, 2005. This charge consisted of a cash payment of $5.0 million made to Dr. Sandhu in November 2005 and a contractual obligation to make a series of milestone payments totaling up to an additional $15.0 million beginning in 2006, a second payment of $5.0 million of which was made in November 2006, according to the terms of the agreement. The license agreement also includes a capped royalty stream on any future developed product that practices Dr. Sandhu's technology.

Later in November 2005, Dr. Sandhu and Kyphon filed suit in federal district court in Memphis, Tennessee against Medtronic Sofamor Danek (MSD) and several other related corporate entities seeking compensatory and punitive damages and injunctive relief for breach of contract and related covenants, trade secret theft, fraud, and correction of inventorship of several patents and patent applications presently owned by MSD, including U.S. Patent No. 6,676,665. The suit also requests, among other relief, that MSD transfer to Dr. Sandhu ownership of the disputed patents and patent applications. The dispute concerns inventions related to an expandable, mechanical bone tamp for use in treating vertebral compression fractures that Dr. Sandhu invented in the late 1990's and which he confidentially disclosed and discussed with MSD. The complaint alleges that MSD later filed for several patents encompassing and claiming Dr. Sandhu's inventions without naming him as inventor of that technology, and that it also incorporated Dr. Sandhu's inventions into its internal *Equestra/Arcuate* project without his permission. In May 2006, the Company also sued MSD in the same Tennessee court for willfully infringing five of the Company's U.S. patents (numbers 4,969,888, 5,108,404, 6,235,043, 6,440,138, and 6,863,672) with its *Equestra/Arcuate* product. Discovery is underway, and various motions are pending that seek to address the merits of Dr. Sandhu's and Kyphon's claims. Trial was initially set for April 2007, but may be delayed so that all of Dr.

Sandhu's and Kyphon's claims may be heard in a single trial. We intend to vigorously prosecute our and Dr. Sandhu's cases against MSD.

In January 2006, we closed our acquisition of InnoSpine, a developer of a proprietary technology platform for the diagnosis and potential treatment of axial low back pain due to disc degeneration. InnoSpine has filed for patent protection on various aspects of the technology.

In connection with our acquisition of St. Francis, we acquired intellectual property rights associated with the *X-STOP* Interspinous Process Decompression System and other technologies related to the treatment of lumbar spinal stenosis. As of December 31, 2006, these assets included over 40 issued U.S. patents, 10 issued foreign patents, 80 pending U.S. patent applications, and 20 pending foreign patent applications.

In connection with our definitive agreement to acquire the non-vertebroplasty, spine-related assets of Disc-O-Tech (for which regulatory approval to close has not yet been received), we will acquire intellectual property rights associated with the *B-Twin* product line, the SKy product line, and associated tools and instruments. In connection with our second definitive agreement to acquire the vertebroplasty assets of Disc-O-Tech (for which regulatory approval to close has not yet been received), we will acquire all of the intellectual property rights of Disc-O-Tech related to its vertebroplasty technology.

We require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us. We also require our employees, consultants and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary. Finally, our competitors may independently develop similar technologies and file for patent rights that we ultimately may infringe or which may undermine our own patent rights. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property rights or are unable to adequately enforce those rights.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. As the number of entrants into our market increases, the possibility of a patent infringement claim against us increases. While we make an effort to ensure that our products do not infringe other parties' patents and proprietary rights, our products and methods may be covered by U.S. patents held by our competitors or others. In addition, our competitors may assert that future products we may market may infringe their patents. From time to time, we may approach, or may be approached by, others about licensing their patent rights, or about their infringement of our patent rights. The outcome of any of these contacts is never certain, and may lead to costly disputes, which may not be resolved in our favor. Any claims, with or without merit, and regardless of whether we are successful on the merits, would be time consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays, require us to develop non-infringing technology or require us to enter into royalty or licensing agreements, which may not be available to us on commercially reasonable terms, if at all. An adverse determination in a judicial or administrative proceeding regarding an infringement claim and failure to obtain necessary licenses or develop alternative non-infringing technologies could prevent us from manufacturing and selling our products, which could have a material adverse effect on our business and financial condition and cause our stock price to decline.

Government Regulation

Our products are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug and Cosmetic Act and by states under various state regulations. FDA regulations govern, among other things, the following activities that we perform:

- product design and development;
- product testing;
- product manufacturing;

- product labeling;
- product storage;
- product advertising and promotion; and
- product sales and distribution.

Unless an exemption applies, each medical device that we wish to commercially distribute in the United States requires either 510(k) clearance or premarket approval from the FDA prior to marketing. The FDA classifies medical devices into one of three categories. Devices deemed to pose relatively less risk are placed in either class I or II, which requires the manufacturer to submit, and FDA to clear, a premarket notification known as a 510(k) submission, demonstrating the device's substantial equivalence to a legally marketed predicate. Some low-risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k)-cleared device, are placed in class III requiring premarket approval.

510(k) Clearance Pathway. To obtain 510(k) clearance, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and technological characteristics (or if different in technological characteristics, a demonstration that the proposed device is at least as safe and effective as the predicate device) to a previously 510(k)-cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of premarket applications, or is a device that has been reclassified from class III to class II or I. The FDA's 510(k) clearance pathway usually takes from three to 12 months, but it can last significantly longer. During this period, the FDA may request additional information.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any manufacturer's decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or premarket approval. The FDA can also require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained.

Our *KyphX* Inflatable Bone Tamps currently have 510(k) clearance for use as conventional bone tamps for the reduction of fractures and/or the creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with *KyphX HV-R* Bone Cement), hand, tibia, radius and calcaneus. The *KyphX* Inflation Syringe is a 510(k)-cleared product that we currently obtain from contract suppliers. We believe our *KyphX* Introducer Tool Kit, *Osteo Introducer* System, Advanced *Osteo Introducer* System, Bone Biopsy Device, Bone Access needles, *Latitude* Curette, and *KyphX* Bone Filler Device, when sold as manual orthopaedic surgical instruments, are Class I devices and are therefore exempt from 510(k) clearance or premarket approval requirements. Our 510(k) clearances permit us to promote particular short and/or long-term benefits of balloon kyphoplasty, including, for example:

- vertebral body height restoration;
- angular deformity correction;
- vertebral body volume increase;
- significant reduction in back pain;
- significant reduction in the number of days per month that the patient remains in bed;
- significant improvement in the patient's quality of life;
- significant improvement in the patient's ability to perform the activities of daily living;
- high rates of patient satisfaction with the procedure;
- significant improvement in pain and mobility; and a
- low complication rate.

Premarket Approval. A premarket approval application, or PMA, must be submitted if a device cannot be

cleared through the 510(k) process. A PMA must normally be supported by extensive data including, but not limited to, technical, preclinical and clinical studies, manufacturing information and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA is filed, the FDA begins an in-depth review of the submitted information, which generally takes between one to three years, but may take longer. During this review period, the FDA may request additional information or clarification of the information already provided. Also, in many cases, an advisory panel of experts from outside the FDA will 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 the quality system regulations and may also conduct inspections of the clinical investigators' and study sponsors' sites involved in the clinical studies supporting the PMA. New PMAs or PMA supplements are required for significant modifications to the manufacturing process, labeling and design of a device that is approved through the premarket approval process. PMA supplements in certain circumstances require submission of the same type of information as that contained in an original PMA, but limited in scope to the changes from the device covered by the original premarket approval. PMA supplements may not require extensive clinical data or review of the application by an advisory panel, but both are possible.

Clinical Studies. Clinical studies are almost always required to support a premarket approval application and are sometimes required for a 510(k) premarket notification. These studies may require submission of an application for an investigational device exemption (IDE). 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 unless the product is deemed to be a non-significant risk device eligible for more abbreviated IDE requirements. Clinical studies for significant risk devices may begin once the IDE application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites.

Any clinical studies we sponsor in the United States must be conducted in accordance with FDA regulations. These clinical studies will require that we submit, and obtain FDA approval of, an IDE prior to commencing clinical studies, unless they are conducted after marketing approval or clearance has been obtained and the products are used within their cleared/approved Indications for Use. The results of any clinical studies that we conduct or sponsor may not be sufficient for us to obtain any additional clearances or approvals or to support additional marketing claims for our devices over what we already have.

Postmarket. After a device is placed on the market, numerous regulatory requirements apply. These include:

- the Quality System regulations, which require manufacturers to follow extensive testing, control, documentation and other quality assurance procedures during the design and production processes;
- the Medical Device Reporting (MDR) regulation, which requires that manufacturers report to the FDA instances where their device may have caused or contributed to a death or serious injury or may have malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and
- FDA regulations that prohibit the promotion of medical devices for unapproved or "off-label" uses.

We have had to file what we believe is a low number of MDRs for our products, although more may be required as the number of procedures performed with our products increases. Through 2006, we have not faced any product liability litigation although such litigation is common in the medical device industry and we may have to defend such litigation at some point in the future.

We are subject to inspection by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions including:

- fines, injunctions, and civil penalties;

- 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;
- withdrawing 510(k) clearance or premarket approvals already granted; and
- criminal prosecution.

The FDA also has the authority to require us to repair, replace or refund the cost of any medical device that we have manufactured or distributed in certain circumstances.

Other Federal and State Healthcare Laws. Our operations are subject to various federal and state healthcare laws commonly referred to as "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws prohibiting health care fraud and false statements. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration directly or indirectly to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The Department of Health and Human Services (HHS) has issued regulations, commonly known as safe harbors, that deem certain arrangements meeting specified requirements to comply with the federal Anti-Kickback Statute. We seek to have our business conduct and arrangements with health care professionals comply with such safe harbors and have adopted codes of conduct to guide our activities in that regard. Business conduct and arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the HHS Office of Inspector General. Scrutiny of our industry under these laws appears to be increasing and several orthopaedic companies were recently subpoenaed by the federal government regarding their relationships with, and payments to, health care professionals. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute. Some of these state laws apply to health care services reimbursed by any source, not only by the Medicare and Medicaid programs, and do not have exceptions identical to those under the federal law.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented for payment, a false or fraudulent claim for payment to the federal government. Suits filed under the False Claims Act, known as "*qui tam*" actions, can be brought by any individual (known as a "relator" or, more commonly, "whistleblower") on behalf of the government. In addition, certain states have enacted laws modeled after the federal False Claims Act. The frequency of filing of *qui tam* actions has increased significantly in recent years, causing greater numbers of health care companies to have to defend a False Claim action. Although we believe we are in substantial compliance with the health care laws relevant to our Company, we are aware that a complaint against us, which we believe is a *qui tam* complaint, is presently being investigated by a U.S. Attorney's Office (Please see the related discussion in Item 1A, Risk Factors).

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), includes at least two related federal statutes: health care fraud and false statements relating to health care matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

We have adopted corporate policies, compliance programs and codes of conduct to assist our employees in complying with these laws and we train our employees on how to engage appropriately with health care providers under these laws. We believe we are in substantial compliance with these laws. Nevertheless, given the nature of our business and our industry, our activities relating to the sale and marketing of our products may be subject to scrutiny under any or all of these health care laws. We may also face increased risk of investigation and enforcement based on the actions of our customers. For example, the amount of facility reimbursement available for balloon kyphoplasty performed on an out-patient basis, while recently increased, has been and remains lower than reimbursement available for balloon kyphoplasty performed on an in-patient basis with an overnight stay. While a treating physician typically decides to perform kyphoplasty on a particular patient in either an in-patient or an out-patient basis based on the standard of

medical necessity, we believe the difference in reimbursement available may sometimes influence the treatment decisions of certain hospitals and physicians. Violations of these laws may be punishable by criminal and/or civil sanctions, including significant fines and civil monetary penalties, as well as possible exclusion from federal health care programs (including Medicare and Medicaid). Our activities could be challenged due to the broad scope of these laws and increased attention being given to them by law enforcement authorities. An accusation that we have violated these laws, and any resulting enforcement or other regulatory or legal activity against us, or against the physicians who perform procedures with our products or our customers who purchase our products could adversely affect our business and our financial condition, which could cause our stock price to decline.

International. International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. The primary regulatory authority in Europe is that of the European Union, or EU, which consists of 25 countries encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices. The EU has transposed into law numerous directives and adopted many harmonizing standards pertaining to the design, manufacture, clinical study, labeling and adverse event reporting of medical devices. Devices that comply with the requirements of relevant EU medical device directives will be entitled to bear the CE marking of conformity, indicating that the device conforms to the requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." This third-party assessment includes an audit of the manufacturer's quality system and possibly specific testing of the manufacturer's product. An assessment by a Notified Body residing in one country within the EU is required in order for a manufacturer to commercially distribute the product throughout the EU. During this process, we must demonstrate compliance with recognized harmonized standards pertaining to our quality systems for the design and manufacture of products.

We have obtained CE Marking permitting us to commercialize certain of our products in Europe, including a calcium phosphate biomaterial that we acquired with the acquisition of Sanatis GmbH. While no additional premarket approvals in individual EU countries are required prior to the marketing of a device bearing the CE Mark, practical complications with respect to market introduction may occur. For example, differences among countries have arisen with regard to labeling requirements.

Seasonality

Our business is seasonal in nature. Historically, demand for our products has been the highest in the first and second quarters in the U.S. and in the second and fourth quarters in Europe. In the U.S., during the fourth quarter, our net sales generally reflect the reduced number of selling days due to the holiday season. In Europe, we traditionally experience somewhat lower sales volumes in the third quarter months than throughout the rest of the year as a result of the European summer holiday schedule. In addition, the fourth quarter in Europe is typically favorably impacted by our customers' budget utilization and our distributors' fulfillment of their annual purchase commitments.

Operating Segment and Geographic Information

We operate in one segment, using one measurement of profitability to manage our business. Sales and other financial information by geographic area is provided in Note 11 to our consolidated financial statements that are included in this Annual Report.

Employees

As of December 31, 2006, we had a total of 1,090 employees, with 127 people in operations, 113 people in research and development, 674 people in sales, marketing and professional education and 176 people in general and administrative. None of our employees are represented by a labor union, and we believe our

employee relations are good.

Available Information

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission (SEC), including reports on the following forms: annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. These reports and other information concerning the Company may be accessed through the SEC's website at http://www.sec.gov.

You may also find free electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 on our website at http://www.kyphon.com. Such filings are placed on our website as soon as reasonably practicable after they are filed with the SEC.

ITEM 1A. RISK FACTORS

Factors Affecting Future Operating Results

Our future success depends on our ability to develop and successfully introduce new products, product extensions and improvements to existing products to address unmet patient and market needs.

Our current products offer orthopaedic surgeons and neurosurgeons, interventional radiologists and interventional neuroradiologists minimally invasive treatments for the spine in three areas: Spinal Fracture Management, Disc Disease Diagnosis and Therapies and Spinal Motion Preservation with the majority of our revenues derived from balloon kyphoplasty for the treatment of vertebral compression fractures using our *KyphX* instruments. We cannot assure you that the market for the treatment of spinal fractures will continue to generate significant or consistent demand for our *KyphX* instruments.

Also, the *X-STOP* device, our product for treating lumbar spinal stenosis, or LSS, was approved for sale in the United States only in late 2005. It is difficult to predict the market acceptance and future growth rate or size of the market for the *X-STOP* device. The expansion of the *X-STOP* device market depends on a number of factors, such as:

- physician and patient preference for the *X-STOP* device over current therapies or procedures;
- physician and patient experience with the *X-STOP* device 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* device;
- effectiveness of sales and marketing efforts to increase physician and patient awareness of the *X-STOP* device; and
- availability of adequate coverage and reimbursement for hospitals and surgeons.

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

Demand for our products could be significantly diminished by alternative treatment methods, and by new technologies or products that replace and render our products obsolete or too expensive. Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory clearance or approval for, manufacture, sell and achieve market acceptance of new products, product extensions and improvements to our existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables. These variables include price, safety, efficacy, reliability, marketing and sales efforts, the availability of adequate third-party coverage and reimbursement for procedures using our new products and the existence of competing products and general economic conditions affecting purchasing patterns. Our ability to market and sell new products, product extensions and improvements to our existing products may also be subject to government regulation, including

clearance and approval by the FDA and foreign government agencies. Any failure in our ability to successfully develop, obtain regulatory approval for, manufacture, sell and achieve market acceptance of our new products, product extensions or improvements to our existing products could adversely affect our business and our financial condition, which could cause our stock price to decline.

Our success is dependent upon the availability of adequate physician and hospital reimbursement by third-party payors for our products.

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, including governmental payors such as Medicare. Uncertainty exists as to the coverage and reimbursement status of new medical technologies. Procedures using our *X-STOP* technology and our *KyphX* instruments are currently covered and reimbursed by the Medicare program and other governmental and private third-party payors. As a result of developments in both physician and hospital reimbursement, including the establishment of new reimbursement codes describing kyphoplasty or the lack of specific reimbursement codes in the case of the *X-STOP* technology, some physicians and hospitals in some states may believe that the level of reimbursement they receive is too low to support performing these procedures. Continued use of our *X-STOP* and *KyphX* technologies by the medical community may be adversely impacted if physicians perceive that they do not receive sufficient reimbursement from third-party payors for their services in performing the procedures using our instruments. As of now, it is not possible to assess with any degree of certainty whether the implementation of reimbursement code changes has had or will have any material impact on the behavior of clinicians with respect to their interest in performing our procedures.

Specifically, with regards to the *X-STOP* device, physician reimbursement is governed by two new Category III CPT codes, effective January 1, 2007. Category III codes are temporary codes for emerging technology and services. In the future, new, Category I CPT codes, for which national payment levels are established, could be implemented with respect to the *X-STOP* device or may not be available at all. 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. As of now, it is not possible to assess the full impact of procedure-specific *X-STOP* device CPT codes on our business or results of operations.

In addition, reimbursement for competing procedures, such as laminectomies or vertebroplasty, may also continue to be perceived in some cases as more favorable for the physician or hospital than that available for using our products and thus may reduce the frequency with which procedures using our products are performed, which could harm our revenues.

If domestic or international third-party payors adversely change coverage or reimbursement policies for certain procedures, our ability to market and sell our products would be adversely impacted, which would harm our business, revenues and operating results.

Third-party payors, including Medicare and private health maintenance organizations and insurance plans, are increasingly challenging the prices charged for medical products and services and may institute adverse changes in their coverage or reimbursement policies for procedures using our products. Governmental and private third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and are exploring more cost-effective methods of delivering healthcare, including the placement of limitations on the circumstances under which a procedure is covered and other restrictions. While many governmental and private third-party payors currently provide coverage and reimbursement for the procedures in which our instruments are used, we cannot assure you that procedures in which our technology is used will continue to be reimbursed at current rates or that third-party payors will continue to consider our technology cost-effective and provide coverage and reimbursement for our technology, in whole or in part. If third-party payors adopt new limits or restrictions on coverage and reimbursement of procedures using our products, such a development could significantly impact the willingness of hospitals, clinics and doctors to purchase and use our instruments, which in turn could adversely affect our business and our financial condition, which could cause our stock price to decline.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory proposals to change the healthcare system, including the Medicare program. Some of these proposals have involved changes that could significantly affect our business. Future legislative or policy initiatives directed at increasing the accessibility of healthcare and reducing costs could be introduced on either the federal or state level. We cannot predict the impact on our business of any legislation or regulations related to the healthcare system that may be enacted or adopted in the future. In addition, healthcare cost containment efforts similar to those we face in the United States are prevalent in many of the other countries in which we intend to, or already do, sell our instruments, and these efforts are expected to continue in both the United States and abroad. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government-sponsored healthcare and private insurance. Given that the vast majority of our revenues indirectly rely on government-funded healthcare systems that reimburse our customers for their use of our products to treat patients, any adverse change in governmental payors' coverage and/or reimbursement policies, including as a result of reaction to rapidly escalating budget pressures, would adversely impact our ability to market and sell our products, harm our business and reduce our revenues.

If we are unable to successfully integrate our recent acquisitions into our business, we could encounter difficulties that harm our business.

We have not previously attempted to integrate businesses or assets of the size or complexity presented by both the acquisition of St. Francis and the proposed acquisition of certain spine-related assets of Disc-O-Tech. St. Francis' implantable technology is technology with which we have little experience. Disc-O-Tech's spine-related assets include other technologies to treat disease states with which we are unfamiliar. We are faced with many challenges in integrating what we have acquired, including becoming an effective competitor in markets where we have not previously participated and adequately protecting our investments in those acquisitions. We must quickly learn and incorporate into our business the acquired clinical, regulatory, reimbursement, intellectual property, legal, operational, distribution and financial control environment for Sarbanes-Oxley Act compliance, which will require a large amount of financial and personnel resources. If we are unable to effectively and efficiently integrate these acquisitions while remaining sufficiently focused on our existing balloon kyphoplasty business, our present business and financial condition may be harmed. Even if we successfully integrate these acquisitions, we may still fail to achieve the revenues, cost savings, growth prospects and any or other synergies expected from the transactions, which may prevent us from realizing the full potential related to these significant financial investments. These acquisitions and their resulting integrations may dilute our earnings per share, harm our liquidity, disrupt our ongoing business, distract our management and employees, increase our expenses, create an unfavorable impression of our company in the public markets for our equity, and expose us to new risks and liabilities, any or all of which could harm our business and cause our stock price to decline. We may also be subject to similar risks if we acquire other companies in the future.

We have taken on a significant amount of debt in order to finance our acquisition of St. Francis Medical Technologies, Inc. and our proposed acquisitions of certain assets of Disc-O-Tech Medical Technologies, Ltd. and its U. S. subsidiary. Our substantial indebtedness could restrict our operations and make us more vulnerable to adverse business or economic conditions.

On January 18, 2007, we borrowed $425.0 million pursuant to a senior secured credit agreement in order to finance our acquisition of St. Francis, and on January 31, 2007, we effected a private placement of $400.0 million principal amount of convertible senior notes under Rule 144A. Approximately $355.0 million of the net proceeds of the convertible note offering, together with borrowings of approximately $70.0 million under our revolving credit facility, were used to pay down the term loan in its entirety. Our substantial indebtedness could have important consequences for our stockholders. For example, it could:

- make it difficult for us to satisfy our financial obligations, including making scheduled principal and interest payments;

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions and general corporate and other purposes;

- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and acquisitions and for other general corporate purposes;

- increase our vulnerability to economic downturns and competitive pressures in our industry;

- place us at a competitive disadvantage compared to our competitors that have less debt in relation to cash flow; and

- limit our flexibility in planning for, or reacting to, changes in our business and our industry.

The absence of prospective, randomized, controlled clinical trial data supporting surgical treatment of vertebral compression fractures over conservative care and the treatment of such fractures with balloon kyphoplasty has caused some influential physicians to speak out against adoption of balloon kyphoplasty, which may adversely affect our business and our financial condition.

A handful of vocal physicians continue to publicly criticize the cost and merits of balloon kyphoplasty as a procedure for treating vertebral compression fractures. We believe this is due, in part, to the absence to-date of prospective, randomized, controlled clinical trial data on the effectiveness of balloon kyphoplasty and the perceived economic cost difference between balloon kyphoplasty and vertebroplasty. Certain influential physicians and others in professional societies, have publicly stated their opposition to both balloon kyphoplasty and Kyphon based on this lack of perceived justification for the cost or economics of the procedure. We have recently completed enrollment in a randomized, controlled trial comparing balloon kyphoplasty versus non-surgical management. While one month data is available, one year follow-up data will not be available until late 2007 or early 2008. In addition, while we have commenced enrollment in a randomized, controlled trial comparing balloon kyphoplasty to vertebroplasty, we believe it will be several years before enrollment is completed and any data is available. We cannot predict whether the trials' results or the response to such results will demonstrate the benefits of treatment of vertebral compression fractures with balloon kyphoplasty. We also cannot predict how the presence of negative public criticism to adoption of our products for treating patients ultimately may affect our business or our revenues.

If primary care physicians are unwilling or unable to refer patients to trained clinicians that use our *X-STOP* and *KyphX* products to treat LSS or vertebral compression fractures, respectively, our revenues will suffer and our business may not expand or may decline.

A key element of our business strategy is to educate primary care physicians and spine specialists on the use of our *X-STOP* and *KyphX* technologies as an alternative to conservative pain management therapies and more invasive surgical procedures. We believe primary care physicians are an important source of patient referral, and, therefore, it is important to educate them about our products and the clinical outcomes of these procedures. We believe that primary care physicians and spine specialists may not widely adopt our products unless they determine, based on experience, clinical data, published, peer-reviewed journal articles and recommendations and support of our products by influential practitioners, that our products provide benefits or an attractive alternative to conventional treatments of lumbar spinal stenosis and spinal fractures. In the case of balloon kyphoplasty, such clinical data is not currently available and we cannot predict when such data will be available or the response to such data. If primary care physicians do not recommend and support our products, then our future growth will be harmed and our business may decline.

We may experience delays in obtaining, or may be unable to obtain, the regulatory approvals necessary to close either or both of the transactions with Disc-O-Tech.

The Federal Trade Commission (FTC) has issued second requests for information in connection with our agreements to acquire the vertebroplasty and non-vertebroplasty spinal assets of Disc-O-Tech. The FTC's

review process may delay for many months our ability to close either transaction and incorporate those assets into our business, and may result in material conditions being placed on our ability to obtain the necessary regulatory approvals or in our inability to close one or both of the transactions. We may have to divest or license to third parties some or all of the assets proposed to be acquired, which may be detrimental to our business and our ability to recoup our material investment in the assets subject to this agreement. Regardless of the outcome with the FTC, we are required to pay Disc-O-Tech the full amount due in connection with the transaction. In the event that we are forced to dispose of some or all of the assets that we propose to acquire, the price we receive may be significantly less than the price we are obligated to pay Disc-O-Tech. In addition, pursuant to a development agreement to be entered into in connection with our proposed acquisition of Disc-O-Tech's vertebroplasty assets, we will be obligated to pay two of the Disc-O-Tech founders up to an aggregate of $20 million if they develop, at their own cost and expense, a vertebral compression fracture repair system. In addition, they will be entitled to receive contingent service payments equal to 5% of the worldwide consolidated gross sales for this product, less standard returns and allowances. In order to dispose of the vertebroplasty assets, we will either have to ensure that the acquirer assumes our obligations under the development agreement or that the founders are otherwise compensated.

Because we may face significant competition from other companies with greater resources or superior technology than we have, we may be unable to maintain our competitive position and sales of our products may decline, and our revenues may decline as a result.

The market for medical devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. While the direct competition we have faced to date has been limited, we are aware that several companies, some with more resources than ours, are developing and have already introduced products to directly compete with ours in similar procedures, both in the United States and abroad, including, in some instances, copies of our technology for distribution in one or more foreign markets. For example, in September 2006, Medtronic Sofamor Danek, or MSD, also known as Medtronic Spine, a company with significantly more resources than Kyphon, introduced its *Equestra/Arcuate* product to compete with our technology for treating vertebral compression fractures. Additionally, Medtronic Spine, Abbott Labs, and Paradigm Spine have opened IDEs in the U.S. to seek regulatory approval for their respective interspinous process spacer products to treat lumbar stenosis and are already selling their products in Europe to compete with our *X-STOP* technology. Some of these competitors' products may be successful as a result of being less expensive alternatives to our products, or other advantages that make their products more attractive than ours, which could significantly impact our reimbursement levels, anticipated revenues and future growth. Our industry also includes large pharmaceutical companies that are developing drug products that may reduce the incidence of osteoporosis and cancer and, therefore, the market for our *KyphX* instruments, in particular. Our ability to compete successfully depends in part on our ability to respond quickly to medical and technological changes and user preferences through the development and introduction of new products that are of high quality, are subject to sufficient levels of government and third party reimbursement, and address patient and surgeon requirements. We compete with many larger companies that enjoy competitive advantages, including:

- longer-standing distribution networks and relationships with healthcare providers and payors;
- additional lines of products and the ability to bundle products to offer higher discounts or other incentives to gain a competitive advantage;
- greater experience completing preclinical testing and clinical trials and obtaining FDA and other regulatory approvals; and
- greater resources for product development, manufacturing, sales and marketing and patent litigation.

If we are unable to compete effectively against existing or future competitors, sales of our instruments will decline.

If we are unable to prevent third parties from using our intellectual property, our ability to compete in the market will be harmed.

We believe that the proprietary technology embodied in our instruments and methods gives us a competitive advantage. Maintaining this competitive advantage is important to our future success. We rely on patent protection in the U.S. and abroad, as well as on a combination of copyright, trade secret and trademark laws, 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. For example, our patents may be challenged, invalidated or circumvented by third parties. Our two earliest patents, which we believe provide broad protection to our technology, expire as early as February 2009. Our patent applications may not issue as patents at all or in a form that will be advantageous to us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees and current employees, despite the existence of nondisclosure and confidentiality agreements and other contractual restrictions. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States and may permit others to copy our products abroad without effective recourse. We have recently detected what we believe are the first attempts to copy some of our products for distribution in one or more foreign countries. In addition, in many foreign jurisdictions, we have either acquired patent protection that is narrower in scope than our corresponding protection in the U.S. or chosen, for various business reasons, not to pursue any patent protection at all. We also may not have the ability to prevent infringing products from remaining on the market in at least some geographic locations, and we may lose market share or have our growth impeded in those geographic markets as a result. To protect our rights, we may in the future initiate other claims or litigation against third parties for infringement of our proprietary rights. We may also begin one or more patent proceedings in various administrative agencies and patent offices to protect our patent rights and prevent them from being undermined by our competitors' patent filings. If we decide to enforce our intellectual property rights to prevent or inhibit appropriation of our technology by competitors, that process will be expensive and time consuming to litigate or otherwise dispose of, will divert management's attention from our core business, and may harm our business if we do not prevail.

Our instruments could infringe on the intellectual property rights of others, which may lead to costly litigation, payment of substantial damages or royalties and/or our inability to use essential technologies.

The medical device industry has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights. Whether a medical device infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that our instruments and methods infringe their patents, especially as we expand our business into other areas of technology, such as for diagnosis and treatment of spinal conditions. For example, Medtronic has brought suit against us in the United States alleging that our *KyphX* technology for the treatment of vertebral compression fracture, and which provides the majority our revenues, infringes four of its patents. Medtronic or others may choose to assert other patents against us at any time. From time to time, we receive correspondence from various third parties accusing us of infringing their patents or inviting us to license their patents. In addition, they may claim that their patents have priority over ours because they invented first or their patents were filed or issued first. Because patent applications can take many years to issue, there may be applications now pending of which we may be aware or unaware, which may later result in issued patents that our instruments or methods may infringe. There could also be existing patents that one or more of our instruments or methods may inadvertently be infringing. As the number of competitors in the market for minimally invasive spine disorder treatments grow, the possibility of a patent infringement claim against us increases.

Infringement and other intellectual property claims, with or without merit, against us can be expensive and time-consuming to litigate or otherwise dispose of and can divert management's attention from our core business. In addition, if we lose an intellectual property litigation matter, a court could require us to pay substantial damages and royalties, as well as issue a preliminary or permanent injunction that would prohibit us from developing, manufacturing or selling our products. Also, although we may seek to obtain a license under a third party's intellectual property rights to bring an end to any claims or actions asserted or threatened against us or to address an injunction or simply if we believe it makes business sense to do so, we may not be able to obtain a license on reasonable terms or at all. If we cannot design around a patent,

are enjoined from infringing it, and cannot obtain a satisfactory license, we may be forced to cease selling our products, which could cause substantial harm to our business and could cause our stock price to decline.

We expend considerable effort complying with federal and state healthcare "fraud and abuse" laws, but, if we are found not to have fully complied with such laws, our business and financial condition could be adversely affected, which could cause our stock price to decline.

As part of the medical device industry, we are subject to various federal and state healthcare laws generally collectively referred to as the healthcare "fraud and abuse" laws. Investigations and enforcement under these laws within our industry is increasing, and at least five other medical device manufacturers have recently been the subject of investigations and/or enforcement activities by the United States government in connection with the industry's interactions with, and payments to, healthcare professionals. While we educate and train our employees on how to interact appropriately with healthcare providers under applicable laws, and while we believe we are in substantial compliance with these laws, we cannot assure you that we will not be subject to investigations or enforcement actions under any of these laws based on the actions of our employees. We may also face increased risk of investigation and enforcement based on the actions of our customers under these same laws. If our past or present operations are judged to be in violation of any of the laws described above or the other similar governmental regulations to which we are subject, we may ultimately face associated adverse consequences, such as fines, penalties, exclusion from healthcare programs and/or the curtailment and restructuring of our operations, which could harm our business and our financial condition and cause our stock price to decline. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. This, in turn, could adversely affect our business and our financial condition, which could cause our stock price to decline.

We are aware that a complaint, which we believe is a *qui tam* complaint, is being evaluated by a U.S. Attorney's Office in connection with our marketing and sales practices, including those relating to the Medicare reimbursement available to our customer hospitals. Our business and financial condition could be adversely affected if a subpoena or an enforcement or other action ultimately results from this investigation or through the process the USAO will use with our customers to investigate the allegations even if no enforcement or other action ultimately results. This could cause our stock price to decline.

In 2005, a U.S. Attorney's Office in New York, or USAO, received a complaint that we believe is a *qui tam* complaint that alleges impropriety in our business, including regarding our reimbursement practices. *Qui tam* is a provision under the False Claims Act (31 U.S.C. § 3729 et seq.), which allows for a private individual, or whistleblower with alleged knowledge of past or present fraud on the U.S. federal government to bring suit on behalf of the government. Although no suit has been filed and no subpoena has been issued to us in connection with this complaint, the USAO is investigating our sales and marketing practices, including how we communicated with our customers in the past regarding the Medicare reimbursement available to hospitals and the appropriate site-of-service for using our products in surgery. The USAO has begun to review some of our documentation that may be relevant to the investigation, which we have produced, and has also interviewed some of our ex-employees and some of our customers. We continue to voluntarily cooperate with the USAO and to permit the USAO to develop an informed opinion on whether or not to pursue any action in connection with the complaint, although timing on that decision is uncertain. At the time, although we believe we are in substantial compliance with the healthcare laws applicable to us, we do not know whether the investigation itself, or the outcome of the investigation will have a material adverse impact to our business, and cannot assure you regarding any future path the USAO or any related lawsuit may take. Our business and financial condition could be adversely affected if a subpoena or an enforcement or other action ultimately results from this investigation, either against us, or against the physicians who perform procedures with our products or our customers who purchase our products, and could also be harmed through the process the USAO will use with our customers to investigate the allegations, even if no enforcement or other action ultimately results. This could cause our stock price to decline.

We are involved in patent infringement litigation with Medtronic and related entities that may harm our competitive position, may be costly to us and may prevent us from selling our products.

Medtronic and several other related corporate entities (MSD) have filed suit against us in federal district court in the Northern District of California, alleging that our vertebral bone tamps infringe four balloon dilatation catheter patents (numbers 4,820,349, 5,759,191, 5,759,173 and 6,179,856). The suit seeks damages based upon the making, using, selling and offering for sale of our products, seeks enhanced damages for alleged willful infringement, and seeks to enjoin our continued activities relating to these products. While we intend to vigorously defend this action, we cannot assure you that the outcome of this litigation will be favorable to us. If we lose the suit against us, it will hurt our competitive position, it may be costly to us and it may prevent us from selling our products. In addition, if we lose, we may need to obtain a license to the patented technology, which could be expensive, and which MSD may not grant us or we could be required to license to MSD some of our own technology, which would result in a partial loss of our competitive advantage in the marketplace, each of which could seriously harm our business. If MSD is successful in its patent suit and is unwilling to grant us a license, we may be required to stop selling our products that are found to infringe any of the asserted patents unless we can redesign them so they do not infringe, which we may be unable to do. In addition, if we lose, we could be required to pay damages, including treble damages, which could be substantial and harm our financial position and cause our stock price to decline.

MSD has also alleged that several of our patents relating to our vertebral bone tamps are invalid. We cannot assure you that we will be able to successfully defend this action. If MSD is successful in invalidating these patents, we will not be able to prevent our competitors, including MSD, from using the technology claimed in these patents. This will have a negative impact on our competitive position and could seriously harm our business.

Defending this suit and prosecuting our related suit against MSD in federal court in Memphis, Tennessee, will be expensive, the litigation may be protracted and our confidential information may be compromised. Whether or not we are successful in these lawsuits, this litigation could consume substantial amounts of our financial and managerial resources. At any time, MSD may file additional claims against us, or we may file further claims against MSD, which could increase the risk, expense and duration of the litigations. For more information on our litigation with MSD, see "Part II-Item 1: Legal Proceedings."

We are involved in a gender discrimination lawsuit that six of our current and former female sales employees filed against us. Failure to successfully defend against this action could harm our business, financial condition and operating results.

In June 2006, six of our current and former female U.S.-based sales employees filed a gender discrimination lawsuit against Kyphon in federal district court in the Northern District of California asking for injunctive relief and damages in excess of $100 million. The plaintiffs also seek to convert their case against us into a class action. Although we intend to vigorously defend plaintiffs' lawsuit, this lawsuit threatens our reputation and subjects us to potential liability for significant damages. While we believe we have multiple meritorious defenses to this action, we cannot assure you that we ultimately will prevail on any issue in the litigation or that we will be able to successfully defend plaintiffs' charges. Failure to successfully defend against this action could harm our business, financial condition and operating results and cause our stock price to decline.

Our failure to maintain necessary regulatory clearances or approvals, or to obtain additional regulatory clearances or approvals, in the United States and abroad could hurt our ability to commercially distribute and market our products.

Our products are considered medical devices and are subject to extensive regulation in the United States and in foreign countries where we currently conduct, or intend to conduct, our business. Unless an exemption applies, each medical device that we wish to market in the United States must first receive either 510(k) clearance or premarket approval from the FDA. The FDA's 510(k) clearance process usually takes

from three to 12 months, but may take longer. The premarket approval process generally takes from one to three years from the time the application is filed with the FDA, but it can take longer, require more information, and be significantly more expensive than the 510(k) clearance process. So far, we have obtained 510(k) clearance for the *KyphX* Inflatable Bone Tamps for fracture reduction or void creation in specific sites including the spine (including for use during balloon kyphoplasty using our bone cement), hand, tibia, radius and calcaneus, and clearance for our *KyphX HV*-R Bone Cement for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions during balloon kyphoplasty procedures. These clearances allow us to promote numerous short-and long-term clinical benefits associated with balloon kyphoplasty procedures. The *X-STOP* device has received approval under the more rigorous premarket approval application (PMA) process since it is classified as a Class III device. We have also procured CE marking for promoting our products in Europe and the appropriate governmental regulatory clearances to conduct business in Canada and several other foreign countries. Nevertheless, our 510(k), PMA and foreign regulatory clearances can be revoked if safety or effectiveness problems develop. We also will be required to obtain 510(k) clearance or premarket approval and foreign regulatory clearances to market additional products, such as new biomaterials for use in balloon kyphoplasty, which will likely require clinical data, and to market our existing products for new indications, such as treatment of fractures caused by trauma. If the clinical data gathered are not supportive, then applications will not be filed. If we choose to seek additional clearances or approvals by filing one or more applications, we cannot be certain that we would obtain any further regulatory clearances or premarket approvals in a timely manner or at all, and delays in obtaining clearances or approvals may adversely affect our revenue growth, future profitability and ability to penetrate what otherwise might be lucrative markets for our products.

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.

We have begun to invest significant financial resources to conduct clinical trials of our products, which will reduce our earnings during the foreseeable future, and which may not ultimately provide data supportive of the use and clinical efficacy of our products.

We anticipate conducting significant additional clinical trial activity both in the United States and abroad to collect further data that may support the use and clinical efficacy of our products. The cost of these trials will be significant, which may reduce our net income and earnings for the foreseeable future.

In addition, the results of our clinical trials may not ultimately produce data that are supportive of our products over other treatment alternatives, that may support unfavorable conclusions regarding our technology, and that ultimately may provide information that leads to a decreased rate of adoption of our products for balloon kyphoplasty, which would harm our business and cause our stock price to decline.

Finally, we may be unable to complete the clinical trials for a variety of reasons, and therefore may not be able to provide additional clinical data on our products.

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

As a condition of receipt of premarket approval from the FDA, for the *X-STOP* technology, 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 are required to continue 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 safety concerns arise, the FDA could require us to modify the labeling of the *X-STOP* device which could reduce 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* device, any such action would also likely adversely affect our plans for expanding the indications for the *X-STOP* device. Any FDA action to limit the indicated patient population for the *X-STOP* device 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 aware that third parties are conducting a variety of clinical studies involving the *X-STOP* technology. If those studies support conclusions that reflect negatively on the safety or efficacy of the *X-STOP* technology, our business and results of operations could be harmed, which could cause our stock price to decline.

We are aware that third parties are in the process of conducting clinical studies involving the *X-STOP* technology for the treatment of lumbar spinal stenosis. These studies were commenced before we purchased the technology and may not have been designed or conducted in an optimal manner. Additionally, clinicians involved with the studies may not have had adequate training prior to performing procedures involving the *X-STOP* IPD System. We do not have and may not obtain a full understanding of these studies or of all of the data that have been generated. Nevertheless, if one or more of those studies ultimately supports a conclusion that reflects negatively on the safety or efficacy of the *X-STOP* technology, our business and results of operations could be harmed, which could cause our stock price to decline.

We have had no experience to date with the complex compliance and regulatory requirements associated with developing, acquiring approval for and marketing FDA class III devices, and if we are unable to successfully comply with these more complex requirements, our business could be harmed.

To date, we have had no experience with developing, seeking regulatory approval for or marketing in the U.S. class III medical devices, such as the *X-STOP IPD* System for lumbar spinal stenosis that we recently acquired from St. Francis. Class III medical devices have more complex compliance and regulatory requirements associated with them than class I or class II devices, with which we are more familiar, and typically require more onerous clinical trials in order to gain and maintain FDA approval for marketing and promotion. We can provide no assurance that we will be able to implement the necessary systems, processes and procedures to ensure compliance with the more complex regulations associated with class III devices. If we unable to successfully navigate all of the increased complexities associated with class III devices, we will be unable to successfully integrate into our business, and realize the full potential of our acquisition of, the *X-STOP* technology, which could harm our business and cause our stock price to decline.

We may seek additional financing, which could result in dilution to our stockholders or may not be available to us on acceptable terms, if at all.

As of December 31, 2006, we had $81.9 million of cash and cash equivalents and $120.2 million of short-term investments. We believe our cash generated from operations, together with our cash, cash equivalents, investments, and borrowings available under our revolving credit facility will be sufficient to meet our anticipated cash needs for working capital, capital expenditures and any contingent payments that become due related to our recent acquisitions for at least the next 12 months. If existing cash, cash equivalents, cash generated from operations and borrowings available to us under our revolving credit facility are insufficient to satisfy our cash requirements, whether as a result of expansion of product lines, increased capital expenditures, additional clinical trials, or investment in new markets or businesses, or for other reasons related to our business, we may seek to sell additional equity or debt securities. The sale of additional equity or the sale of additional convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock, and could contain covenants that would restrict our operations. Additional financing may not be available to us when we need it or it may not be available on favorable terms, if at all. If we are unable to obtain adequate financing when needed, we may

have to delay, reduce the scope of or eliminate our business development activities which could cause our stock price to decline.

If we are unable to generate or borrow sufficient cash to make payments on our indebtedness or to refinance our indebtedness on acceptable terms, our financial condition would be materially harmed, our business may fail and you may lose all of your investment.

Our ability to make payments on and to refinance our debt will depend on our financial and operating performance, which may fluctuate significantly from quarter to quarter, and is subject to prevailing economic conditions and financial, business and other factors, many of which are beyond our control. We cannot assure you that we will continue to generate sufficient cash flow or that we will be able to borrow funds in amounts sufficient to enable us to service our debt or to meet our working capital and capital expenditure requirements. If we are not able to generate sufficient cash flow from operations or to borrow sufficient funds to service our debt, we may be required to sell assets or equity, reduce capital expenditures, refinance all or a portion of our existing debt or obtain additional financing. If we are unable to meet our debt obligations or fund our other liquidity needs, we may need to restructure or refinance all or a portion of our debt on or before maturity or sell certain of our assets. We cannot assure you that we will be able to restructure or refinance any of our debt on commercially reasonable terms, if at all, which could cause us to default on our debt obligations and impair our liquidity. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations.

We may not be able to finance future needs or adapt our business plan to changes because of restrictions placed on us by our credit facility, the indentures governing our notes and instruments governing our other indebtedness.

The indentures for our notes and our credit facility contain affirmative and negative covenants which restrict, among other things, our ability to:

- incur additional debt;
- sell assets;
- create liens or other encumbrances;
- make certain payments and dividends; or
- merge or consolidate.

All of these restrictions could affect our ability to operate our business and may limit our ability to take advantage of potential business opportunities as they arise. A failure to comply with these covenants and restrictions would permit the relevant creditors to declare all amounts borrowed under the relevant facility, together with accrued interest and fees, to be immediately due and payable. If the indebtedness under the credit facility or our notes is accelerated, we may not have sufficient assets to repay amounts due under the credit facility, the notes or on other indebtedness then outstanding. If we are not able to refinance our debt, we could become subject to bankruptcy proceedings, and you may lose all or a portion of your investment because the claims of our creditors on our assets are prior to the claims of our stockholders.

If we are unable to expand our in-house manufacturing capacity in a timely manner, or if we do not accurately project demand, we could have excess capacity or insufficient capacity, either of which could adversely affect our operating results.

We currently manufacture substantially all of our *KyphX* instruments in our facilities located in Sunnyvale, California. We plan to expand our manufacturing capacity at this facility. In addition, we will be devoting significant resources during 2007 towards establishing our new facilities in Neuchâtel, Switzerland that will include manufacturing capacity. We plan to manufacture a secondary supply of our *KyphX* instruments in this facility, in addition to manufacturing our proprietary *KyphOs* calcium phosphate bone cement. We

could experience difficulties and disruptions in the manufacture of our *KyphX* instruments during capacity expansion in our Sunnyvale facility, prior to bringing up our Neuchâtel facility. In both our Sunnyvale and Neuchâtel facilities, we could also face the inability to procure and install the necessary manufacturing equipment, a shortage of components used in our products, a lack of availability of qualified manufacturing personnel, difficulties in achieving consistent quality control from new manufacturing lines, difficulties in obtaining or maintaining compliance with regulatory requirements mandated by the FDA and the European Union and an inability to maintain sufficient manufacturing capacity. We may experience delays, disruptions, capacity constraints and other problems in our manufacturing operations, and, as a result, product shipments to our customers could be delayed, which would negatively impact our revenues, competitive position and reputation. If we are unable to expand our manufacturing capacity in a timely manner, or if we do not accurately project demand, we will have excess capacity or insufficient capacity, either of which could seriously harm our profitability and cause our stock price to decline.

We are dependent on single source suppliers and manufacturers for the *X-STOP* device, 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.

Any significant delay or interruption in the supply of the *X-STOP* device 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.

Our reliance on suppliers could limit our ability to meet demand for our products in a timely manner or within our budget.

We are dependent upon outside suppliers to provide us with key components necessary for the manufacture of our products. In addition, we are presently sourcing our *KyphX* Inflation Syringe and our *KyphX HV-R* Bone Cement from single suppliers, without any present viable alternative suppliers qualified. Generally, since we obtain components through purchase orders rather than long-term supply agreements and do not maintain large volumes of inventory, a product recall, disruption or termination of the supply of components could adversely affect our continued ability to conduct business, including causing:

- a significant increase in manufacturing costs associated with the need to obtain replacement components;
- our inability to meet demand for our instruments, which could lead to customer dissatisfaction and damage our reputation; and
- delays associated with regulatory qualifications required for use of replacement suppliers.

Any one of these results could harm our sales and profits and make it difficult to meet our business goals.

Because injuries that occur during spine surgery can be significant, we are subject to an increased

risk of product liability lawsuits and/or regulatory action. If we are sued in a product liability action, we could be forced to pay substantial damages.

We manufacture medical devices that are used on patients in spine surgery procedures. Spine surgery, including implantation of the *X-STOP* device or balloon kyphoplasty, involves risk of serious complications, including cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, and death. The use of bone filler material by surgeons to fill the void created using our *KyphX* Inflatable Bone Tamp may also lead to these complications, as a result of leakage of the bone filler material into the spinal canal or surrounding tissue or for other reasons. We are aware that some of these complications have occurred during procedures performed with our products, including our *KyphX HV*-R bone cement and *KyphO*s calcium phosphate, and we have had to publicly report that information through filing a Medical Device Report to the FDA or Vigilance Reports in the EU. Increased reporting of adverse events in connection with the use of our or other bone void filler materials during balloon kyphoplasty could expose us to increased risk of product liability litigation, and our current insurance coverage limits may not be adequate and we may not be able to obtain continued product liability coverage on commercially reasonable terms, if at all. Companies, including ours, which produce devices for use in the spine, are subject to a significant risk of product liability litigation. If any of our devices are found to have caused or contributed to any injury, we could be held liable for substantial damages, and our current product liability coverage limits may not be adequate to protect us from any liabilities we might incur. In addition, we may require increased product liability coverage if sales of our devices increase. Product liability insurance is expensive and may not be available to us in the future on acceptable terms, if at all. In addition, increased reporting of adverse events may lead to regulatory action by the FDA which could adversely affect our ability to market products and/or result in other adverse consequences to our Company, our employees and our business, including but not limited to civil and criminal penalties, recall, seizure, and product withdrawal, which in turn could adversely affect our business and our financial condition and cause our stock price to decline.

We derive a significant portion of our operating results from sales outside the United States, which are subject to additional risks arising from international operations and sales.

Sales outside of the United States account for a significant percentage of our revenues and we intend to continue to expand our presence in international markets. International net sales accounted for $83.7 million or approximately 21% of total net sales in 2006. Our international operations and sales are subject to a number of further risks in addition to those faced for our business, generally including:

- our products may sell at lower prices outside the United States;
- agreements may be difficult to enforce;
- receivables may be difficult to collect through a foreign country's legal system;
- foreign customers may have longer payment cycles;
- foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- U.S. export licenses may be difficult to obtain;
- intellectual property may be more difficult to acquire and enforce in foreign countries, and copying of our products in certain jurisdictions may become widespread;
- terrorist activity may interrupt distribution channels or impact our customers or employees; and
- fluctuations in exchange rates may affect product demand and adversely affect the profitability, in U.S. dollars, of products sold in foreign markets where payments are made in local currencies.

Any one or more of these factors stated above could have an adverse effect on our non-U.S. financial condition, results of operations and business and cause our stock price to decline.

Since we depend upon distributors in some markets, if we lose a distributor or a distributor fails to perform, our revenues will be harmed in those geographic markets.

With the present exception of Canada, South Africa and some of the larger countries in Europe, we sell our *KyphX* instruments in foreign markets through distributors and sales agents. To the extent we rely on distributors, our success will depend upon the efforts of others, over which we may have little control. We are in the process of terminating *X-STOP IPD* distributors in the U.S. and in certain countries in Europe. We may not be able to effect a successful transition to either our own sales force or to new distributors. We both establish and terminate relationships with distributors in foreign jurisdictions in the ordinary course of business. We may also terminate or modify other distribution relationships in further geographic locations in the future. If we lose a distributor or a distributor fails to perform, our revenues will be harmed in those geographies, and the market for our products may also be harmed in those geographies as a result of the distributor's or agent's actions. Alternative sales channels are available in these geographic markets; however, their establishment could consume substantial time and resources.

If we do not effectively manage our growth, our existing infrastructure may become strained, and as a result we may be unable to increase sales of our products or generate significant revenue growth.

Our world-wide direct sales organization has increased from approximately 31 employees in October 2000 to over 480 field-based employees in December 2006, which we believe represents significant growth over a relatively short period of time. Our world-wide organization as a whole has increased from approximately 131 employees in October 2000 to over 1,090 employees in December 2006. We intend to continue growing rapidly. The growth that we have experienced, and in the future likely will experience, provides challenges to our organization, requiring us to rapidly expand our personnel and manufacturing operations. We may not be able to hire sufficient personnel to meet our growth goals or may have difficulty managing such rapid growth. As a result, our failure to recruit additional sales and other personnel may result in our inability to meet our projections. Future growth may strain our infrastructure, operations, product development and other managerial and operating resources. If our business resources become strained, we may not be able to deliver instruments in a timely manner.

We are dependent on our senior management team and key personnel, and the loss of any of them could harm our business.

Our continued success depends in part upon the continued availability and contributions of our senior management team and key personnel. We have entered into an employment agreement with Richard W. Mott, but this agreement does not guarantee his service for any specified period of time. We have not entered into employment agreements with any of our other senior management or key personnel. The loss of members of our senior management or key personnel, or our inability to attract and retain other qualified personnel or advisors could adversely affect our business and financial condition, which could cause our stock price to decline.

We may be adversely affected by the impact of environmental and safety regulations.

We are subject to federal, state, local and foreign laws and regulations governing the protection of the environment and occupational health and safety, including laws regulating the disposal of hazardous wastes and the health and safety of our employees. We may be required to obtain permits for governmental authorities for certain operations. If we violate or fail to comply with these laws and regulations, we could incur fines, penalties or other sanctions, which could adversely affect our business and our financial condition and cause our stock price to decline. We could incur material expenses in the future relating to compliance with future environmental laws. In addition, we could be held responsible for costs and damages arising from any contamination at our present facilities or third-party waste disposal sites. Such costs could be material. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur material liability as a result of any contamination or injury.

Our certificate of incorporation and by-laws include anti-takeover provisions that may enable our management to resist an unwelcome takeover attempt by a third party.

Our basic corporate documents and Delaware law contain provisions that enable our management to attempt to resist a takeover unless it is deemed by management and our Board of Directors to be in the best interests of our stockholders. Those provisions might discourage, delay or prevent a change in the control of our company or a change in our management. Our Board of Directors may also choose to adopt further anti-takeover measures without stockholder approval. The existence and adoption 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.

We have experienced and may continue to experience increases in our general and administrative costs as a result of additional securities and corporate governance laws and regulations.

The Sarbanes-Oxley Act of 2002 that became law in July 2002, as well as the rules and regulations subsequently implemented by the SEC and the NASDAQ exchange on which we are listed, required significant changes to our corporate governance practices. These new rules and regulations have resulted in increased legal and financial compliance costs, make some activities more difficult, time consuming and/or costly, and make it more difficult and more expensive for us to obtain directors and officers liability insurance, all of which may affect our financial performance. These new rules and regulations may also make it more difficult for us to attract or retain qualified executive officers and members of our Board of Directors, particularly to serve on our Audit Committee. We may experience additional increases in our general and administrative costs as a result of additional securities and corporate governance laws and regulations that may be enacted in the future.

We can provide no assurance regarding our, or our independent registered public accountants', conclusions after December 31, 2006 with respect to the effectiveness of our internal control over financial reporting.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to include an internal control report from management in our Annual Report on Form 10-K. The internal control report must include a statement:

- about management's responsibility for establishing and maintaining adequate internal control over financial reporting;
- identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting;
- concerning management's assessment of the effectiveness of our internal control over financial reporting as of the period covered by the Annual Report, including a statement as to whether or not internal control over financial reporting is effective; and
- that our independent auditors have issued an attestation report on management's assessment of internal control over financial reporting.

While we expended significant resources in developing the necessary documentation and testing procedures required by Section 404, given the risks inherent in the operation of internal controls over financial reporting, we can provide no assurance as to our, or our independent auditor's, conclusions after December 31, 2006 with respect to the effectiveness of our internal control over financial reporting. Although we received unqualified opinions as of December 31, 2006, if we are unable to maintain compliance with all of the requirements imposed by Section 404, or if we are unable to complete any assessment of our internal controls, or if our internal controls are not designed or operating effectively, we may conclude that our internal control over financial reporting is not effective and our external auditors may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal control or may issue a qualified opinion on the effectiveness of our internal controls. Investors may lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and which could affect our business and financial condition.

Our facilities are located near known earthquake fault zones, and the occurrence of an earthquake or other natural disaster or catastrophic event could cause damage to our facilities and equipment, which could require us to cease or curtail operations and could hurt our revenues.

Our facilities are located near known earthquake fault zones and are vulnerable to significant damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fires, floods, power loss, communications failures and similar events including the effects of war or acts of terrorism. If any disaster of this sort were to occur, our ability to operate our business at our facilities could be seriously or completely impaired or destroyed and our revenues could be significantly impacted as a result of our inability to continue to supply products to our customers. The insurance we maintain may also not be adequate to cover our own losses resulting from disasters or other business interruptions.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

Our United States operations and our corporate headquarters are located in an approximately 151,000 square foot facility in Sunnyvale, California, where we conduct our manufacturing, warehousing, research, regulatory and administrative activities. This includes an additional 43,434 square feet which we leased pursuant to an amendment to our existing lease agreement on September 28, 2005. The combined facilities are leased through August 2014. Under the terms of the lease agreement, we have the option to have additional square footage built and leased to us in the same surrounding campus.

Our European operations are located in an approximately 28,000 square foot facility in Brussels, Belgium, where we conduct sales, clinical, regulatory and administrative activities. The facility is leased through December 2011 and includes offices, storage and warehouse facilities. We also have a leased research facility located in Rosbach, Germany through January 2008. In addition, we have leased individual sales offices in many of the major countries in Europe and offices in Japan and Canada, expiring at various dates through 2013. In November 2005, we entered into a two year lease for an approximately 16,000 square foot facility in Neuchâtel, Switzerland. This lease will serve as a temporary facility for us to conduct administrative and distribution activities for our international business while we build a larger facility in Neuchâtel. In May 2006, we entered into a Real Estate Leasing Contract with Credit Suisse for the financing of the new facility. The construction of the building began in July 2006, and we anticipate the completion of the new building in late 2007. We plan to conduct manufacturing, distribution, administrative and certain research and development activities in this facility to support the growth of our international business.

We believe that our facilities are suitable and have adequate capacity to meet our current needs and that additional or substitute space will be available to accommodate our future needs.

ITEM 3. LEGAL PROCEEDINGS

In November 2005, Dr. Harvinder Sandhu, a well-respected orthopaedic surgeon, and Kyphon filed suit in federal district court in Memphis, Tennessee against Medtronic Sofamor Danek (MSD) and several other related corporate entities seeking compensatory and punitive damages and injunctive relief for breach of contract and related covenants, trade secret theft, fraud, and correction of inventorship of several patents and patent applications presently owned by MSD, including U.S. Patent No. 6,676,665. The suit also requests, among other relief, that MSD transfer to Dr. Sandhu ownership of the disputed patents and patent applications. The dispute concerns inventions related to an expandable, mechanical bone tamp for use in treating vertebral compression fractures that Dr. Sandhu invented in the late 1990's and which he confidentially disclosed and discussed with MSD. The complaint alleges that MSD later filed for several patents encompassing and claiming Dr. Sandhu's inventions without naming him as inventor of that technology, and that it also incorporated Dr. Sandhu's inventions into its internal *Equestra/Arcuate* project without his permission. In May 2006, the Company also sued MSD in the same Tennessee court for willfully infringing five of the Company's U.S. patents (numbers 4,969,888, 5,108,404, 6,235,043, 6,440,138, and 6,863,672) with its *Equestra/Arcuate* product. Discovery is underway, and various motions

are pending that seek to address the merits of Dr. Sandhu's and Kyphon's claims. Trial was initially set for April 2007, but may be delayed. We intend to vigorously prosecute our and Dr. Sandhu's case against MSD.

In April 2006, MSD and several related entities filed suit against us in federal district court in the Northern District of California, alleging that our vertebral bone tamps and/or related products infringe three angioplasty balloon dilatation catheter patents (numbers 4,820,349, 5,759,191 and 6,179,856) and a single claim of patent number 6,096,038, which generally concerns treatment of the disc space. MSD has since dropped the '038 patent from the suit and asserted another dilatation catheter patent, number 5,759,173. The suit seeks damages based upon the making, using, selling and offering for sale of our products, seeks enhanced damages for alleged willful infringement, and seeks to enjoin our continued activities relating to these products. In October 2006, we were denied permission to seek a declaratory judgment that another MSD patent generally concerned with treatment of the disc space and related to the `038 patent, number 7,115,128 also has no application to our kyphoplasty technology. Although we intend to vigorously defend MSD's California lawsuit, MSD's action against us subjects us to potential liability for damages, including treble damages, and could require us to cease making, using or selling the affected products, or to obtain a license in order to continue to manufacture, use or sell the affected products. While we believe we have multiple meritorious defenses to this action, we cannot assure you that we ultimately will prevail on any issue in the litigation or that we will be able to successfully defend MSD's charges, nor can we provide assurance that any license required would be made available on commercially acceptable terms, if at all. Failure to successfully defend against MSD's action could harm our business, financial condition and operating results. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of this matter at this time and, therefore, cannot estimate the range of possible loss.

In 2005, a U.S. Attorney's Office (USAO) received a complaint that we believe is a *qui tam* complaint that alleges impropriety in our business, including regarding our reimbursement practices. Although no subpoena has been issued to us in connection with this complaint, the USAO is investigating our sales and marketing practices, including how we communicated with our customers in the past regarding the Medicare reimbursement available to hospitals and the appropriate site-of-service for using our products in surgery. The USAO has asked to review some of our documentation that may be relevant to the investigation, much of which we have already produced. We believe we are in substantial compliance with the healthcare laws applicable to us. Even though we have not received a subpoena regarding the complaint or its allegations, we continue to voluntarily cooperate with the USAO, to permit the USAO to develop an informed opinion on whether or not to pursue any action in connection with the complaint based in part on the information we provide, although timing on that decision is uncertain. At this time, we do not know whether the investigation or its outcome will have a material adverse impact to our business, and cannot assure you regarding any future path the USAO or any related lawsuit may take. Due to the uncertainties inherent in this process, we cannot accurately predict the ultimate outcome of this matter at this time and, therefore, cannot estimate the range of possible loss.

In June 2006, six of our current and former female U.S.-based sales employees filed a lawsuit against Kyphon in federal district court in the Northern District of California. They allege, among other things, that Kyphon has engaged in gender and pregnancy discrimination against them, and also contend that they and their lawyers should be permitted to represent an alleged class of all of our present and many former female Spine Education Specialists, Spine Associates and Spine Consultants because all of those women were also allegedly discriminated against on account of their gender and pregnancy status. The plaintiffs claim that they are due assorted damages of at least $100 million. The case is in its early stages; no trial date has been set. Although we intend to vigorously defend plaintiffs' lawsuit, this lawsuit threatens our reputation and subjects us to potential liability for significant damages. While we believe we have multiple meritorious defenses to this action, we cannot assure you that we ultimately will prevail on any issue in the litigation or that we will be able to successfully defend plaintiffs' charges. Failure to successfully defend against this action could harm our business, financial condition and operating results. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of this matter at this time and, therefore, cannot estimate the range of possible loss.

In addition, we are subject to legal proceedings, claims, and litigation arising in the ordinary course of business, including employment-based claims and intellectual property litigation. While the outcome of these matters is currently not determinable, we do not expect that the ultimate costs to resolve these matters will have a material adverse effect on our consolidated financial position, results of operations, or cash flows.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this Annual Report on Form 10-K.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is quoted on the NASDAQ Stock Market under the symbol "KYPH". The following table shows the high and low closing sale prices of our common stock for each quarterly period for the past two years as reported on the NASDAQ Stock Market:

	Common Stock	
	High	Low
Fiscal Year 2005		
First quarter	$ 28.47	$ 23.86
Second quarter	$ 34.79	$ 24.28
Third quarter	$ 44.93	$ 34.06
Fourth quarter	$ 46.40	$ 37.76
Fiscal Year 2006		
First quarter	$ 42.95	$ 33.74
Second quarter	$ 43.50	$ 33.11
Third quarter	$ 39.58	$ 31.16
Fourth quarter	$ 44.98	$ 33.10

We had 96 stockholders of record as of February 15, 2007.

Since our incorporation, we have never declared or paid any dividends on our capital stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business, repayment of debt and do not anticipate paying any cash dividends in the foreseeable future. In addition, our current credit facility places certain restrictions on paying cash dividends.

We did not sell any unregistered securities during the period covered by this Annual Report on Form 10-K, other than our convertible senior notes as described in our Current Report on Form 8-K filed with the SEC on February 12, 2007.

Our Board of Directors approved a stock repurchase program on November 7, 2002, pursuant to which we may purchase up to 2,000,000 shares of our outstanding common stock. The duration of the repurchase program is open-ended. Under the program, we may purchase shares of common stock through open market transactions at prices deemed appropriate by management and the Board of Directors. The purchases will be funded from available working capital. In 2002, we repurchased 30,000 shares pursuant to this repurchase program. We have not repurchased any of our common stock since 2002.

ITEM 6. SELECTED FINANCIAL DATA

The following tables contain selected consolidated financial data derived from our consolidated financial statements for each of the last five years. The consolidated statement of operations data for the years ended December 31, 2006, 2005 and 2004, and the consolidated balance sheet data as of December 31, 2006 and 2005 are derived from our audited consolidated financial statements included in this Annual Report on Form 10-K. The consolidated statement of operations data for the years ended December 31, 2003 and 2002, and the consolidated balance sheet data as of December 31, 2004, 2003 and 2002 are derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results. The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. In 2007, we completed our acquisition of St. Francis and expect to complete our proposed acquisitions of certain spine-related assets of Disc-O-Tech, and its U.S. subsidiary if we are able to obtain the necessary regulatory approvals to close those acquisitions. The selected consolidated financial data set forth below excludes the results of these transactions.

	Year Ended December 31,				
	2006	2005	2004	2003	2002
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Net sales	$ 407,790	$ 306,082	$ 213,414	$ 131,028	$ 76,316
Cost of goods sold	52,176	35,843	24,734	16,794	10,416
Gross profit	355,614	270,239	188,680	114,234	65,900
Operating expenses:					
Research and development	39,971	46,383	22,238	16,031	22,512
Sales and marketing	194,057	144,768	106,103	69,538	44,083
General and administrative	60,351	34,951	25,972	16,328	11,849
Total operating expenses	294,379	226,102	154,313	101,897	78,444
Income (loss) from operations	61,235	44,137	34,367	12,337	(12,544)
Interest income (expense) and other, net	9,487	3,979	1,250	986	(2,794)
Income (loss) before income taxes	70,722	48,116	35,617	13,323	(15,338)
Provision (benefit) for income taxes	30,990	18,280	13,900	(14,000)	--
Net income (loss)	$ 39,732	$ 29,836	$ 21,717	$ 27,323	$ (15,338)
Net income (loss) per share:					
Basic	$ 0.89	$ 0.70	$ 0.54	$ 0.71	$ (0.63)
Diluted	$ 0.86	$ 0.66	$ 0.50	$ 0.65	$ (0.63)
Weighted-average shares outstanding:					
Basic	44,436	42,803	40,449	38,433	24,405
Diluted	46,313	45,336	43,670	42,090	24,405

	As of December 31,				
	2006	2005	2004	2003	2002
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 202,153	$ 194,473	$ 115,799	$ 85,479	$ 74,303
Working capital	228,046	216,504	153,926	86,564	83,504
Total assets	428,606	316,632	213,389	154,480	101,524
Deferred stock-based compensation	--	116	2,113	6,435	11,947
Total stockholders' equity	$ 344,700	$ 250,056	$ 179,635	$ 134,250	$ 91,514

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Introduction

Management's discussion and analysis of financial condition and results of operations is organized as follows:

- *Executive summary.* This section provides a general description and history of our business, a brief discussion of our product lines and the opportunities, trends, challenges and risks we focus on in the operation of our business.

- *Critical accounting policies and estimates.* This section discusses those accounting policies that both are considered important to our financial condition and results of operations, and require us to exercise subjective or complex judgments in their application. In addition, all of our significant accounting policies, including our critical accounting policies, are summarized in Note 2 to our consolidated financial statements.

- *Results of operations.* This section provides our analysis and outlook for the significant line items on our condensed consolidated income statements.

- *Stock-based compensation.* This section describes the accounting method and financial reporting of our stock options granted to employees and non-employees.

- *Seasonality.* This section describes the effects of seasonality on our business.

- *Liquidity and capital resources.* This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of December 31, 2006.

- *Recent accounting pronouncements.* This section describes the issuance and effects of recently issued accounting pronouncements.

- *Factors affecting future operating results.* This section discusses the most significant factors that could affect our future financial results. The factors discussed in this section are in addition to factors that may be described in the captions discussed above and elsewhere in this report.

Executive Summary

Company Description. We are a global medical device company specializing in the design, manufacture and marketing of medical devices used to treat and restore spinal anatomy and diagnose low back pain using minimally invasive technology. Our original technology for performing balloon kyphoplasty is presently used primarily by spine specialists, including orthopaedic surgeons and neurosurgeons, interventional radiologists and interventional neuroradiologists, who repair compression fractures of the spine caused by osteoporosis, trauma, cancer or benign lesions through minimally invasive spine surgeries. Most alternative treatments for these types of spinal fractures are either highly invasive or are only pain management therapies. In 2006, we acquired rights to *Functional Anaesthetic Discography* (*F.A.D.*) technology which is used to diagnose the source of low back pain and is useful to provide additional information to physicians in determining how to appropriately treat their patients. We commenced a limited initial launch of our *F.A.D.* technology in the third quarter 2006 and we expect to pursue a measured, deliberate market roll-out throughout 2007. In January 2007, we also acquired rights to the *X-STOP* Interspinous Process Decompression (*IPD*) technology for treating lumbar spinal stenosis (LSS), which is complimentary to some of our own internally developed technology for treating LSS. Our commercial products presently consist of our *KyphX* instruments, which are used to treat spinal fractures during balloon kyphoplasty, including our proprietary *KyphX* balloon technology and our proprietary brands of bone filler materials; our *Discyphor F.A.D.* technology for diagnosing low back pain; our *X-STOP IPD* technology for treating lumbar spinal stenosis; and our internally developed *Aperius PercLID*

technology for treating lumbar spinal stenosis which we are presently trialing on a very limited basis in several European locations.

In January 2007, we acquired rights to the *X-STOP* Interspinous Process Decompression (*IPD*) technology, a proprietary technology platform for the treatment of lumbar spinal stenosis, through our acquisition of St. Francis Medical Technologies, Inc. (St. Francis), a privately held company in Alameda, California. The *X-STOP* technology is complementary to our existing extension limiting technology for the treatment of LSS. The total estimated purchase price, excluding transaction costs, of approximately $725.0 million comprised $525.0 million in cash upon closing, plus additional revenue-based contingent payments of up to $200.0 million payable in either cash or a combination of cash and stock, at Kyphon's election. The payments are contingent upon the attainment of certain revenue thresholds during specified periods through June 2008. We expect to record $204.9 million of identifiable intangible assests as a result of this acquistion, which we expect to amortize on a straight line basis over the next 10 years. We also expect to expense in-process research and development costs of $21.3 million in the first quarter of 2007. We financed the transaction through a combination of cash on hand and bank financing.

We also executed two definitive agreements in December 2006 with Disc-O-Tech Medical Technologies, Ltd. and its U.S. subsidiary (Disc-O-Tech) to acquire, respectively, all of its non-vertebroplasty spine-related assets, including minimally invasive technologies for performing fusion and vertebral body augmentation, for $100.0 million in cash ($60.0 million paid up-front in December 2006 and another $40.0 million paid February 1, 2007), and all of its vertebroplasty assets for a total of an additional $120.0 million payable in three equal annual installments beginning in January 2008. We also agreed to pay up to an additional $20.0 million for the development of future technologies upon closing of the vertebroplasty asset purchase agreement. The closing of the non-vertebroplasty transaction, if and when that occurs, will enable us to further broaden our focus in minimally invasive spine by adding the *B-Twin*™ Expandable Spinal System technology for minimally invasive fusion in patients with degenerative disc disease in the lumbar and cervical spine, which is CE marked but not presently available in the U.S. The non-vertebroplasty assets also include Disc-O-Tech's SKy™ Bone Expander System, which is available only outside the U.S. for use in the treatment of vertebral compression fractures. The assets to be acquired under the vertebroplasty agreement include Disc-O-Tech's Confidence™ Cement System, which would be another treatment option complementary to our existing *KyphX* technology for vertebral compression fractures, depending on a patient's individual needs and a clinician's goals for his or her patients. The Confidence System incorporates a delivery mechanism that is designed to provide controlled injection of putty-like cement, reduce clinician radiation exposure and streamline cement preparation. Kyphon's ability to offer such additional minimally invasive diagnostic and therapeutic tools to our customers is a natural next step in broadening our product offerings. We have not yet received clearance from the Federal Trade Commission to close either of these transactions and may not be able to do so for some time, if at all. We will still be obligated to pay the purchase price even if the closings do not occur.

Our corporate headquarters and United States operations are located in Sunnyvale, California, where we conduct our manufacturing, warehousing, research and development, regulatory and administrative activities. Outside the United States, we operate a sales, clinical, regulatory and administrative facility in Brussels, Belgium, a research and biomaterials manufacturing facility in Rosbach, Germany, a clinical, regulatory and administrative facility in Japan, and we have direct selling operations in many of the major countries in Europe, South Africa, Australia and in Canada. In November 2005, we leased a temporary facility in Neuchâtel, Switzerland in which to conduct our administrative and distribution activities for our international business while we build a larger facility in that same location. In May 2006, we entered into a real estate leasing contract with Credit Suisse for the financing of the new facility. The construction of the building began in July 2006, and we anticipate the completion of the new building in late 2007. We plan to conduct manufacturing, distribution, administrative and certain research and development activities in the Switzerland facility to support the growth of our international business. In August 2006, we commenced distribution activities to our European customers and established a shared financial services center in Neuchâtel. Our global distribution network consists of a direct sales organization of almost 480 individuals who market our products in the U.S., Europe and Canada. We also have distributors and sales agents in other countries in which we do not have a direct sales force. In Japan, we are presently focused primarily on procuring the appropriate governmental regulatory clearances and approvals necessary to market and

sell our *KyphX* products, and as of December 31, 2006, we have enrolled 57 of the 81 patients required in our Japanese clinical trial.

Products and Significant Business Trends. Our net sales in 2006 consisted almost entirely of the sales of our *KyphX* instruments, including our *KyphX* Inflatable Bone Tamps, *KyphX* Inflation Syringe, *KyphX* Bone Access Systems, *KyphX* Bone Filler Device, *KyphX* Curettes, *KyphX* Bone Biopsy Device, *KyphX HV-R* Bone Cement, *KyphX* Mixer and our CE-Marked *KyphOs* calcium phosphate from our acquisition of Sanatis GmbH (Sanatis). Our *Discyphor F.A.D.* technology contributed an immaterial amount to our revenues in 2006.

During 2006, our business experienced significant growth. Net sales in 2006 increased to $407.8 million, compared to $306.1 million in 2005, representing growth of 33%. We trained over 2,400 physicians during 2006 to perform balloon kyphoplasty with our technology, primarily in the United States and in Europe. In the U.S., we added 267 new hospitals to our balloon kyphoplasty customer base during 2006.

We have now moved beyond our original sole focus of Spinal Fracture Management and Repair, through treatment of vertebral compression fractures, to our second and third business platforms, disc disease diagnosis and therapies and spinal motion preservation. We have a variety of internal resources dedicated to supporting research and development in this area as well as potential business development opportunities. Another business focus, cancer therapy aimed at addressing the actual cancerous conditions that affect the spine rather than merely the effects of those cancerous conditions, such as vertebral compression fractures, remains an area of interest for us, and we continue to investigate how we can best serve this market. We also will continue to evaluate other additional potential opportunities for growth in our business by evaluating external products and technologies. Some of the opportunities we are presently investigating include technologies and products that address degenerative disc disease. These efforts may require us to seek additional funding and may be dilutive to our earnings. Although we have succeeded in diversifying our business through our recent external business development activities, we will remain largely dependent on our balloon kyphoplasty technologies for treating vertebral compression fractures for the foreseeable future. We thus will continue, at least for the foreseeable future, to bear the traditional risks associated with being a company whose revenues are principally derived from one procedure. In addition, in connection with our recent acquisitions, we now are engaged in trying to efficiently and successfully integrate St. Francis' business into our ongoing balloon kyphoplasty business, which will take substantial resources and may result in significant distraction of our management team. If we are successful in gaining clearance from the FTC to close our transactions with Disc-O-Tech, we may also have to integrate those assets into our business at the same time we are integrating St. Francis' business, which will require further resources.

We are beginning to experience increasing competition in our business for treating vertebral compression fractures, including from companies introducing products that are significantly less expensive than our own technologies and apparently are intended to compete with our products on price. We believe trial of such products by our customers will continue for the foreseeable future, which is beginning to cause us to lose revenues, undermine some of our existing customer relationships, bring pricing pressures to bear on our existing business and product lines, cause at least some slow-down in adoption of our technologies, and potentially harm our reputation. We are also on the verge of entering markets for our products, such as for the treatment of lumbar spinal stenosis and spinal fusion, in which significant competition already exists, the type of which we have not faced before in our business. We believe that if we are unable to compete aggressively and effectively against the other companies who are either entering our markets or are already serving the markets we are entering, including through effective enforcement of our intellectual property rights, we may not be able to realize the type of growth in our business that we have experienced in the past or that we otherwise might be able to experience in the absence of such competition.

As our company grows and we achieve more success in the markets we serve, we face increasing scrutiny from various regulatory authorities. Although we believe we are in substantial compliance with the healthcare and other laws that are applicable to us, we may have to defend our company against various charges that we have violated laws, rules or regulations applicable to us. As discussed in detail in *Item 3 – Legal Proceedings*, we are presently involved in discussions with a U.S. Attorney's office relating to

various aspects of our past conduct. If we are unable to successfully navigate such issues, our business could be at risk, especially due to the restrictions to which we are subject as a result of the significant debt we have undertaken in connection with our recent acquisitions.

During 2006, several developments in reimbursement for our core kyphoplasty business occurred. In August 2006, for example, the Centers for Medicare & Medicaid Services (CMS) published the 2007 Final Rule with tentative payment rates regarding the Hospital Inpatient Prospective Payment System (HIPPS) proposing that the tentative reimbursement rates available to hospitals in 2007 would reflect a slight increase in rates over 2006 levels. In October 2006, the final payment rates were published in the Federal Register and the two primary DRG payment rates related to kyphoplasty increased by 2.1% and 5.8%, respectively, over 2006 levels. The payment rates were effective October 2006 for fiscal year 2007. On November 1, 2006, CMS posted the Final Rule on the Hospital Outpatient Prospective Payment System (HOPPS), stating that the reimbursement available to a facility for performing balloon kyphoplasty in an outpatient setting in 2007 would be increased by approximately 54% for one-level and 53% for two-level procedures, respectively, over 2006 levels. Both of these rules are effective for procedures performed on or after January 1, 2007.

The status of our significant current clinical trials follows:

- We completed enrollment of 300 patients in the fracture reduction evaluation study, a prospective, randomized, controlled multi-center trial designed to compare balloon kyphoplasty to non-surgical management in the treatment of painful, acute vertebral compression fractures. We expect to submit one year follow-up data for publication in 2007.

- We secured approval from the Japanese Ministry of Health to begin our clinical trial in the third quarter of 2005. Our Japanese trial is a single arm study that will enroll a total of 81 patients with spinal fractures and follow them for 2 years. Patient enrollment is presently expected to conclude in the first half of 2007. Data from this trial, in addition to clinical data obtained from studies previously completed in the U.S. and Europe, will be used to support regulatory approval in Japan for balloon kyphoplasty. If approved, we could begin commercialization in Japan in approximately 2009.

- In 2005 we also initiated patient enrollment for CAFE, a randomized trial of balloon kyphoplasty treatment for patients with cancer-related VCFs. Currently, 66 patients are enrolled in the study. A total of 200 patients are expected to be enrolled in the study.

- We initiated a randomized controlled trial comparing balloon kyphoplasty and vertebroplasty in October 2006. This trial will consider several important study endpoints including perioperative safety, function, quality of life, vertebral body height restoration, rate of subsequent fractures and angular deformity correction. It will also include an economic and healthcare utilization analysis. This trial is designed to enroll approximately 1,200 patients at up to 75 sites with two-year follow-up.

Substantial portions of our pre-clinical studies and all of our clinical trials are performed by third-party contract research organizations and other vendors. We accrue costs for clinical trial activities performed by contract research organizations based upon the level of patient enrollment and amount of work completed on each study. The difficulty in predicting the timing of patient enrollment can create volatility in our expenses. All such costs are charged to research and development expenses as incurred.

During 2006, we continued to strengthen our board of directors and management team. In July 2006, Frank M. Phillips, M.D. joined our board of directors. Dr. Phillips is currently Professor of Orthopaedic Surgery and Director of the Section of Minimally Invasive Spine Surgery at Rush University Medical Center in Chicago. Prior to this position, Dr. Phillips served as the Director of The University of Chicago Spine Center, in addition to being an Associate Professor of Surgery at The University of Chicago. Dr. Phillips is certified by the American Board of Orthopaedic Surgery and has authored over 50 clinical and basic science publications and presentations dealing with spinal procedures.

In September 2006, Maureen L. Lamb joined Kyphon as our Vice President, Chief Financial Officer and Treasurer. Ms. Lamb has over 20 years of financial management experience and comes to Kyphon from Photon Dynamics, Inc., where she served as Chief Financial Officer. Before that, she held several senior financial management positions for eleven years at KLA-Tencor, including serving as its Vice President of Finance for five years. Ms. Lamb received her Bachelor's degree in Government from Harvard College and her Masters in Business Administration from the Wharton School of the University of Pennsylvania. She succeeds Arthur T. Taylor as our Chief Financial Officer, who had served as both Chief Operating Officer and Chief Financial Officer since his promotion in February 2006. Mr. Taylor continues as our Chief Operating Officer.

Also in September 2006, Alexandre M. DiNello joined Kyphon as our Vice President, Research and Development. Mr. DiNello has over 17 years of medical device industry experience, including senior research and development and/or strategic development roles at Abbott Spine, OmniSonics Medical Technologies, DePuy Spine, a division of Johnson & Johnson and AcroMed Corporation, which was purchased by DePuy Spine. He received his Bachelor of Science degree in Mechanical Engineering from the University of California, Santa Barbara, a Masters degree in Biomedical Engineering from the University of Virginia, and a Masters in Business Administration from the Weatherhead School of Management at Case Western Reserve University in Ohio.

In May 2006, Dr. Clemens Troche joined Kyphon as our Vice President, Marketing and Business Development, International. Prior to joining Kyphon, Dr. Troche worked in various pharmaceutical companies (PharmaVentures, Bayer Inc., Boehringer Ingelheim and Schwarz Pharma) in various marketing, pricing, health economics and business development functions. He has also worked as a consultant for various life sciences and health care companies to address projects in the areas of business development, organizational management, strategic marketing and research and development. Dr. Troche studied human medicine in Germany (Universities of Muenster and Heidelberg) and the U.S. (Tulane University, New Orleans, LA). After also completing a doctorate focusing on epidemiological psychiatry at the University of Heidelberg, Dr. Troche worked as a fully licensed physician and a researcher in neurosciences. He then obtained a Master of Public Health from Yale University and a Masters in Business Administration in a joint program from the University of Bradfod (UK) and NIMBAS in Utrecht (The Netherlands).

In June 2006, Robert E. Johnson, joined Kyphon as our Vice President, Chief Compliance Officer. Prior to joining Kyphon, Mr. Johnson served as the Chief Compliance Officer for Chiron Corporation (now Novartis Vaccines & Diagnostics, Inc.). Mr. Johnson also worked for eight years for Sabre Holdings Corporation, where he created its first corporate compliance program, led its London legal department and served as General Counsel and Senior Vice President for its GetThere LP subsidiary in Menlo Park, California. He began his career as a commercial litigator with the Houston law firm of Baker Botts LLP. Mr. Johnson earned his Bachelor of Arts degree summa cum laude in American Studies and English from The University of North Carolina at Chapel Hill and his J.D. from The University of Virginia School of Law.

Significant Industry Factors. Our industry is impacted by numerous competitive, regulatory and other significant factors. The growth of our business relies on our ability to continue to develop new products and innovative technologies, obtain regulatory clearances and compliance for our products, obtain adequate public and private payor reimbursements for our products, protect the proprietary technology of our products and our manufacturing processes, manufacture our products cost-effectively, and successfully market and distribute our products in a profitable manner. We, and the entire industry, are subject to extensive government regulation, including but not limited to the United States Food and Drug Administration (FDA). Failure to comply with regulatory requirements could adversely affect our business and our financial condition, which could cause our stock price to decline. Additionally, our industry is highly competitive and our success depends on our ability to compete successfully. A detailed discussion of these and other factors is provided in the "Factors Affecting Future Operating Results" section below.

Critical Accounting Policies and Estimates

All of our significant accounting policies are described in Note 2 to our consolidated financial statements. However, certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers, and information available from other outside sources, as appropriate. Different, reasonable estimates could have been used in the current period. Additionally, changes in accounting estimates are reasonably likely to occur from period to period. Both of these factors could have a material impact on the presentation of our financial condition, changes in financial condition, or results of operations. We believe that the following financial policies and estimates are both important to the portrayal of our financial condition and results of operations and require subjective or complex judgments. Further, we believe that the items discussed below are properly recorded in the consolidated financial statements for all periods presented. Management has discussed the development, selection, and disclosure of our most critical financial estimates with the Audit Committee of our Board of Directors and our independent registered public accounting firm. The judgments about those financial estimates are based on information available as of the date of the consolidated financial statements. Those financial policies and estimates include:

Revenue recognition. Our revenue is derived primarily from the sale of our products to customers and distributors. Revenue is considered to be realized or realizable and earned when all of the following criteria are met: persuasive evidence of a sales arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectibility is reasonably assured. These criteria are generally met at the time of shipment when the risk of loss and title passes to the customer or distributor. Allowances are established for product returns and discounts based upon historical trends and are recorded as a reduction to revenue.

Accounts receivable allowances. We make estimates on the collectibility of customer accounts based primarily on analysis of historical trends and experience and changes in customers' financial condition. Management uses its best judgment, based on the best available facts and circumstances, and records a reserve against the amounts due to reduce the receivable to the amount that is expected to be collected. These reserves are reevaluated and adjusted as additional information is received that impacts the amount reserved. Our accounts receivable allowances have been less than 1% of net sales for each of the years ended December 31, 2006, 2005 and 2004.

Our accounts receivable balance was $73.9 million and $55.5 million, net of allowances for doubtful accounts and for product returns of $1.9 million and $1.6 million at December 31, 2006 and 2005, respectively.

Excess and obsolete inventories. We value our inventory at the lower of cost or market. Cost is computed on a first-in, first-out basis. We regularly review inventory quantities on hand and record a provision for excess and obsolete inventory based primarily on our estimated forecast of product demand and production requirements for the next twelve months. A significant decrease in demand could result in an increase in the amount of excess inventory quantities on hand. Additionally, our industry is characterized by regular new product development that could result in an increase in the amount of obsolete inventory quantities on hand due to cannibalization of existing products. Also, our estimates of future product demand may prove to be inaccurate, in which case we may be required to increase the provision needed for excess and obsolete inventory. In the future, if additional inventory write-downs are required, we would recognize additional cost of goods sold at the time of such determination. Regardless of changes in our estimates of future product demand, we do not increase the value of our inventory above its adjusted cost basis. Therefore, although we make every effort to ensure the accuracy of our forecasts of future product demand, significant unanticipated decreases in demand or technological developments could have a significant impact on the value of our inventory and our reported operating results.

Our reserve for excess and obsolete inventories was $861,000 and $991,000 at December 31, 2006 and 2005, respectively.

Accounting for income taxes. We determine deferred tax assets and liabilities based upon the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. The tax consequences of most events recognized in the current year's financial statements are included in determining income taxes currently payable. However, because tax laws and financial accounting standards differ in their recognition and measurement of assets, liabilities, equity, revenue, expenses, gains and losses, differences arise between the amount of taxable income and pretax financial income for a year and between the tax bases of assets or liabilities and their reported amounts in the financial statements. Because it is assumed that the reported amounts of assets and liabilities will be recovered and settled at their carrying value, respectively, a difference between the tax basis of an asset or a liability and its reported amount in the balance sheet will result in a taxable or a deductible amount in some future years when the related liabilities are settled or the reported amounts of the assets are recovered, hence giving rise to a deferred tax asset or liability. We must then assess the likelihood 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.

As part of the process of preparing our consolidated financial statements, we are required to determine our income taxes. This process involves determining our actual current tax exposure together with assessing temporary differences that may result in deferred tax assets. Management judgment is required in determining any valuation allowance recorded against our deferred tax assets. Any such valuation allowance would be based on objective positive evidences and the period over which our deferred tax assets would be recoverable. As of December 31, 2006 and 2005, we have recorded no valuation allowance, based on our belief that it is more likely than not that we will be able to utilize our deferred tax assets before they expire.

Purchase accounting. Purchase accounting requires extensive accounting estimates and judgments to allocate the purchase price between in-process research and development, other identifiable intangible assets, tangible assets, and goodwill as required by generally accepted accounting principles in the United States. To assist in determining the value of any in-process research and development and certain other intangibles, a third party valuation is typically obtained as of the acquisition date. Purchased in-process research and development is defined as the value assigned to those projects for which the related products have not received regulatory approval when acquired. At the time of the purchase, the research and development projects were not considered to have reached technological feasibility and they had no alternative future use. Determining the portion of the purchase price allocated to in-process research and development and other intangible assets requires us to make significant estimates. The amount of the purchase price allocated to purchased in-process research and development and other intangible assets is determined by estimating the future cash flows of each project or technology and discounting the net cash flows back to their present values. The discount rate used is determined at the time of the acquisition in accordance with standard valuation methods. For purchased in-process research and development, these methodologies include consideration of the risk of the project not achieving commercial feasibility.

Goodwill and Impairment of Long Lived Assets, Including Acquisition-Related Intangibles. Under generally accepted accounting principles in the United States, we evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired. We will also evaluate other intangible assets for impairment when impairment indicators are identified. In assessing the recoverability of our goodwill and other intangibles, we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. These estimates include forecasted revenues, which are inherently difficult to predict. If these estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets. We perform an annual impairment review in the first quarter of each year and compare the fair value of the reporting unit in which the goodwill resides to its carrying value. If the carrying value exceeds the fair value, the goodwill of the reporting unit is potentially impaired. For purposes of impairment testing under Statement of Financial Accounting Standards ("SFAS") 142, Goodwill and Other Intangible Assets, Kyphon operates as a single reporting unit. We use the quoted market price method to determine the fair value of the reporting unit. To date, no impairment indicators have been identified. There have been no events or changes in circumstances subsequent to our annual test which may indicate the asset is impaired.

Significant judgments and assumptions are required in the forecast of future operating results used in the preparation of the estimated future cash flows, including profit margins, long-term forecasts of the amounts and timing of overall market growth and our percentage of that market, groupings of assets, discount rates and terminal growth rates. In addition, significant estimates and assumptions are required in the determination of the fair value of our tangible long-lived assets, including replacement cost, economic obsolescence, and the value that could be realized in orderly liquidation. Changes in these estimates could have a material adverse effect on the assessment of our long-lived assets, thereby requiring us to write down the assets.

Stock Option Valuation. The preparation of the financial statements requires us to estimate the fair value of stock options granted to employees. While fair value may be readily determinable for awards of stock, market quotes are not available for long-term, nontransferable stock options because these instruments are not traded. Option valuation models require the input of highly subjective assumptions, including the stock price volatility. Our stock options have characteristics significantly different from those of traded options and changes to the subjective input assumptions can materially affect the fair value of our employee stock options.

Prior to January 1, 2006, we accounted for our stock-based employee compensation arrangements under the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB No. 25"), as allowed by SFAS No. 123, Accounting for Stock-based Compensation ("SFAS No. 123"), as amended by SFAS No. 148, Accounting for Stock-Based Compensation—Transition and Disclosure ("SFAS No. 148"). As a result, no expense was recognized for options to purchase our common stock that were granted with an exercise price equal to fair market value at the date of grant and no expense was recognized in connection with purchases under our employee stock purchase plan for the years ended December 31, 2005 and 2004. During the years ended December 31, 2005 and 2004, we recognized employee stock-based compensation expense of $1.8 million and $2.9 million, respectively, under APB No. 25 related to stock options previously issued with exercise prices below the deemed fair market value of our common stock at the date of grant.

Effective January 1, 2006, we adopted the provisions of SFAS No. 123(R), "Share-Based Payment", which requires the measurement and recognition of compensation expense in the financial statements for all share-based payment awards made to employees and directors, including employee stock options and employee stock purchases based on estimated fair values. Accordingly, stock-based compensation cost is measured at grant date, based on the fair value of the award, and is recognized as expense over the employee requisite service period for each separately vesting tranche of the award. To estimate the fair value of an award, we use the binomial-lattice option pricing model. This model considers a range of assumptions related to volatility, risk-free interest rate and employee exercise behavior. Expected volatilities are based on a blend of implied market volatilities, historical and peer group volatilities. The risk-free rate is derived from the U.S. Treasury zero-coupon yield curve in effect at the time of grant over the contractual term of the option. The binomial-lattice model also incorporates exercise and forfeiture assumptions based on an analysis of historical data. The expected life of the stock option grants is derived from the output of the binomial-lattice model and represents the period of time that options granted are expected to be outstanding. Further, the forfeiture rate also impacts the amount of aggregate compensation. Under SFAS No. 123 forfeitures are recognized only as they actually occur whereas under SFAS No. 123(R) forfeiture rates are included in the initial accrual of compensation cost and revised as actual experience differs from initial estimates. These inputs are subjective and generally require significant analysis and judgment to develop.

We have adopted SFAS No. 123(R) using the modified prospective method. Accordingly, previously reported amounts have not been restated. Under this method, compensation cost recognized during the year ended December 31, 2006, includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123 amortized on a straight-line basis over the options' vesting period, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the

grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R) amortized on a graded vesting basis over the options' vesting period. Kyphon has elected to use the method described in paragraph 81 of SFAS No. 123(R) (the "long form" method) for the calculation of its pool of excess tax benefits available to absorb tax deficiencies recognized subsequent to the adoption of SFAS No. 123(R). Employee stock-based compensation expense recognized under SFAS No. 123(R) for the year ended December 31, 2006 was $27.6 million.

Prior to the adoption of SFAS No. 123(R), we used the intrinsic value method in accounting for our employee stock options, and presented disclosure of pro forma information as if we had accounted for stock-based compensation using the fair value method.

Results of Operations

Comparison of years ended December 31, 2006, 2005 and 2004

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands) and as percentages of net sales:

	Year Ended December 31,					
	2006		2005		2004	
	Amount	% of Net sales	Amount	% of Net sales	Amount	% of Net sales
U.S. net sales	$ 324,108	79 %	$ 257,558	84 %	$ 187,526	88 %
International net sales	83,682	21 %	48,524	16 %	25,888	12 %
Net sales	407,790	100 %	306,082	100 %	213,414	100 %
Cost of goods sold	52,176	13 %	35,843	12 %	24,734	12 %
Gross profit	355,614	87 %	270,239	88 %	188,680	88 %
Operating expenses:						
Research and development	39,971	10 %	46,383	15 %	22,238	10 %
Sales and marketing	194,057	47 %	144,768	47 %	106,103	50 %
General and administrative	60,351	15 %	34,951	12 %	25,972	12 %
Total operating expenses	294,379	72 %	226,102	74 %	154,313	72 %
Income from operations	61,235	15 %	44,137	14 %	34,367	16 %
Interest income and other, net	9,487	2 %	3,979	2 %	1,250	1 %
Income before income taxes	70,722	17 %	48,116	16 %	35,617	17 %
Provision for income taxes	30,990	7 %	18,280	6 %	13,900	7 %
Net income	$ 39,732	10 %	$ 29,836	10 %	$ 21,717	10 %

Net Sales. Net sales increased $101.7 million, or 33%, in 2006 compared to 2005, and increased $92.7 million, or 43%, in 2005 compared to 2004. The increases in net sales in 2006 primarily resulted from an increase in the number of physicians trained in the use of our *KyphX* instruments as well as a 27% increase in the number of procedures performed by trained physicians per month compared to 2005. During 2006 approximately 2,400 physicians were trained in the use of our *KyphX* instruments. The increases in net sales in 2005 primarily resulted from the 2,200 more physicians trained in the use of our *KyphX* instruments during 2005 as well as a 18% increase in the number of procedures performed by trained physicians per month compared to 2004. Domestic sales increased $66.6 million, or 26% in 2006 compared to 2005 and $70.0 million, or 37% in 2005 compared to 2004. International sales increased $35.2 million, or 72% in 2006 compared to 2005, and $22.6 million, or 87% in 2005 compared to 2004. International sales also reflected the favorable currency impact of $2.1 million in 2006 and an unfavorable currency impact of $0.5 million in 2005 based on prior year's average Euro exchange rates. No customer accounted for more than 10% of total net sales in 2006, 2005 or 2004. As of December 31, 2006, we believe we have trained approximately 6,000 spine specialists in the U.S. and approximately 4,400

clinicians in other parts of the world, primarily Europe. These physicians have used our *KyphX* instruments in approximately 285,000 patients and 335,000 spinal fractures worldwide. We believe the total number of potential physicians who may perform balloon kyphoplasty procedures using our products is approximately 11,000 in the U.S. Internationally, the number of physicians who may perform balloon kyphoplasty is not as well-defined, but we believe it to be more than 10,000. Including sales of the *X-STOP* products and the products from our proposed acquisitions of the spine-related assets of Disc-O-Tech, we have targeted a range of $565 million to $585 million in net sales for 2007, with international net sales comprising 21% to 24% of total net sales. We expect 80% to 85% of our net sales for 2007 will be derived from balloon kyphoplasty procedures.

Cost of Goods Sold. Cost of goods sold consists of material, labor, subcontract, and overhead costs. Cost of goods sold increased $16.3 million, or 46%, in 2006 compared to 2005, and increased $11.1 million, or 45%, in 2005 compared to 2004. The absolute increase in cost of goods sold over the years from 2004 to 2006 resulted primarily from increased material, labor, subcontract and overhead costs in relation to the increased sales volume of our products. The cost of goods sold as a percentage of net sales increased from 2005 to 2006 primarily as a result of employee stock-based compensation expense recognized under SFAS No. 123(R), increased inventory reserves taken during 2006, increased distribution costs associated with shipping product throughout the European Union and developed technology amortization of InnoSpine. Our cost of goods sold and corresponding gross profit percentages can be expected to fluctuate in future periods depending upon changes in our product sales mix and prices, distribution channels and geographies, manufacturing yields, period expenses and levels of production volume. Cost of goods sold for 2007 will include additional costs of approximately $8.0 million due to the sale of inventory acquired from St. Francis which was written-up to reflect the fair value at the date of acquisition.

Research and Development. Research and development expenses consist of costs for product research, product development, clinical functions and outside costs related to clinical trials and personnel. Research and development expenses decreased $6.4 million, or 14%, in 2006 compared to 2005. Research and development expenses increased $24.1 million, or 109%, in 2005 compared to 2004. Expenses for 2005 included license acquisition charges of $20.0 million to Dr. Harvinder Sandhu and $1.0 million to Dr. Lee Berger. Excluding these charges research and development expenses increased $14.6 million, or 57%, in 2006 as compared to 2005. Excluding the license charges the increase in 2006 from 2005 was primarily attributable to a $4.0 million increase in stock-based compensation expense due to the adoption of FAS 123(R), increased personnel costs of $3.6 million, increased clinical studies expense of $2.8 million, increased consulting expenses of $1.6 million, increased engineering and lab expenses of $894,000, increased facilities costs of $787,000, and increased travel expenses of $497,000. The increase in 2005 from 2004 was primarily attributable to the license acquisition charges of $21.0 million. The remaining increase of $3.1 million was attributable to increased personnel costs of $2.3 million, increased clinical studies expense of $1.3 million, increased engineering and lab expenses of $611,000, increased travel expenses of $604,000, and increased facilities costs of $576,000, offset by a decreased research and development consulting fees of $1.4 million and decreased educational grants of $990,000. We expect to continue to make substantial investments in research and development and anticipate that research and development expenses in 2007 will increase in absolute dollars due largely to new product development in our three product platforms and due to the continuation of and commencement of clinical studies. We anticipate conducting significant additional clinical trial activity both in the United States and abroad to collect further data that may support the use and clinical efficacy of our products. As a result of our acquisition of St. Francis and the closing of our proposed acquisitions of the spine-related assets of Disc-O-Tech, we expect to expense in-process research and development costs of approximately $55.8 million in 2007.

Sales and Marketing. Sales and marketing expenses consist of costs for personnel, physician training programs and marketing activities. Sales and marketing expenses increased $49.3 million, or 34%, in 2006 compared to 2005. Sales and marketing expenses increased $38.7 million, or 36%, in 2005 compared to 2004. The increase in 2006 from 2005 was primarily attributable to a $27.7 million increase in the costs of hiring, training and compensating additional direct selling representatives, a $10.5 million increase in stock-based compensation expense due to the adoption of SFAS No. 123(R), increased sales and marketing travel expenses of $6.7 million, and increased facility expenses of $4.0 million. The increase in 2005 from

2004 related primarily to a $28.3 million increase in the costs of hiring, training and compensating additional direct selling representatives, increased advertising, trade shows, educational and promotional activity expenses of $3.5 million, increased sales and marketing travel expenses of $3.1 million, increased facilities expenses of $1.6 million and increased educational grants of $1.1 million. As we continue to commercialize our *KyphX* instruments on a global basis and integrate the *X-STOP* products and the products from our proposed acquisitions of the spine-related assets of Disc-O-Tech into our sales channel, we expect to significantly increase our sales and marketing efforts and expenditures in absolute dollars.

General and Administrative. General and administrative expenses consist of costs for personnel, professional service fees, expenses related to intellectual property rights, Sarbanes-Oxley compliance and general corporate expenses. General and administrative expenses increased $25.4 million, or 73%, in 2006 compared to 2005. General and administrative expenses increased $9.0 million, or 35%, in 2005 compared to 2004. The increase in 2006 from 2005 was primarily attributable to a $10.2 million increase in stock-based compensation expense due to the adoption of SFAS No. 123(R), increased personnel costs of $8.0 million, increased consulting fees of $2.5 million, increased litigation expenses of $1.6 million, and increased travel expense of $1.4 million. The increase in 2005 from 2004 was primarily attributable to increased consulting and outside professional service fees of $3.7 million, increased personnel costs of $3.0 million, and increased litigation costs of $1.3 million. We expect general and administrative expenses to increase in the future as we add personnel, incur litigation expenses and integration costs related to our acquisitions, continue to expand our patent portfolio and incur additional public reporting, governmental compliance and investor-related expenses as a public company, and incur start-up costs for our new facility in Switzerland. Therefore, we anticipate that our general and administrative expenses will increase in absolute dollars as we expand our infrastructure.

Amortization of Acquired Identifiable Intangible Assets. As a result of the acquisition of St. Francis and the proposed acquisitions of certain spine-related assets of Disc-O-Tech, we expect to incur significant amortization expense related to these acquired identifiable intangible assets in 2007. We have not yet determined the appropriate income statement classification of the amortization expense of the acquired identifiable intangible assets.

Interest Income and Other, Net. Interest income and other, net, increased $5.5 million in 2006 compared to 2005. Interest income and other, net, increased $2.7 million in 2005 compared to 2004. The increase in 2006 compared to 2005, and the increase in 2005 compared to 2004 resulted primarily from an increase in interest income due to higher cash, cash equivalents and investment balances, as well as higher interest rates. Our cash, cash equivalents and investments balances were $202.2 million, $194.5 million, and $115.8 million as of December 31, 2006, 2005, and 2004, respectively. We expect interest expense for 2007 to increase as a result of our borrowings under the credit facility and the convertible notes issuances, and the amortization of the related debt issuance costs. In addition, due to the retirement of the Term Loan Facility, we expect to write-off debt issuance costs of approximately $8.4 million in 2007.

Provision for Income Taxes. The provision for income taxes in 2006 was $31.0 million at an effective tax rate of 44% for the year. The provision for income taxes in 2005 was $18.3 million at an effective tax rate of 38% for the year. The provision for income taxes in 2004 was $13.9 million at an effective tax rate of 39% for the year. The higher effective tax rate for 2006 is primarily due to the impact of expensing certain non-tax deductible stock-based compensation in accordance with SFAS No. 123(R). We recorded an $8.0 million deferred tax asset for the book expenses associated with the nonqualified stock options as of December 31, 2006. We believe that in 2007 our effective tax rate, excluding any in-process research and development charges, will be relatively consistent with 2006, with the actual amount of taxes paid potentially reduced by factors including the utilization of research and development tax credit carryforwards, deductions due to stock option activities and deductions due to the book-tax basis difference in the Company's convertible notes resulting from the associated note hedge transactions. Our effective tax rate may be impacted by factors including, but not limited to, changes in the split of earnings between countries with differing statutory tax rates, by the tax benefits or detriments derived from employee stock option activities, and by changes in tax laws, regulations, accounting principles or interpretations thereof.

At December 31, 2006, we had utilized all federal and state net operating loss carryforwards and federal

research and development tax credit carryforwards.

At December 31, 2006, we had research and development tax credit carryforwards of approximately $2.8 million for state income tax purposes. The state research and development tax credit can be carried forward indefinitely.

Changes to Previously Announced 2006 Fourth Quarter and Annual Results. On January 30, 2007, we announced our 2006 results. In connection with preparing our Form 10-K we identified two balance sheet adjustments. The first adjustment in the amount of approximately $149.3 million eliminates deferred payments previously recorded at December 31, 2006 in connection with our proposed acquisition agreements with Disc-O-Tech. We concluded the deferred payments should be recorded when due. The second adjustment, of approximately $4.0 million, reflects the netting of our deferred tax assets and deferred tax liabilities, where right of offset exists.

There was no change to our fiscal 2006 annual or fourth quarter net income as previously announced.

Stock-Based Compensation

Effective January 1, 2006, we adopted the provisions of SFAS No. 123(R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including employee stock options and employee stock purchases based on estimated fair values. Accordingly, stock-based compensation cost is measured at grant date, based on the fair value of the award, and is recognized as expense over the employee requisite service period for each separately vesting tranche of the award. Employee stock-based compensation expense recognized under SFAS No. 123(R) for the year ended December 31, 2006 was $27.6 million. Prior to the adoption of SFAS 123(R), Kyphon used the intrinsic value method in accounting for our employee stock options, and presented disclosure of pro forma information as if we had accounted for stock-based compensation using the fair value method. Kyphon elected to adopt the modified prospective application method as provided by SFAS No. 123(R). Accordingly, previously reported amounts have not been restated. During the years ended December 31, 2005 and 2004, we recognized employee stock-based compensation expense of $1.8 million and $2.9 million, respectively, under APB No. 25 related to stock options previously issued with exercise prices below the deemed fair market value of our common stock at the date of grant.

We estimate the value of employee stock options on the date of grant using a binomial-lattice model. The determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors.

During the year ended December 31, 2006, we recognized stock-based compensation charges related to our employee stock options and employee stock purchase plan of $24.5 million, and $3.1 million, respectively. As of December 31, 2006, stock-based compensation expense of $150,000 was capitalized as inventory. As of December 31, 2006, the unrecorded stock-based compensation balance related to employee stock options was $25.3 million after estimated forfeitures and will be recognized over an estimated weighted-average remaining requisite service period of 2.6 years. As of December 31, 2006, the unrecorded stock-based compensation balance related to employee stock purchase rights under the 2002 ESPP was $119,000 which will be recognized in January 2007.

Stock-based compensation expense for stock options granted to non-employees is recognized as the stock options are earned. The stock-based compensation expense will fluctuate as the fair market value of our common stock fluctuates. In connection with the grant of stock options to non-employees, we recorded stock-based compensation expense of approximately $1.4 million, $1.3 million and $929,000 in 2006, 2005 and 2004, respectively.

In June 2006, our stockholders approved the termination of our 2002 Employee Stock Purchase Plan, or 2002 ESPP, effective after the February 1, 2007 purchase, and the adoption of our 2007 Employee Stock

Purchase Plan, or 2007 ESPP. The 2007 ESPP took effect after the final purchase date under the 2002 ESPP of February 1, 2007, at which time the 2002 ESPP automatically terminated. The 2007 ESPP reduces the "look-back" period available under any offering, by eliminating the 24-month "look-back" period presently available under the 2002 ESPP and replacing it with a six-month "look-back" period. The price of the common stock purchased shall be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The maximum number of shares authorized for sale under the 2007 ESPP is 1,000,000. The Board of Directors may amend, suspend or terminate the 2007 ESPP at any time. Kyphon has determined that the cancellation of the 2002 ESPP effectively occurred in June 2006 at the time of stockholder approval. As the cancellation of purchase periods subsequent to February 1, 2007 were not accompanied by a concurrent replacement grant, in accordance with the provisions of SFAS No. 123(R), unrecognized compensation cost of $562,000 was recognized immediately in June 2006 for the awards cancelled.

Seasonality

Our business is seasonal in nature. Historically, demand for our products has been the highest in the first and second quarters in the U.S. and in the second and fourth quarters in Europe. In the U.S., during the fourth quarter, our net sales generally reflect the reduced number of selling days due to the holiday season. In Europe, we traditionally experience somewhat lower sales volumes in the third quarter months than throughout the rest of the year as a result of the European summer holiday schedule. In addition, the fourth quarter in Europe is typically favorably impacted by our customers' budget utilization and our distributors' fulfillment of their annual purchase commitments.

Liquidity and Capital Resources

Credit Facility. As of December 31, 2006, we had $81.9 million of cash and cash equivalents, $120.2 million of short-term investments, and working capital of $228.0 million. Our cash and cash equivalents and investments increased by $7.7 million during 2006. As of December 31, 2006, unrealized losses related to available-for-sale-investments are considered to be temporary.

In October 2006, we entered into a syndicated credit facility which provided us with a five-year $300.0 million revolving line of credit, including a $50.0 million sublimit for the issuance of standby letters of credit, a $25.0 million sublimit for swing line loans and a $100.0 million sublimit for multicurrency borrowings. On January 18, 2007, we amended the October 2006 credit facility, and in conjunction with the acquisition of St. Francis, Kyphon, together with certain of its subsidiaries, entered into a credit agreement (the Credit Agreement) to replace and refinance the above-described credit facility with Bank of America, N.A., as administrative agent, swing line lender and letter of credit issuer, and Banc of America Securities LLC as sole lead arranger and sole book manager. The credit facilities thereunder were syndicated to a group of lenders (the Lenders).

The Credit Agreement provides for a $250.0 million senior secured revolving credit facility, maturing October 20, 2011, which can be expanded to $300.0 million under certain circumstances. The revolving credit facility includes a $50.0 million sublimit for the issuance of standby U.S. dollar letters of credit, a $25.0 million sublimit for U.S. dollar swingline loans and a $100.0 million sublimit for multicurrency borrowings. The Credit Agreement also provided for a $425.0 million term loan facility maturing seven years from the closing date which, together with the revolving credit facility, we refer to as the Facility. Kyphon may terminate or permanently reduce the commitments available under the revolving credit facility and prepay the Term Loan Facility without premium or penalty at any time.

The Facility was used by Kyphon to finance the acquisition of St. Francis, and may be used for general corporate purposes including acquisitions, capital expenditures, working capital and other purposes. In addition to certain initial fees, Kyphon is obligated to pay a commitment fee based on the total revolving commitment. In January 2007, in connection with the acquisition of St. Francis, we borrowed $425.0 million under the Facility.

The revolving credit facility will bear interest at Base Rate plus 0.25-1.25 or LIBOR plus 1.25-2.25% (such range of margins being related to the consolidated leverage ratio of Kyphon). Letter of credit fees are based on the LIBOR loan margins.

Kyphon's obligations under the Facility are secured by substantially all of its assets.

The Credit Agreement contains customary affirmative covenants regarding Kyphon and its subsidiaries. Upon the occurrence of an event of default under the Credit Agreement, the Lenders could elect to declare all amounts outstanding under the Facility to be immediately due and payable. Events of default under the Credit Agreement include payment defaults, breaches of covenants and bankruptcy events.

The Credit Agreement contains negative covenants which restrict Kyphon from: (i) incurring liens other than liens incurred pursuant to the Facility and other customary permitted liens; (ii) making investments, other than customary permitted investments and investments subject to certain baskets; (iii) incurring debt other than indebtedness pursuant to the Credit Agreement, subordinated indebtedness, an unsecured convertible note offering, customary permitted indebtedness and indebtedness subject to certain baskets; (iv) entering into mergers and consolidations other than the Acquisition, acquisitions paid 100% with equity of Kyphon or acquisitions not exceeding a certain purchase price, where such limitation on price is based on the consolidated senior secured leverage ratio and other limitations; (v) selling assets, subject to certain customary exceptions; (vi) issuing dividends, stock redemptions and other restricted payments; (vii) incurring capital expenditures exceeding a certain threshold; (viii) transactions with affiliates; (ix) the cash payment of the cash/stock earnout obligations of Kyphon incurred in connection with the Acquisition, where such payments are subject to certain limitations; (x) permitting the consolidated interest coverage ratio to fall below a certain threshold and the consolidated leverage ratio and the consolidated senior secured leverage ratio to be greater than a certain threshold; (xi) prepaying subordinated indebtedness, other than prepayments pursuant to a refinancing permitted thereunder or if certain requirements are satisfied and (xi) other customary negative covenants for a facility of this nature.

Convertible Notes. In February 2007, we issued $200.0 million aggregate principal amount of Convertible Senior Notes due 2012 and $200.0 million aggregate principal amount of Convertible Senior Notes due 2014. Interest on the notes due 2012 will be paid semiannually at a rate of 1.00% per year and interest on the notes due 2014 will be paid semiannually at a rate of 1.25% per year. Upon the occurrence of certain defined events, the Convertible Senior Notes will be convertible into cash up to the principal amount, and if applicable, shares of common stock in respect of any conversion value above the principal amount, based on an initial conversion rate of 17.1951 shares of common stock per $1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately $58.16 per share.

The Senior Convertible Notes rank equal in right of payment to all of our other existing and future senior unsecured indebtedness. The Senior Convertible Notes will rank senior in right of payment to all of Kyphon's existing and future subordinated indebtedness and effectively subordinated in right of payment to all of its subsidiaries' obligations (including secured and unsecured obligations) and subordinated in right of payment to its secured obligations to the extent of the assets securing such obligation.

In connection with the offering, we entered into convertible note hedge transactions with affiliates of the initial purchasers. These transactions are intended to reduce the potential dilution to our stockholders upon any future conversion of the notes. The call options, which cost an aggregate $112.0 million, were recorded as a reduction of additional paid-in capital, net of tax benefit. We also entered into warrant transactions concurrently with the offering, pursuant to which we sold warrants to purchase our own common stock to the same counterparties that entered into the convertible note hedge transactions. The convertible note hedge and warrant transactions effectively will increase the conversion price of the convertible notes to approximately $75.04 per share of our common stock. Proceeds received from the issuance of the warrants totaled approximately $77.0 million and were recorded as an addition to additional paid-in capital.

On February 6, 2007, we used net proceeds of approximately $355.0 million from the issuance of the Convertible Senior Notes, described below, together with borrowings under the Revolving Credit Facility, to prepay the Term Loan Facility in its entirety.

Cash Provided by Operating Activities. Our operating cash flow in 2006 was primarily the result of our operational profitability. Net cash provided by operations was $54.9 million attributable primarily to net income of $39.7 million and adjustments for non-cash charges related to stock-based compensation of $29.1 million and depreciation and amortization of $6.7 million. Net cash provided by operations in 2005 was $67.9 million attributable primarily to net income of $29.8 million and adjustments for non-cash charges related to tax benefits from stock options of $18.5 million. Net cash provided by operations in 2004 was $31.0 million in 2004 attributable primarily to net income of $21.7 million and adjustments for non-cash charges related to tax benefits from stock options of $8.7 million. In January 2006, we adopted SFAS No. 123(R), which requires that the excess benefit of tax deductions over the recognized compensation cost for employee stock options be reported as cash flow from financing activities rather than as cash flow from operations.

The increases in cash provided by operating activities for all periods was adjusted by changes in our working capital, primarily in accounts receivable, inventories and accrued liabilities. Accounts receivable increased by $16.9 million, $16.4 million and $17.6 million during 2006, 2005, and 2004, respectively, due to increases in our net sales. Inventories increased by $7.3 million in 2006 to meet the increased demand for our products and full launch of our FAD product in 2007. Inventories decreased by $552,000 in 2005 due to improved inventory management. Inventories increased by $5.1 million during 2004 to meet the increased demand for our products. Accrued liabilities increased by $6.8 million, $26.3 million and $9.0 million during 2006, 2005, and 2004, respectively, due to our increased operating expenses and income taxes. As of December 31, 2005, accrued liabilities included $15.0 million relating to the license acquisition charge from our agreement with Dr. Sandhu.

Cash Used in Investing Activities. Net cash used in investing activities was $75.7 million, $100.9 million, and $11.2 million in 2006, 2005, and 2004, respectively. Cash used in investing activities reflected purchases of property and equipment for all periods. During 2006, cash used for investing activities reflected the net purchases of investments of $1.5 million, payment of $2.2 million in connection with an equity investment in a private company, and payment of $60.0 million in connection with our definitive agreements to acquire Disc-O-Tech. During 2005, cash used for investing activities reflected the net purchases of investments of $90.4 million, and payment of $2.4 million in connection with the acquisition of InnoSpine. During 2004, cash used in investing activities reflected the net purchases of investments of $1.6 million. We expect our purchases of property and equipment in 2007 to increase due to the expansion of our Sunnyvale facility and the establishment of our new manufacturing, distribution and research and development facilities in Switzerland.

Cash Provided by Financing Activities. Net cash provided by financing activities was $24.5 million, $22.3 million, and $9.8 million in 2006, 2005, and 2004, respectively. Cash provided during 2006 was attributable to proceeds from the issuance of common stock under the employee stock plan of $6.3 million, the exercise of stock options of $13.9 million, and excess tax benefit related to stock-based compensation plans of $4.4 million. Cash provided by financing activities during 2005 was attributable to proceeds from the issuance of common stock under the employee stock purchase plan of $4.7 million and the exercise of stock options of $17.6 million. Cash provided during 2004 was attributable to proceeds from the issuance of common stock under the employee stock purchase plan of $3.4 million and the exercise of stock options of $6.4 million.

Contractual Cash Obligations. At December 31, 2006 we had contractual cash obligations as follows (in thousands):

	Payment Due by Periods				
	Total	2007	2008-2009	2010-2011	After 2011
Operating leases	$ 22,347	$ 3,567	$ 6,115	$ 6,038	$ 6,627
Consulting agreement	1,656	944	712	--	--
License agreement	10,000	10,000	--	--	--
Disc-O-Tech payment obligations	160,000	40,000	80,000	40,000	--
Purchase commitments with contract manufacturers and suppliers	8,779	8,779	--	--	--
Purchase obligations	7,169	7,169	--	--	--
Asset retirement obligation	669	--	--	373	296
Total commitments	$ 210,620	$ 70,459	$ 86,827	$ 46,411	$ 6,923

The amounts reflected in the table above for operating leases represent aggregate future minimum lease payments under non-cancellable facility leases. Portions of these payments and a portion of the asset retirement obligations are denominated in foreign currencies and were translated in the tables above based on their respective U.S. dollar exchange rates at December 31, 2006. These future payments are subject to foreign currency exchange rate risk.

We remain obligated to make a series of annual payments totaling up to $15.0 million related to the license acquisition agreement with Dr. Sandhu of which $5.0 million was paid in the fourth quarter of 2006. The payments of these additional obligations may be accelerated upon defined events and circumstances or may be forgiven upon the occurrence of a third party event, outside the control of the Company. Based on management judgment, ability and intent, this remaining obligation in the amount of $10.0 million has been classified as current liability as of December 31, 2006.

In January 2006, we completed our acquisition of InnoSpine, Inc. (InnoSpine), a privately held company focused on developing and marketing its proprietary technology platform for the diagnosis and potential treatment of axial low back pain due to disc degeneration. The terms of the acquisition called for an initial purchase price of $2.5 million in cash to the shareholders of InnoSpine, plus the possibility of up to an additional $27.5 million in cash or stock, based on achievement of clinical and other milestones as well as royalties on future net sales. This contingent purchase price liability is not included in the table above.

In December 2006, we executed two definitive agreements with Disc-O-Tech Medical Technologies, Ltd. and its U.S. subsidiary (Disc-O-Tech) to acquire, respectively, all of its non-vertebroplasty spine-related assets, including minimally invasive technologies for performing fusion and vertebral body augmentation, for $100.0 million in cash ($60.0 million paid up-front in December 2006 and another $40.0 million paid February 1, 2007), and all of its vertebroplasty assets for a total of an additional $120.0 million payable in three equal annual installments beginning in January 2008. We will still be obligated to pay the purchase price even if the closings do not occur. We also agreed to pay up to an additional $20.0 million for the development of future technologies upon closing of the vertebroplasty asset purchase agreement. This contingent purchase price liability is not included in the table above. We have not yet received clearance from the Federal Trade Commission to close either of these transactions and may not be able to do so for some time, if at all.

In January 2007, we completed our acquisition of St. Francis Medical Technologies, Inc. (St. Francis). The total estimated purchase price, excluding transaction costs, of approximately $725.0 million was comprised $525.0 million in cash upon closing, plus additional revenue-based contingent payments of up to $200.0 million payable in either cash or a combination of cash and stock, at Kyphon's election. The payments are contingent upon the attainment of certain revenue thresholds during specified periods through June 2008. Neither the initial purchase price or the contingent purchase price liability are included in the table above. We financed the transaction through a combination of cash on hand and bank financing.

Purchase Commitments with Contract Manufacturers and Suppliers. We purchase components from a variety of suppliers and use contract manufacturers to provide manufacturing services for our products. During the normal course of business, in order to manage manufacturing lead times and to help assure adequate component supply, we enter into agreements with contract manufacturers and suppliers that either allow them to procure inventory based upon criteria as defined by us or that establish the parameters defining our requirements. In certain instances, these agreements allow us the option to cancel, reschedule, and adjust our requirements based on our business needs prior to firm orders being placed. Consequently, only a portion of our reported purchase commitments arising from these agreements are firm, noncancelable, and unconditional commitments. The purchase commitments for inventory are expected to be fulfilled within one year.

Purchase Obligations. Purchase obligations represent an estimate of all open purchase orders and contractual obligations in the ordinary course of business, other than commitments with contract manufacturers and suppliers, for which we have not received the goods or services. Although open purchase orders are considered enforceable and legally binding, the terms generally allow us the option to cancel, reschedule, and adjust our requirements based on our business needs prior to the delivery of goods or performance of services.

Off-Balance Sheet Arrangements. We do not have any off-balance sheet financing as of December 31, 2006. All of our subsidiaries are included in the financial statements, and we do not have relationships with any special purpose entities.

Stock Repurchase. Our Board of Directors approved a stock repurchase program on November 7, 2002, pursuant to which we may purchase up to 2,000,000 shares of our outstanding common stock. The duration of the repurchase program is open-ended. Under the program, we may purchase shares of common stock through open market transactions at prices deemed appropriate by management and the Board of Directors. The purchases will be funded from available working capital. In 2002, we repurchased 30,000 shares pursuant to this repurchase program. We have not repurchased any of our common stock since 2002.

Summary. We believe our cash generated from operations, together with our cash, cash equivalents, investments, and borrowings available under our revolving credit facility will be sufficient to meet our anticipated cash needs for working capital, capital expenditures and our contractual payments and any contingent payments that become due related to the acquisitions described for at least the next 12 months.

Recent Accounting Pronouncements

In June 2006, the FASB issued Interpretation No. 48, “Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement No. 109” (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in a company’s financial statements in accordance with SFAS No. 109, “Accounting for Income Taxes.” FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact of the adoption of FIN 48 will have on our financial statements or related disclosures.

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements” (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for fiscal years beginning after November 15, 2007 and is to be applied prospectively. We are currently evaluating the impact, if any, of the adoption of SFAS 157 will have on our financial reporting.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 (SAB 108) in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements. Traditionally, there have been two widely-recognized methods for quantifying the effects of financial statement misstatements: the “roll-over” method and the “iron curtain” method. The “roll-over” method

focuses primarily on the impact of a misstatement on the income statement, including the reversing effect of prior period misstatements; but its use can lead to the accumulation of misstatements in the balance sheet. The "iron-curtain" method, on the other hand, focuses primarily on the effect of correcting the period-end balance sheet with less emphasis on the reversing effects of prior period errors on the income statement. We currently use the "iron-curtain" method for quantifying identified financial statement misstatements. In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of our financial statements and the related financial statement disclosures. This model is commonly referred to as a "dual approach" because it requires quantification of errors under both the "iron curtain" and the "roll-over" methods. SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the "dual approach" had always been used or (ii) recording the cumulative effect of initially applying the "dual approach" as adjustments to the carrying values of assets and liabilities as of the beginning of the current fiscal year with an offsetting adjustment to the opening balance of retained earnings in the year of adoption. Use of the "cumulative effect" transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The provisions of SAB 108 must be applied to annual financial statements no later than the first fiscal year ending after November 15, 2006. Upon adoption, there was no impact on our financial statements or related disclosures.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest rate risk at December 31, 2006 is related primarily to our investment portfolio. Our investment portfolio includes fixed rate debt instruments of the U.S. government and its agencies and high quality corporate issuers. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk, investments are generally held to maturity and the weighted average duration of our investments is 12 months or less. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

We have operated mainly in the United States, and 79%, 84%, and 88% of our sales were made in U.S. dollars in 2006, 2005, and 2004, respectively. The majority of our non-U.S. sales are derived from European Union countries and denominated in the Euro. Monthly income and expense from our European operations are translated using average rates and balance sheets are translated using month end rates. Differences are recorded within stockholders' equity as a component of accumulated other comprehensive income or to the income statement, as applicable. As our revenues denominated in currencies other than the dollar increase, we have an increased exposure to foreign currency rate risk. Based on our overall exposure for foreign currency at December 31, 2006, a hypothetical 10% change in foreign currency rates would not have a material impact on our net sales and operating expenses. We may elect to mitigate this rate risk, in part or in whole, through the purchase of forward currency contracts.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORTS OF MANAGEMENT

Statement of Management's Responsibility

Kyphon's management has always assumed full accountability for maintaining compliance with our established financial accounting policies and for reporting our results with objectivity and the highest degree of integrity. It is critical for investors and other users of the Consolidated Financial Statements to have confidence that the financial information that we provide is timely, complete, relevant, and accurate. Management is responsible for the fair presentation of Kyphon's Consolidated Financial Statements, prepared in accordance with generally accepted accounting principles (GAAP), and has full responsibility for their integrity and accuracy.

Management, with oversight by Kyphon's Board of Directors, is working to continually strengthen an ethical climate so that our affairs are conducted to the highest standards of personal and corporate conduct. Management also has established an effective system of internal control over financial reporting. Kyphon's policies and practices reflect corporate governance initiatives that are compliant with the listing requirements of NASDAQ and the corporate governance requirements of the Sarbanes-Oxley Act of 2002. We are committed to enhancing shareholder value and fully understand and embrace our fiduciary oversight responsibilities. We are dedicated to ensuring that our high standards of financial accounting and reporting as well as our underlying system of internal controls are maintained. Our culture demands integrity and we have the highest confidence in our processes, our internal controls, and our people, who are objective in their responsibilities and who operate under the highest level of ethical standards.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for Kyphon. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management (with the participation of the principal executive officer and principal financial officer) conducted an evaluation of the effectiveness of Kyphon's internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that Kyphon's internal control over financial reporting was effective as of December 31, 2006. Management's assessment of the effectiveness of Kyphon's internal control over financial reporting as of December 31, 2006 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

KYPHON INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and
Stockholders of Kyphon Inc.:

We have completed integrated audits of Kyphon Inc.'s consolidated financial statements and of its internal control over financial reporting as of December 31, 2006, in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements and financial statement schedule

In our opinion, the consolidated financial statements listed in the accompanying index, present fairly, in all material respects, the financial position of Kyphon Inc. and its subsidiaries at December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These 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 of financial statements 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.

As discussed in Note 2 to the Notes to Consolidated Financial Statements, the Company changed the manner in which it accounts for stock-based compensation in 2006.

Internal control over financial reporting

Also, in our opinion, management's assessment, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 8, that the Company maintained effective internal control over financial reporting as of December 31, 2006 based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance

regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP
San Jose, California
February 28, 2007

KYPHON INC.
CONSOLIDATED INCOME STATEMENTS
(in thousands, except per share amounts)

	Year Ended December 31,		
	2006	**2005**	**2004**
Net sales	$ 407,790	$ 306,082	$ 213,414
Cost of goods sold	52,176	35,843	24,734
Gross profit	355,614	270,239	188,680
Operating expenses:			
Research and development	39,971	46,383	22,238
Sales and marketing	194,057	144,768	106,103
General and administrative	60,351	34,951	25,972
Total operating expenses	294,379	226,102	154,313
Income from operations	61,235	44,137	34,367
Interest income	8,960	3,998	1,314
Other income (expense), net	527	(19)	(64)
Income before income taxes	70,722	48,116	35,617
Provision for income taxes	30,990	18,280	13,900
Net income	$ 39,732	$ 29,836	$ 21,717
Net income per share:			
Basic	$ 0.89	$ 0.70	$ 0.54
Diluted	$ 0.86	$ 0.66	$ 0.50
Weighted-average shares outstanding:			
Basic	44,436	42,803	40,449
Diluted	46,313	45,336	43,670

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

KYPHON INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share amounts)

	December 31, 2006	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 81,939	$ 76,149
Investments	120,214	118,324
Accounts receivable, net of allowances of $1,864 in 2006 and $1,577 in 2005	73,859	55,480
Inventories	11,869	9,265
Prepaid expenses and other current assets	7,520	5,899
Deferred tax assets	6,072	10,488
Total current assets	301,473	275,605
Property and equipment, net	27,590	15,977
Goodwill and other intangible assets, less accumulated amortization of $1,232 in 2006 and $88 in 2005	14,742	15,377
Deferred tax assets	14,955	6,749
Other assets	69,846	2,924
Total assets	$ 428,606	$ 316,632
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,447	$ 9,308
Accrued liabilities	62,980	49,793
Total current liabilities	73,427	59,101
Other liabilities	10,479	7,475
Total liabilities	83,906	66,576
Commitments and contingencies (Notes 4, 5 and 7)		
Stockholders' equity:		
Preferred stock, par value: $0.001		
Authorized: 5,000 shares; none issued and outstanding	--	--
Common stock, par value: $0.001		
Authorized: 120,000 shares		
Issued: 44,969 shares in 2006 and 43,843 shares in 2005		
Outstanding: 44,939 shares in 2006 and 43,813 shares in 2005	45	44
Additional paid-in capital	284,672	231,312
Treasury stock, at cost: 30 shares in 2006 and 2005	(201)	(201)
Deferred stock-based compensation	--	(116)
Accumulated other comprehensive income	1,607	172
Retained earnings	58,577	18,845
Total stockholders' equity	344,700	250,056
Total liabilities and stockholders' equity	$ 428,606	$ 316,632

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

KYPHON INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2006	**2005**	**2004**
Cash flows from operating activities:			
Net income	$ 39,732	$ 29,836	$ 21,717
Adjustments to reconcile net income to net cash provided by operating activities:			
Provision for accounts receivable allowances	714	1,366	737
Provision for excess and obsolete inventories	2,136	757	158
Depreciation and amortization	6,674	4,274	2,817
Deferred tax assets	(2,957)	(3,764)	4,080
Loss on disposal of property and equipment	220	182	93
Tax benefit related to stock-based compensation plans	4,198	18,517	8,741
Excess tax benefit related to stock-based compensation plans	(4,392)	--	--
Stock-based compensation	29,143	3,091	3,852
Changes in operating assets and liabilities, net of effect of acquisition:			
Accounts receivable	(16,865)	(16,408)	(17,581)
Inventories	(7,333)	552	(5,127)
Prepaid expenses and other current assets	(1,466)	(1,270)	343
Other assets	(4,647)	939	(1,975)
Accounts payable	944	3,898	(40)
Accrued liabilities	6,808	26,264	9,030
Other liabilities	1,945	(358)	4,156
Net cash provided by operating activities	54,854	67,876	31,001
Cash flows from investing activities:			
Acquisition of property and equipment	(11,905)	(8,025)	(9,650)
Maturities and sales of investments	202,843	38,600	19,945
Purchases of investments	(204,385)	(129,030)	(21,523)
Disc-O-Tech acquisition deposits	(60,000)	--	--
Other investments and acquisitions, net of cash	(2,238)	(2,448)	--
Net cash used in investing activities	(75,685)	(100,903)	(11,228)
Cash flows from financing activities:			
Proceeds from issuance of common stock	6,286	4,697	3,421
Proceeds from exercise of stock options	13,850	17,597	6,361
Excess tax benefit related to stock-based compensation plans	4,392	--	--
Net cash provided by financing activities	24,528	22,294	9,782
Effect of foreign exchange rate changes on cash	2,093	(354)	187
Net increase (decrease) in cash and cash equivalents	5,790	(11,087)	29,742
Cash and cash equivalents at beginning of year	76,149	87,236	57,494
Cash and cash equivalents at end of year	$ 81,939	$ 76,149	$ 87,236
Supplementary disclosure of non-cash investing and financing activities:			
Capitalized building and related capitalized interest	$ 5,038	$ --	$ --
Lease financing liability	$ 4,992	$ --	$ --
Write-off of fully depreciated property and equipment	$ 2,442	$ 847	$ 187
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 100	$ --	$ --
Cash paid during the year for income taxes	$ 32,282	$ 1,696	$ 400

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

KYPHON INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-In	Treasury	Deferred Stock-Based	Accumulated Other Comprehensive	Retained Earnings (Accumulated	Total Stockholders'
	Shares	Amount	Capital	Stock	Compensation	Income	Deficit)	Equity
Balance at January 1, 2004	39,440	$ 39	$ 171,359	$ (201)	$ (6,435)	$ 2,196	$ (32,708)	$ 134,250
Exercise of stock options	1,542	2	6,359	--	--	--	--	6,361
Issuance of common stock under employee stock purchase plan	338	--	3,421	--	--	--	--	3,421
Issuance of common stock upon exercise of warrants	5	--	--	--	--	--	--	--
Tax benefits from exercise of common stock options	--	--	8,741	--	--	--	--	8,741
Deferred stock-based compensation, net of cancellations	--	--	(470)	--	470	--	--	--
Amortization of deferred stock-based compensation	--	--	--	--	2,923	--	--	2,923
Non-employee stock-based compensation	--	--	--	--	929	--	--	929
Components of other comprehensive income:								
Changes in unrealized gains (losses) on available-for sale investments, net of taxes	--	--	--	--	--	(73)	--	(73)
Cumulative translation adjustments	--	--	--	--	--	1,366	--	1,366
Net income	--	--	--	--	--	--	21,717	21,717
Total comprehensive income								23,010
Balance at December 31, 2004	41,325	41	189,410	(201)	(2,113)	3,489	(10,991)	179,635
Exercise of stock options	2,174	2	17,595	--	--	--	--	17,597
Issuance of common stock under employee stock purchase plan	314	1	4,696	--	--	--	--	4,697
Tax benefits from exercise of common stock options	--	--	18,517	--	--	--	--	18,517
Deferred stock-based compensation, net of cancellations	--	--	(165)	--	165	--	--	--
Amortization of deferred stock-based compensation	--	--	--	--	1,832	--	--	1,832
Non-employee stock-based compensation	--	--	1,259	--	--	--	--	1,259
Components of other comprehensive income:								
Changes in unrealized gains (losses) on available-for sale investments, net of taxes	--	--	--	--	--	(90)	--	(90)
Cumulative translation adjustments	--	--	--	--	--	(3,227)	--	(3,227)
Net income	--	--	--	--	--	--	29,836	29,836
Total comprehensive income								26,519
Balance at December 31, 2005	43,813	44	231,312	(201)	(116)	172	18,845	250,056
Exercise of stock options	875	1	13,849	--	--	--	--	13,850
Issuance of common stock under employee stock purchase plan	251	--	6,286	--	--	--	--	6,286
Tax benefits from exercise of common stock options	--	--	4,198	--	--	--	--	4,198
Deferred stock-based compensation, net of cancellations	--	--	(116)	--	116	--	--	--
Stock-based compensation	--	--	29,143	--	--	--	--	29,143
Components of other comprehensive income:								
Changes in unrealized gains (losses) on available-for sale investments, net of taxes	--	--	--	--	--	140	--	140
Cumulative translation adjustments	--	--	--	--	--	1,295	--	1,295
Net income	--	--	--	--	--	--	39,732	39,732
Total comprehensive income								41,167
Balance at December 31, 2006	44,939	$ 45	$ 284,672	$ (201)	$ --	$ 1,607	$ 58,577	$ 344,700

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

KYPHON INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION

Kyphon Inc. ("Kyphon" or the "Company") is a medical device company focused on the design, manufacture and marketing of instruments used in minimally invasive therapies by surgeons and their patients for the treatment and restoration of spinal anatomy. The Company is currently commercializing surgical tools that use its proprietary balloon technologies for the repair of spinal fractures. The Company markets its products through sales representatives in North America, and through a combination of sales representatives, distributors and agents in its international markets. The Company is headquartered in Sunnyvale, California, has subsidiaries in many countries in Europe, as well as in Canada, Japan, Australia and South Africa.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Consolidation and Foreign Currency Translation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All material intercompany balances and transactions have been eliminated.

The Company analyzes the functional currency determination for its international subsidiaries on an annual basis, or more often as necessary. For the Company's international subsidiaries which use their local currency as their functional currency, assets and liabilities are translated at exchange rates in effect at the balance sheet date and revenue and expense accounts at average exchange rates during the period. Resulting translation adjustments are recorded directly to cumulative comprehensive income. Translation adjustments resulting from the process of remeasuring into the United States dollar from the foreign currency financial statements of the Company's wholly owned subsidiaries, for which the United States dollar is the functional currency, are included in other income (expense), net.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents include money market funds, corporate notes and commercial paper. Cash equivalents comprised commercial paper and corporate notes in the amounts of $25,906,000 and $7,251,000, as of December 31, 2006 and 2005, respectively. Cash equivalents are classified as available-for-sale and therefore are carried at fair market value. Related unrealized gains and losses were insignificant as of December 31, 2006 and 2005.

Investments

Restricted Cash. Under the terms of one of its facility leases, the Company is required to issue an irrevocable standby letter of credit to the lessor for the term of the facility lease. The letter of credit is secured by a certificate of deposit in the amount of $1,105,000 which was classified within other assets as of December 31, 2006 and 2005.

Available-for-Sale. All marketable investments are classified as available-for-sale and therefore are carried at fair market value. Unrealized gains and losses, net of taxes, are reported as a separate component of stockholders' equity. Realized gains and losses on the sale of all such investments are reported in earnings and computed using the specific identification cost method and were insignificant for the years ended December 31, 2006, 2005 and 2004. All of the Company's investments as of December 31, 2006 have maturities of one year or less. The Company's available-for-sale investments are summarized as follows (in thousands):

	December 31,	
	2006	2005
Asset-backed securities	$ 6,249	$ 29,441
Variable-rate demand notes (1)	113,965	--
U.S. government and agency securities	--	6,506
Corporate debt secruities	--	82,377
Total short-term investments	$ 120,214	$ 118,324

	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
December 31, 2006				
Asset-backed securities	$ 6,248	$ 1	$ --	$ 6,249
Variable-rate demand notes	113,965	--	--	113,965
Total short-term investments	$ 120,213	$ 1	$ --	$ 120,214
December 31, 2005				
Asset-backed securities	$ 29,474	$ --	$ (33)	$ 29,441
U.S. government and agency securities	6,509	--	(3)	6,506
Corporate debt securities	82,575	--	(198)	82,377
Total short-term investments	$ 118,558	$ --	$ (234)	$ 118,324

(1) Variable-rate securities are securities with perpetual maturities that are structured with short-term reset dates of generally 7 days. At the end of the reset period, investors can sell or continue to hold the securities at par.

The following table summarizes the estimated fair value of our securities held in short-term investments classified by the stated maturity date of the security (in thousands):

	As of December 31, 2006
Due within 1 year	$ 6,249
Due from 1 year through 5 years	--
Due from 5 years through 10 years	--
Due after 10 years	113,965
Total short-term investments	$ 120,214

Investments in Other Entities. In August 2006, the Company invested $2,238,000 in a privately held company that designs and develops devices for posterior fusion and dynamic stabilization of the lumbar spine. The investment is accounted for under the cost method of accounting and is included in other assets in the Company's consolidated balance sheet as of December 31, 2006. The Company will monitor this investment for impairment and make appropriate reductions in carrying value if the Company determines that an impairment charge is required based primarily on the financial condition and near-term prospects of the company. As of December 31, 2006, the Company has determined that an impairment charge is not required.

Accounts Receivable Allowances

The Company estimates allowances for doubtful accounts and for product returns. Specifically, the Company makes estimates on the collectibility of customer accounts receivable and product returns based primarily on an analysis of historical trends and experience and changes in customers' financial condition. The Company uses its judgment, based on the best available facts and circumstances, and records an allowance against amounts due to reduce the receivable to the amount that is expected to be collected. These allowances are reevaluated and adjusted as additional information is received that impacts the amount reserved.

Inventories

Inventories are stated at the lower of cost or market. Cost is computed on a first-in, first-out basis. The Company provides inventory allowances based on excess and obsolete inventories determined primarily by future demand forecasts. The allowance is measured as the difference between the cost of the inventory and market based upon assumptions about future demand and charged to the provision for inventory, which is a component of cost of goods sold. At the point of the loss recognition, a new, lower-cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

Depreciation and Amortization

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, generally two to five years. Amortization of leasehold improvements is provided on a straight-line basis over the life of the related asset or the lease term, if shorter. Upon the sale or retirement of assets, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in other income (expense), net. Repairs and maintenance expenses are expensed as incurred.

Asset Retirement Obligations

The fair value of the asset retirement obligation is recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. In addition, the associated asset retirement cost is added to the carrying amount of the associated asset and this additional carrying amount is amortized over the life of the asset. The Company's asset retirement obligations are associated with its commitment to return property subject to operating leases in London, UK, Brussels, Belgium, and Sunnyvale, California to original condition upon lease termination. The Company estimated that gross expected future cash flows of approximately $894,000 would be required to fulfill these obligations.

As of December 31, 2006, the Company has recorded asset retirement obligations of approximately $669,000 and a corresponding increase in leasehold improvements. This amount represents the present value of expected future cash flows associated with returning the leased properties to original condition. A portion of this amount is subject to foreign exchange rate fluctuations and has been translated using the exchange rate at December 31, 2006. The leasehold improvements are being amortized to depreciation expense over the term of the lease. Related amortization expense was approximately $135,000, $61,000 and $39,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

Goodwill and Other Intangible Assets

The Company is amortizing its acquired intangible assets on a straight line basis over a five to ten year period. No amortization of goodwill has been recorded. Instead, the Company performs an impairment assessment by applying a fair-value based test on an annual basis, or more frequently if changes in circumstances or the occurrence of events suggest the remaining value is not recoverable. The annual goodwill impairment analysis is completed in the first quarter of each year. To date there has been no impairment of goodwill. There have been no events or changes in circumstances subsequent to the Company's annual tests which may indicate the asset is impaired.

Impairment of Long-Lived Assets

Long-lived assets are evaluated for impairment annually and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recovered. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. Through December 31, 2006, there have been no such impairments.

Treasury Stock

In November 2002, the Board of Directors approved a stock repurchase program pursuant to which up to 2,000,000 shares of the Company's outstanding common stock may be repurchased from time to time. The duration of the repurchase program is open-ended. Under the program, the Company may purchase shares of common stock through open market transactions at prices deemed appropriate by management and the Board of Directors. As of December 31, 2006 and 2005, the Company held 30,000 shares of treasury stock. Treasury stock is accounted for using the cost method.

Accounting for Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), "Share Based Payment" ("SFAS No. 123(R)"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including employee stock options and employee stock purchases based on estimated fair values. Accordingly, stock-based compensation cost is measured at grant date, based on the fair value of the award, and is recognized as expense over the employee requisite service period for each separately vesting tranche of the award. The Company elected to adopt the modified prospective application method as provided by SFAS No. 123(R). Accordingly, previously reported amounts have not been restated. The Company also elected to use the method described in paragraph 81 of SFAS No. 123(R) (the "long form" method) for the calculation of its pool of excess tax benefits available to absorb tax deficiencies recognized subsequent to the adoption of SFAS No. 123(R). Employee stock-based compensation expense recognized under SFAS No. 123(R) for the year ended December 31, 2006 was $27,625,000.

The Company estimates the value of employee stock options on the date of grant using a binomial-lattice model. The binomial-lattice model used by the Company to value employee stock options on the date of grant considers a range of assumptions related to volatility, risk-free interest rate and employee exercise behavior. Expected volatilities are based on a blend of implied market volatilities, historical and peer group volatilities. The risk-free rate is derived from the U.S. Treasury zero-coupon yield curve in effect at the time of grant over the contractual term of the option. The binomial-lattice model also incorporates exercise and forfeiture assumptions based on an analysis of historical data. The expected life of the stock option grants is derived from the output of the binomial-lattice model and represents the period of time that options granted are expected to be outstanding.

The following table shows total stock-based compensation expense for the year ended December 31, 2006, 2005 and 2004 (in thousands):

	Year Ended December 31,		
	2006	2005	2004
Cost of goods sold	$ 1,337	$ 124	$ 317
Research and development	3,876	790	903
Sales and marketing	11,596	797	1,324
General and administrative	10,816	121	380
	$ 27,625	$ 1,832	$ 2,924

The effect of adopting SFAS No. 123(R) was as follows (in thousands, except per share amounts):

	Year Ended December 31, 2006
Stock-based compensation by type of award:	
Employee stock options	$ 24,473
Employee stock purchase rights	3,152
Total stock-based compensation expense	27,625
Tax effect on stock-based compensation	(8,478)
Net effect on net income	$ 19,147
Effect on net income per share:	
Basic	$ 0.43
Diluted	$ 0.41

As of December 31, 2006, stock-based compensation charges of approximately $150,000 were capitalized as inventory.

During the year ended December 31, 2005 and 2004, the Company recognized employee stock-based compensation

expense of $1,832,000 and $2,924,000, respectively, under APB No. 25 related to stock options previously issued with exercise prices below the deemed fair market value of the Company's common stock at the date of grant. Upon the adoption of SFAS No. 123(R) on January 1, 2006, the Company recorded a cumulative effect adjustment to eliminate the remaining unrecognized deferred stock-based compensation of approximately $116,000 against additional paid-in capital. The Company did not record a cumulative effect adjustment to record estimated forfeitures for these stock-based awards upon the adoption of SFAS No. 123(R) as it was not significant.

Prior to the adoption of SFAS No. 123(R), the Company used the intrinsic value method in accounting for its employee stock options, and presented disclosure of pro forma information as if the Company had accounted for stock-based compensation using the fair value method of each option on the date of grant as follows (in thousands, except per share amounts):

	Year Ended December 31,	
	2005	2004
Net income, as reported	$ 29,836	$ 21,717
Add: Stock-based employee compensation expense included in reported net income, net of taxes	1,136	1,784
Deduct: Total stock-based employee compensation expense, determined under fair value based method for all awards, net of taxes	(15,698)	(9,897)
Pro forma net income	$ 15,274	$ 13,604
Net income per share		
Basic:		
As reported	$ 0.70	$ 0.54
Pro forma	$ 0.36	$ 0.34
Diluted:		
As reported	$ 0.66	$ 0.50
Pro forma	$ 0.34	$ 0.31

Valuation Assumptions

The weighted-average assumptions used are as follows:

	Year Ended December 31,		
	Employee Stock Options		
	2006	2005	2004
Risk-free interest rate	4.82%	3.97%	3.04%
Expected volatility	45%	51%	62%
Expected life (in years)	5.1	3.6	4.0
Dividend yield	--	--	--
Fair value per option granted	$ 14.58	$ 12.36	$ 12.61

	Employee Stock Purchase Plan		
	2006	2005	2004
Risk-free interest rate	4.75%	3.21%	1.22%
Expected volatility	37%	58%	66%
Expected life (in years)	0.7	1.3	1.5
Dividend yield	--	--	--
Fair value per share purchase	$ 10.98	$ 11.96	$ 6.80

As of December 31, 2006, the Company had an unrecorded stock-based compensation balance related to stock options of approximately $25,341,000 after estimated forfeitures, which will be recognized over an estimated weighted-average remaining requisite service period of 2.6 years. As of December 31, 2006, the unrecorded stock-based compensation balance related to employee stock purchase rights was $119,000, which will be recognized in January 2007. During the year ended December 31, 2006, the Company granted approximately 1,883,000 stock options with an estimated total grant-date fair value of approximately $27,451,000.

Non-Employee Stock-Based Compensation

The Company accounts for equity instruments issued to non-employees at their fair value on the measurement date. The Company uses the Black-Scholes option pricing model to measure the value of the options granted to non-employees at each vesting date to determine the appropriate charge to stock-based compensation. The options generally vest ratably over four years. The values attributable to these options have been amortized over the service period on a graded vesting method. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. The Company recognized stock-based compensation expense related to non-employee options as follows (in thousands):

	Year Ended December 31,		
	2006	2005	2004
Research and development	$ 1,045	$ 159	$ 231
Sales and marketing	323	619	36
General and administrative	--	481	662
	$ 1,368	$ 1,259	$ 929

Concentrations of Credit Risk and Other Risks and Uncertainties

The Company's cash and cash equivalents are maintained with several financial institutions. Deposits in those institutions may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and are maintained with financial institutions of reputable credit and therefore bear minimal credit risk.

For financial instruments consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities included in the Company's financial statements, the carrying amounts approximate fair value due to their short maturities. Estimated fair values for marketable securities, which are separately disclosed elsewhere, are based on quoted market prices for the same or similar instruments.

The Company performs ongoing credit evaluations of its customers' financial condition and, generally, requires no collateral from its customers. No customer accounted for more than 10% of total net sales for the years ended December 31, 2006, 2005 and 2004. No customer accounted for more than 10% of total accounts receivable at December 31, 2006 and 2005.

The Company receives certain of its components from sole suppliers. Additionally, the Company relies on certain contract manufacturers and suppliers to provide manufacturing services for its products.

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 and suppliers, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance and reimbursement of products, product liability and the need to obtain additional financing.

Revenue Recognition

The Company's revenue consists primarily of the sale of its products to customers and distributors. Revenue is considered to be realized or realizable and earned when all of the following criteria are met: persuasive evidence of a sales arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectibility is reasonably assured. These criteria are generally met at the time of shipment when the risk of loss and title passes to the customer or distributor. Allowances are established for product returns based upon historical trends and are recorded as a reduction to revenue.

Shipping and Handling of Products

Amounts billed to customers for shipping and handling of products is included in net sales and was approximately $1,463,000, $1,151,000 and $766,000 for the years ended December 31, 2006, 2005 and 2004, respectively. Costs incurred related to shipping and handling of products are included in cost of goods sold.

Research and Development

Research and development costs, including new product development programs, regulatory compliance, and clinical research are expensed as incurred.

Advertising Costs

Advertising costs, included in sales and marketing expenses, are expensed as incurred. Advertising costs were approximately $4,313,000, $4,934,000 and $3,515,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

Income Taxes

The Company accounts for income taxes under the asset and liability method whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and 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 more likely than not expected to be realized.

Comprehensive Income

The components of other comprehensive income are as follows (in thousands):

	December 31,	
	2006	2005
Unrealized gain (losses) on available-for-sale investments, net of taxes	$ 1	$ (139)
Translation adjustments	1,606	311
	$ 1,607	$ 172

Net Income per Share

Basic net income per share is computed by dividing net income by the weighted-average number of common stock shares outstanding for the period. Diluted net income per share is computed giving effect to all potential dilutive common stock, including stock options, employee stock purchase rights and warrants. A reconciliation of the numerator and denominator used in the calculation of basic and diluted net income per share follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2006	2005	2004
Net income	$ 39,732	$ 29,836	$ 21,717
Weighted-average shares outstanding	44,436	42,803	40,451
Less: weighted-average shares subject to repurchase	--	--	(2)
Basic weighted-average shares outstanding	44,436	42,803	40,449
Dilutive effect of:			
Employee stock options and purchase rights	1,877	2,533	3,218
Warrants	--	--	3
Diluted weighted-average shares outstanding	46,313	45,336	43,670
Net income per share:			
Basic	$ 0.89	$ 0.70	$ 0.54
Diluted	$ 0.86	$ 0.66	$ 0.50

The following potential dilutive securities were excluded from the computation of diluted net income per share, as they had an antidilutive effect (in thousands):

	December 31,		
	2006	2005	2004
Options to purchase common stock	2,049	575	509

Recent Accounting Pronouncements

In June 2006, the FASB issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement No. 109" ("FIN No. 48"). FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements in accordance with SFAS No. 109, "Accounting for Income Taxes." FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN No. 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact of the adoption of FIN No. 48 will have on its financial statements or related disclosures.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157"). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. The provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2007 and are to be applied prospectively. The Company is currently evaluating the impact, if any, of the adoption of SFAS No. 157 will have on its financial reporting.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 ("SAB 108") in order to eliminate the diversity of practice surrounding how public companies quantify financial statement misstatements. Traditionally, there have been two widely-recognized methods for quantifying the effects of financial statement misstatements: the "roll-over" method and the "iron curtain" method. The "roll-over" method focuses primarily on the impact of a misstatement on the income statement, including the reversing effect of prior period misstatements; but its use can lead to the accumulation of misstatements in the balance sheet. The "iron-curtain" method, on the other hand, focuses primarily on the effect of correcting the period-end balance sheet with less emphasis on the reversing effects of prior period errors on the income statement. The Company currently uses the "iron-curtain" method for quantifying identified financial statement misstatements. In SAB 108, the SEC staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the Company's financial statements and the related financial statement disclosures. This model is commonly referred to as a "dual approach" because it requires quantification of errors under both the "iron curtain" and the "roll-over" methods. SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the "dual approach" had always been used or (ii) recording the cumulative effect of initially applying the "dual approach" as adjustments to the carrying values of assets and liabilities as of the beginning of the current fiscal year with an offsetting adjustment to the opening balance of retained earnings in the year of adoption. Use of the "cumulative effect" transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The provisions of SAB 108 must be applied to annual financial statements no later than the first fiscal year ending after November 15, 2006. Upon adoption, there was no impact on the Company's financial statements or related disclosures.

3. BALANCE SHEET COMPONENTS

Inventories (in thousands):

	December 31,	
	2006	2005
Raw materials	$ 4,178	$ 4,331
Work-in-process	2,850	1,656
Finished goods	4,841	3,278
	$ 11,869	$ 9,265

Property and Equipment (in thousands):

	December 31,		Depreciation and Amortization
	2006	2005	Period
Furniture and fixtures	$ 3,734	$ 2,405	2 - 5 years
Computer software and hardware	10,843	8,194	3 years
Laboratory and manufacturing equipment	6,297	5,327	5 years
Leasehold improvements	10,274	6,366	7 - 10 years
	31,148	22,292	
Less: Accumulated depreciation and amortization	(12,168)	(8,871)	
Plus: Construction-in-progress	8,610	2,556	
	$ 27,590	$ 15,977	

Depreciation and amortization expense relating to the Company's property and equipment was approximately $5,824,000, $4,216,000 and $2,931,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

Goodwill and Intangible Assets:

Changes in the carrying amount of goodwill during the years ended December 31, 2005 and 2006 are as follows (in thousands):

Goodwill at January 1, 2005	$ 4,927
Foreign currency translation	(617)
Goodwill at December 31, 2005	4,310
Foreign currency translation	492
Goodwill at December 31, 2006	$ 4,802

The components of the Company's intangible assets are as follows (in thousands):

	December 31, 2006				
	Gross Carrying Amount	Foreign Currency Translation	Accumulated Amortization	Net	Amortization Period
Developed technology	$ 11,000	$ --	$ (1,100)	$ 9,900	10 years
Patent	142	30	(132)	40	5 years
Total intangibles	$ 11,142	$ 30	$ (1,232)	$ 9,940	

	December 31, 2005				
	Gross Carrying Amount	Foreign Currency Translation	Accumulated Amortization	Net	Amortization Period
Developed technology	$ 11,000	$ --	$ --	$ 11,000	10 years
Patent	142	13	(88)	67	5 years
Total intangibles	$ 11,142	$ 13	$ (88)	$ 11,067	

Amortization expense for the Company's intangible assets was approximately $1,161,000, $35,000 and $39,000 for the years ended December 31, 2006, 2005 and 2004, respectively. Based on the intangible assets held at December 31, 2006, and exchange rates in effect as of the balance sheet date, the Company expects to recognize amortization expense of approximately $1,134,000 in years 2007, approximately $1,106,000 in 2008, and approximately $1,100,000 annually from 2009 to 2015.

Other Assets (in thousands):

	December 31,	
	2006	2005
Disc-O-Tech nonrefundable deposit (Note 5)	$ 60,000	$ --
Other	9,846	2,924
	$ 69,846	$ 2,924

Accrued Liabilities (in thousands):

	December 31,	
	2006	2005
Payroll and related expenses	$ 27,576	$ 19,665
License acquisition	10,000	15,000
Accrued income taxes	4,912	6,213
Legal, accounting and professional fees	5,496	2,367
Clinical studies	1,608	1,165
Travel and entertainment	1,743	1,184
Professional training courses	299	206
Lease financing liability	4,992	--
Other	6,354	3,993
	$ 62,980	$ 49,793

Other Liabilities (in thousands):

	December 31,	
	2006	2005
Deferred rent	$ 5,149	$ 3,610
Deferred tax liabilities	982	--
Contingent purchase price	3,710	3,424
Other	638	441
	$ 10,479	$ 7,475

4. LICENSE ACQUISITIONS

In April 2005, the Company entered into an agreement to exclusively license, in the field of orthopaedics including all spinal applications, Dr. Lee Berger's ("Dr. Berger") portfolio of patents concerning medical devices and methods for creating voids in, or moving, tissue or bone, including platform cannulae for expandable bodies. The Company made an up-front payment of $1,000,000 in April 2005 and has agreed to provide a lifetime-capped royalty stream on any products that may be developed that practice the licensed patent rights. The $1,000,000 payment was immediately expensed as research and development costs, as the technology acquired may be used to develop products that have not been approved for sale by regulatory authorities, have not yet reached technological feasibility, and was determined to have no alternative future use. In conjunction with the license agreement, the Company entered into a consulting agreement with Dr. Berger for services pertaining to research and development in the area of spinal surgery. Under the terms of the consulting agreement Dr. Berger is paid $100,000 per year for a period of three years in exchange for these services. A small royalty is also now being paid to Dr. Berger on one of the Company's *KyphX* products.

In November 2005, the Company entered into an agreement with Dr. Harvinder Sandhu ("Dr. Sandhu"), an orthopaedic surgeon, to acquire an exclusive license to Dr. Sandhu's early invention rights concerning a directional bone tamp for treating vertebral compression fractures. Under the terms of the agreement, the Company made an up-front payment of $5,000,000 in November 2005, an additional payment of $5,000,000 in November 2006 and is obligated to make a series of payments totaling up to an additional $10,000,000. Based on management judgment, ability and intent, the remaining payment obligation of $10,000,000 has been classified as a current liability as of December 31, 2006. The $20,000,000 charge was immediately expensed to research and development as the technology acquired may be used to develop products that have not been approved for sale by regulatory authorities, have not yet reached technological feasibility, and was determined to have no alternative future use. The license

agreement also provides for a capped royalty stream on any future developed product that practices Dr. Sandhu's technology.

5. ACQUISITIONS

InnoSpine, Inc.

On December 30, 2005, the Company acquired all of the outstanding stock of InnoSpine, Inc. ("InnoSpine"), a privately held company focused on developing and marketing its proprietary technology platform for the diagnosis and potential treatment of axial low back pain due to disc degeneration. The transaction closed in January 2006, however, for accounting purposes the date of acquisition was determined to be December 30, 2005. The acquisition was made to allow the Company to expand its focus on Spinal Fracture Management and Repair to include disc repair and regeneration. The purchase consideration consisted of an initial purchase price of $2,500,000 in cash to the shareholders of InnoSpine and other acquisition costs of $350,000. In addition, the Company agreed to pay up to an additional $27,500,000 in cash or stock, based on achievement of clinical and other milestones as well as royalties on future net sales. These additional amount represents contingent consideration for accounting purposes and have not been included in the purchase price equation set out below. This amount will be recognized as additional purchase price consideration when such contingency has been resolved. To date, no contingent payments have been made.

The acquisition of InnoSpine was accounted for using the purchase method of accounting. The results of operations of InnoSpine have been included in the Company's consolidated financial statements effective December 30, 2005. The purchase price was allocated to the net tangible and identifiable intangible assets acquired and the liabilities assumed based on their estimated fair values at the date of acquisition as determined by management. Independent valuation experts assisted the Company during the valuation of the intangible assets acquired.

The fair value of the net assets acquired from InnoSpine exceeded the consideration paid by the Company resulting in negative goodwill. Because the acquisition involves contingent consideration, the Company is required to recognize additional purchase consideration equal to the lesser of the negative goodwill or the maximum amount of contingent consideration of $27,500,000. Accordingly, contingent consideration totaling $3,751,000 has been included in the Company's determination of the total purchase price, of which $3,710,000 has been classified as a non-current liability. The remaining balance of approximately $41,000 has been classified within accrued liabilities. The total purchase consideration was allocated as follows (in thousands):

Developed technology	$ 11,000
Deferred tax asset	235
Assumed liabilities	(267)
Contingent purchase price	(3,751)
Deferred tax liabilities	(4,367)
	$ 2,850

The income approach was used to value InnoSpine's developed technology, which included an analysis of the completion costs, cash flows, other required assets and risk associated with achieving such cash flows. The present value of these cash flows was calculated with an effective tax rate of 40% and a discount rate of 35% for the developed technology. No amount of goodwill, if any, is expected to be deductible for tax purposes.

Unaudited Pro Forma Financial Information

The following unaudited pro forma financial information is based on the respective historical financial statements of the Company and InnoSpine. The unaudited pro forma financial information reflects the consolidated results of operations as if the acquisition of InnoSpine had occurred at the beginning of each period and includes the amortization of the resulting other intangible assets. The unaudited pro forma financial data presented are not necessarily indicative of the Company's results of operations that might have occurred had the transactions been completed at the beginning of each period, and do not purport to represent what the Company's consolidated results of operations might be for any future period (in thousands, except per share amounts).

	Year Ended December 31,	
	2005	2004
	(unaudited)	
Pro forma net sales	$ 306,082	$ 213,414
Pro forma net income	$ 29,653	$ 21,552
Pro forma net income per share:		
Basic	$ 0.69	$ 0.53
Diluted	$ 0.65	$ 0.49
Weighted-average shares outstanding:		
Basic	42,803	40,449
Diluted	45,336	43,670

St. Francis Medical Technologies, Inc.

On January 18, 2007, the Company acquired all of the fully diluted equity of St. Francis Medical Technologies, Inc. ("St. Francis"), a privately held, California-based company that manufactures the *X-STOP* Interspinous Process Decompression (*IPD*) System, a FDA-approved interspinous process device for treating lumbar spinal stenosis (LSS). The total estimated purchase price, excluding transaction costs, of up to $725,000,000 was comprised of $525,000,000 in cash upon closing, plus additional revenue-based contingent payments of up to $200,000,000 payable in either cash or a combination of cash and stock, at the Company's election. The payments are contingent upon the attainment of certain revenue thresholds during specified periods through June 2008. This additional amount represents contingent consideration for accounting purposes and has not been included in the purchase price equation set out below. This amount will be recognized as additional purchase price consideration when such contingency has been resolved. The Company financed the transaction through a combination of cash on hand and bank financing (see Note 6).

The total estimated initial purchase price of St. Francis is as follows (in thousands):

Cash	$ 108,657
Debt issued (net of issuance costs)	416,343
Estimated direct transaction costs	6,000
	$ 531,000

Disc-O-Tech Medical Technologies, Ltd.

On December 20, 2006, the Company entered into two definitive agreements to acquire all of the spine-related product assets and associated intellectual property rights of Disc-O-Tech Medical Technologies, Ltd. and its U.S. subsidiary ("Disc-O-Tech") in a transaction to be accounted for using the purchase method of accounting. Completion of the first agreement, if and when that occurs, will enable the Company to further broaden its focus in minimally invasive spine by adding the *B-Twin*™ Expandable Spinal System technology for minimally invasive fusion in patients with degenerative disc disease in the lumbar and cervical spine, which is CE marked but not presently available in the U.S. The first agreement assets also include Disc-O-Tech's SKy™ Bone Expander System, which is available only outside the U.S. for use in the treatment of vertebral compression fractures. The second agreement assets include Disc-O-Tech's Confidence™ Cement System, which will be another treatment option complementary to the Company's existing *KyphX* technology for vertebral compression fractures depending on a patient's individual needs and a clinician's goals for his or her patients. The Confidence System incorporates a delivery mechanism that is designed to provide controlled injection of putty-like cement, reduce clinician radiation exposure and streamline cement preparation. The Company's ability to offer such additional minimally invasive diagnostic and therapeutic tools to their customers is a natural next-step in broadening our product offerings.

The aggregate estimated purchase price for both agreements, excluding transaction costs, is approximately $220,000,000, plus a contingent payment of up to $20,000,000 payable in cash. Upon the signing of the first agreement on December 20, 2006 the Company made a nonrefundable payment of $60,000,000 to Disc-O-Tech, comprised of $20,000,000 in cash and the release of $40,000,000 that was held in escrow. As of December 31, 2006, pending closing of the acquisition this payment of $60,000,000 is presented as a nonrefundable deposit on the

accompanying balance sheet. On February 1, 2007, the Company made a nonrefundable payment of an additional $40,000,000 to Disc-O-Tech. Under the second of the agreements, the Company will make nonrefundable payments to Disc-O-Tech for aggregate amount of $120,000,000 in cash on a deferred basis, payable in three equal annual installments beginning in January 2008. An additional $20,000,000 in contingent payments, plus royalties, may also be paid based on the development of further technologies following closing of the second agreement. This additional $20,000,000 represents contingent consideration for accounting purposes. This amount will be recognized as additional purchase price consideration when its payment is finalized. Closing of the acquisitions are subject to various conditions, including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, or HSR Act, however, there can be no assurance that the Federal Trade Commission will not block the Company's purchase of all or any of the assets under either purchase agreement, or that they will otherwise complete all or part of the acquisitions. The Federal Trade Commission has issued second requests for information with respect to its review of the Company's acquisition of the non-vertebroplasty assets and the acquisition of the vertebroplasty assets. The purchase price under both agreements is payable even if regulatory approvals are delayed or not obtained. The Company will complete the closing of the acquisitions as soon as practicable after receipt of regulatory approvals. If regulatory approvals are not obtained, the Company may divest or license to third parties some or all of the assets proposed to be acquired.

6. BORROWINGS

Credit Facility

In October 2006, the Company entered into a syndicated credit facility which provided the Company with a five-year $300,000,000 revolving line of credit, including a $50,000,000 sublimit for the issuance of standby letters of credit, a $25,000,000 sublimit for swing line loans and a $100,000,000 sublimit for multicurrency borrowings. On January 18, 2007, the Company amended the credit facility and, in conjunction with the acquisition of St. Francis, the Company, together with certain of its subsidiaries, entered into a Credit Agreement to replace and refinance the above-described credit facility (the "Credit Agreement") with Bank of America, N.A., as administrative agent, swing line lender and letter of credit issuer, and Banc of America Securities LLC as sole lead arranger and sole book manager. The credit facilities thereunder were syndicated to a group of lenders (collectively, the "Lenders").

The Credit Agreement provides for a $250,000,000 senior secured revolving credit facility (the "Revolving Credit Facility"), maturing October 20, 2011, which can be expanded to $300,000,000 under certain circumstances. The Revolving Credit Facility includes a $50,000,000 sublimit for the issuance of standby U.S. dollar letters of credit, a $25,000,000 sublimit for U.S. dollar swingline loans and a $100,000,000 sublimit for multicurrency borrowings. The Credit Agreement also provides for a $425,000,000 term loan facility maturing seven years from the closing date (the "Term Loan Facility" and together with the Revolving Credit Facility, the "Facility"). The Company may terminate or permanently reduce the commitments available under the Revolving Credit Facility and prepay the Term Loan Facility without premium or penalty at any time.

The Facility was used by the Company to finance the acquisition of St. Francis, (the "Acquisition") and may be used for general corporate purposes including acquisitions, capital expenditures, working capital and other purposes. In addition to certain initial fees, the Company is obligated to pay a commitment fee based on the total revolving commitment. In January 2007, in connection with the Acquisition, the Company borrowed $425,000,000 under this Facility.

The Revolving Credit Facility will bear interest at Base Rate plus 0.25-1.25% or LIBOR plus 1.25-2.25% (such range of margins being related to the consolidated leverage ratio of the Company). Letter of credit fees are based on the LIBOR loan margins.

The Company's obligations under the Facility are secured by substantially all of the assets of the Company.

The Credit Agreement contains customary affirmative covenants regarding the Company and its subsidiaries. Upon the occurrence of an event of default under the Credit Agreement, the Lenders could elect to declare all amounts outstanding under the Facility to be immediately due and payable. Events of default under the Credit Agreement include payment defaults, breaches of covenants and bankruptcy events.

The Credit Agreement contains negative covenants which restrict the Company from: (i) incurring liens other than liens incurred pursuant to the Facility and other customary permitted liens; (ii) making investments, other than customary permitted investments and investments subject to certain baskets; (iii) incurring debt other than indebtedness pursuant to the Credit Agreement, subordinated indebtedness, an unsecured convertible note offering, customary permitted indebtedness and indebtedness subject to certain baskets; (iv) entering into mergers and

consolidations other than the Acquisition, acquisitions paid 100% with equity of the Company or acquisitions not exceeding a certain purchase price, where such limitation on price is based on the consolidated senior secured leverage ratio and other limitations; (v) selling assets, subject to certain customary exceptions; (vi) issuing dividends, stock redemptions and other restricted payments; (vii) incurring capital expenditures exceeding a certain threshold; (viii) transactions with affiliates; (ix) the cash payment of the cash/stock earnout obligations of the Company incurred in connection with the Acquisition, where such payments are subject to certain limitations; (x) permitting the consolidated interest coverage ratio to fall below a certain threshold and the consolidated leverage ratio and the consolidated senior secured leverage ratio to be greater than a certain threshold; (xi) prepaying subordinated indebtedness, other than prepayments pursuant to a refinancing permitted thereunder or if certain requirements are satisfied and (xi) other customary negative covenants for a facility of this nature.

Convertible Notes

In February 2007, the Company issued $200,000,000 aggregate principal amount of Convertible Senior Notes due 2012 and $200,000,000 aggregate principal amount of Convertible Senior Notes due 2014. Interest on the notes due 2012 will be paid semiannually at a rate of 1.00% per year and interest on the notes due 2014 will be paid semiannually at a rate of 1.25% per year. Both the 2012 Notes and the 2014 Convertible Senior Notes will be convertible into cash up to the principal amount, and if applicable, shares of common stock in respect of any conversion value above the principal amount, based on an initial conversion rate of 17.1951 shares of common stock per $1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately $58.16 per share. The notes may be converted by the holders only under the following circumstances: (1) during any fiscal quarter beginning after June 30, 2007 (and only during such fiscal quarter), if the last reported sale price of the Company's common stock for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the immediately preceding fiscal quarter is greater than or equal to 130% of the applicable conversion price; (2) during the five business-day period after any five consecutive trading-day period (the "Measurement Period") in which the trading price per $1,000 principal amount of note for each day of such Measurement Period was less than 98% of the product of the last reported sale price of the Common Stock and the conversion rate on each such day; (3) upon the occurrence of certain specified corporate transactions; and (4) with respect to the 2012 Notes, at any time on or after December 1, 2011, and with respect to the 2014 Notes, at any time on or after December 1, 2013, in each case through the third business day preceding the applicable maturity date.

The conversion rate will be subject to adjustment in some events but will not be adjusted for accrued interest. Upon conversion, the Company will pay cash and shares of common stock, if any, based on a daily conversion value calculated during a 30 trading-day observation period.

The Senior Convertible Notes rank equal in right of payment to all of the Company's other existing and future senior unsecured indebtedness. The Senior Convertible Notes will rank senior in right of payment to all of the Company's existing and future subordinated indebtedness and effectively subordinated in right of payment to all of its subsidiaries' obligations (including secured and unsecured obligations) and subordinated in right of payment to its secured obligations to the extent of the assets securing such obligation.

In connection with the offering, the Company entered into convertible note hedge transactions with affiliates of the initial purchasers. These transactions are intended to reduce the potential dilution to the Company's stockholders upon any future conversion of the notes. The call options, which cost an aggregate $112,000,000 were recorded as a reduction of additional paid-in capital, net of tax benefit. The Company also entered into warrant transactions concurrently with the offering, pursuant to which it sold warrants to purchase its own common stock to the same counterparties that entered into the convertible note hedge transactions. The convertible note hedge and warrant transactions effectively will increase the conversion price of the convertible notes to approximately $75.04 per share of the Company's common stock. Proceeds received from the issuance of the warrants totaled approximately $77,000,000 and were recorded as an addition to additional paid-in capital.

On February 6, 2007, the Company used the remaining proceeds, of approximately $355,000,000, together with borrowings under the Revolving Credit Facility, to retire the $425,000,000 senior secured term loan incurred to complete the acquisition of St. Francis.

7. COMMITMENTS AND CONTINGENCIES

Operating leases

The Company has operations headquartered in Sunnyvale, California. These facilities are leased through August

2014. Under the terms of the lease agreement, the Company has the option to have additional square footage built in the same surrounding campus. Under the terms of the facility lease, the Company is obliged to maintain an irrevocable standby letter of credit of $1,105,000.

The Company's European operations are headquartered in Brussels, Belgium. The facility is leased through December 2011 and includes offices, storage and warehouse facilities. An additional facility is leased in Rosbach, Germany through January 2008 and the Company has leased sales offices in many of the major countries in Europe as well as Japan, South Africa and Canada, with expiration dates through 2013. In November 2005, the Company entered into a two year lease for a facility in Neuchâtel, Switzerland that includes offices, storage and warehouse facilities and will serve as a temporary facility for the Company while it builds a larger facility to support manufacturing, distribution, administrative and certain research and development activities.

The Company records rent expense on a straight-line basis. As of December 31, 2006 and 2005, deferred rent of approximately $5,531,000 and $3,814,000, respectively, had been recorded. Through December 31, 2006, the Company has received cash incentives of $1,194,000 from its landlord to be used for leasehold improvements. These amounts have been reflected as deferred rent and property and equipment and are being amortized to rent expense and depreciation expense, respectively, over the term of the Company's operating lease. The Company recognized rent expense of $3,355,000, $2,423,000 and $2,658,000 during the years ended December 31, 2006, 2005 and 2004, respectively.

The Company's aggregate future minimum facility lease payments are as follows (in thousands):

Fiscal year ending December 31,		
2007	$	3,567
2008		3,077
2009		3,038
2010		3,058
2011		2,980
Thereafter through 2014		6,627
Total	$	22,347

Assets Under Construction

In May 2006, the Company entered into a real estate leasing contract with Credit Suisse (the "lease agreement") for a facility in Neuchâtel, Switzerland. The lease agreement became effective in July 2006 upon Credit Suisse's purchase of the land. The lease agreement has a term of 15 years with a fixed purchase option at expiration. The total commitment under the lease agreement is estimated at CHF 23,000,000 (approximately $18,857,000 in U.S. dollars per the exchange rate as of December 31, 2006), which includes the purchase of land and construction of the facility. In connection with the lease agreement, the Company entered into a guaranty with Credit Suisse in the amount of CHF 11,000,000 (approximately $9,019,000) with respect to its subsidiaries' obligations under the lease agreement and has issued a CHF 4,500,000 (approximately $3,689,000) letter of credit to Credit Suisse pursuant to the terms and conditions of the leasing contract.

Since the Company has substantially all of the construction period risk, the Company is accounting for the transaction as if it were the owner during the construction period. Accordingly, subsequent to commencement of the construction, in July 2006, the Company has capitalized construction costs as construction-in-progress. As of December 31, 2006, the Company has recorded an asset of approximately $5,038,000 for construction-in-process and a corresponding liability of $4,992,000 for construction debt.

Royalty Agreements

The Company has license agreements with third parties. The agreements provide for payment of royalties based upon a specified percentage of future net sales on any products that practice the licensed rights (see Notes 4 & 5).

Consulting Agreements

The Company has entered into various consulting agreements which expire through 2008. Under the terms of the consulting agreements, the Company will be obligated to make payments of approximately $944,000 and $712,000 in the years ending December 31, 2007 and 2008, respectively.

Indemnification Agreements

In the normal course of business, the Company may enter into contractual arrangements under which the Company may agree to indemnify the third party to such arrangement from any losses incurred relating to the services they perform on behalf of the Company or for losses arising from certain events as defined within the particular contract. To date, the Company has not incurred any costs as a result of such indemnifications and has not accrued any liabilities related to such obligations in the accompanying consolidated financial statements.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of a culpable nature; to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified; and to make good faith determinations as to whether or not it is practicable for the Company to obtain directors' and officers' insurance. The Company currently has directors' and officers' insurance.

Litigation

In November 2005, Dr. Harvinder Sandhu, an orthopaedic surgeon, and the Company filed suit in federal district court in Memphis, Tennessee against Medtronic Sofamor Danek ("MSD") and several other related corporate entities seeking compensatory and punitive damages and injunctive relief for breach of contract and related covenants, trade secret theft, fraud, and correction of inventorship of several patents and patent applications presently owned by MSD, including U.S. Patent No. 6,676,665. The suit also requests, among other relief, that MSD transfer to Dr. Sandhu ownership of the disputed patents and patent applications. The dispute concerns inventions related to an expandable, mechanical bone tamp for use in treating vertebral compression fractures that Dr. Sandhu invented in the late 1990's and which he confidentially disclosed and discussed with MSD. The complaint alleges that MSD later filed for several patents encompassing and claiming Dr. Sandhu's inventions without naming him as inventor of that technology, and that it also incorporated Dr. Sandhu's inventions into its internal *Equestra/Arcuate* project without his permission. In May 2006, the Company also sued MSD in the same Tennessee court for willfully infringing five of the Company's U.S. patents (numbers 4,969,888, 5,108,404, 6,235,043, 6,440,138, and 6,863,672) with its *Equestra/Arcuate* product. Discovery is underway, and various motions are pending that seek to address the merits of Dr. Sandhu's and Kyphon's claims. Trial was initially set for April 2007, but may be delayed. No provision for any liability that may result upon resolution of this matter has been made in the accompanying financial statements.

During 2005, a U.S. Attorney's Office ("USAO") received a complaint that the Company believes to be a *qui tam* complaint that alleges impropriety in its business, including regarding its reimbursement practices. Although no subpoena has been issued to the Company in connection with this complaint, the USAO is investigating the Company's sales and marketing practices, including how they communicated with their customers in the past regarding the Medicare reimbursement available to hospitals and the appropriate site-of-service for using their products in surgery. The USAO has asked to review some of the Company's documentation that may be relevant to the investigation, much of which the Company has already produced. The Company believes it is in substantial compliance with the healthcare laws applicable to them. Even though the Company has not received a subpoena regarding the complaint or its allegations, it continues to voluntarily cooperate with the USAO, to permit the USAO to develop an informed opinion on whether or not to pursue any action in connection with the complaint based in part on the information provided, although timing on that decision is uncertain. At this time, the Company does not know whether the investigation or its outcome will have a material adverse impact to its business, and cannot be assured regarding any future path the USAO or any related lawsuit may take. Due to the uncertainties inherent in this process, the Company cannot accurately predict the ultimate outcome of this matter at this time and, therefore, cannot estimate the range of possible loss. Accordingly, no provision for any liability that may result upon resolution of this matter has been made in the accompanying financial statements.

In April 2006, Medtronic and several related entities (MSD) filed suit against the Company in federal district court in the Northern District of California, alleging that the Company's *KyphX* vertebral bone tamps and/or related products infringe three angioplasty balloon dilatation catheter patents (numbers 4,820,349, 5,759,191 and 6,179,856) and a single claim of patent number 6,096,038, which generally concerns treatment of the disc space. MSD has since dropped the '038 patent from the suit and asserted another dilatation catheter patent, number 5,759,173. The suit seeks damages based upon the making, using, selling and offering for sale of the Company's products, seeks enhanced damages for alleged willful infringement, and seeks to enjoin their continued activities relating to these products. In October 2006, the Company was denied permission to seek a declaratory judgment that another MSD patent generally concerned with treatment of the disc space and related to the `038 patent, number 7,115,128, also has no application to

the kyphoplasty technology. Although the Company intend to vigorously defend MSD's California lawsuit, MSD's action against it subjects the Company to potential liability for damages, including treble damages, and could require the Company to cease making, using or selling the affected products, or to obtain a license in order to continue to manufacture, use or sell the affected products. While the Company believes it has multiple meritorious defenses to this action, the Company cannot assure that it ultimately will prevail on any issue in the litigation or that it will be able to successfully defend MSD's charges, nor can the Company provide assurance that any license required would be made available on commercially acceptable terms, if at all. Failure to successfully defend against MSD's action could harm the Company's business, financial condition and operating results. Due to the inherent uncertainties of litigation, the Company cannot accurately predict the ultimate outcome of this matter at this time and, therefore, cannot estimate the range of possible loss. No provision for any liability that may result upon resolution of this matter has been made in the accompanying financial statements.

In June 2006, six of the Company's current and former female U.S.-based sales employees filed a lawsuit against the Company in federal district court in the Northern District of California. They allege, among other things, that the Company has engaged in gender and pregnancy discrimination against them, and also contend that they and their lawyers should be permitted to represent an alleged class of all of our present and many former female Spine Education Specialists, Spine Associates and Spine Consultants because all of those women were also allegedly discriminated against on account of their gender and pregnancy status. The plaintiffs claim that they are due assorted damages of at least $100,000,000. The case is in its early stages; no trial date has been set. Although the Company intends to vigorously defend plaintiffs' lawsuit, this lawsuit threatens its reputation and subjects the Company to potential liability for significant damages. While the Company believes it has multiple meritorious defenses to this action, it cannot assure you that it ultimately will prevail on any issue in the litigation or that the Company will be able to successfully defend plaintiffs' charges. Failure to successfully defend against this action could harm the Company's business, financial condition and operating results. Due to the inherent uncertainties of litigation, the Company cannot accurately predict the ultimate outcome of this matter at this time and, therefore, cannot estimate the range of possible loss. No provision for any liability that may result upon resolution of this matter has been made in the accompanying financial statements.

From time to time, the Company may become involved in litigation relating to additional claims arising from the ordinary course of business. Management of the Company does not believe the final disposition of these matters will have a material adverse affect on the financial position, results of operations or cash flows of the Company.

8. STOCKHOLDERS' EQUITY

Preferred Stock

In April 2002, the Board of Directors approved an amendment to the Company's certificate of incorporation to authorize 5,000,000 shares of undesignated preferred stock. The Company's Board of Directors is authorized to determine the designation, powers, preferences and rights of preferred stock.

Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding. No dividends have been declared or paid as of December 31, 2006.

Employee Stock Purchase Plan

During 2006, the Company had an Employee Stock Purchase Plan (the "2002 ESPP"), under which eligible employees were permitted to purchase common stock at a discount through payroll deductions. The 2002 ESPP contained consecutive, overlapping twenty-four month offering periods. Each offering period included four six-month purchase periods. The price of the common stock purchased was the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The Company issued approximately 251,000, 314,000 and 338,000 shares of common stock in 2006, 2005, and 2004, respectively, under the 2002 ESPP. As of December 31, 2006, approximately 718,000 shares of common stock remained reserved for future issuance under the 2002 ESPP.

In June 2006, the Company's stockholders approved the termination of the 2002 ESPP, effective after the February 1, 2007 purchase, and the adoption of the 2007 Employee Stock Purchase Plan (the "2007 ESPP"). The 2007 ESPP took

effect after the final purchase date under the 2002 ESPP of February 1, 2007, at which time the 2002 ESPP automatically terminated. The 2007 ESPP reduces the "look-back" period available under any offering, by eliminating the 24-month "look-back" period presently available under the 2002 ESPP and replacing it with a six-month "look-back" period. The price of the common stock purchased shall be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The maximum number of shares authorized for sale under the 2007 ESPP is 1,000,000. The Board of Directors may amend, suspend or terminate the 2007 ESPP at any time. The Company determined that the cancellation of the 2002 ESPP effectively occurred in June 2006 at the time of stockholder approval. As the cancellation of purchase periods subsequent to February 1, 2007 were not accompanied by a concurrent replacement grant, unrecognized compensation cost of $562,000 was recognized immediately in June 2006 for the cancelled awards.

Stock Plans

The Company reserved shares of common stock for issuance under the 1996 Stock Incentive Plan (the "1996 Plan"). Under the 1996 Plan, the Board of Directors was authorized to issue incentive stock options to employees and nonqualified stock options to consultants or employees of the Company. The 1996 Plan is inactive, and no shares have been granted under the 1996 Plan since 2002. Upon adoption of the 2002 Stock Plan, all shares previously available for grant under the 1996 Plan were transferred to the 2002 Stock Plan. Any cancellations thereafter from the 1996 Plan are automatically added back to the 2002 Plan.

In April 2002, the Board of Directors adopted the 2002 Stock Plan. The 2002 Stock Plan, which will terminate no later than 2012, provides for the granting of incentive stock options to employees and nonqualified stock options and stock purchase rights to employees, directors and consultants.

In April 2002, the Board of Directors adopted the 2002 Director Option Plan. The 2002 Director Option Plan, which will terminate no later than 2012, provides for the granting of nonqualified stock options to non-employee directors. At December 31, 2006, 90,000 shares of common stock remained reserved for future issuance under the 2002 Director Option Plan.

For the 2002 Director Option Plan and the 2002 Stock Plan, the Board of Directors has the authority to determine to whom options will be granted, the number of shares, the term and exercise price (which cannot be less than the estimated fair market value at date of grant for incentive stock options or 85% of the estimated fair market value for nonqualified stock options). If an employee owns stock representing more than 10% of the outstanding shares, the exercise price of any incentive stock option shall be at least 110% of estimated fair market value, as determined by the Board of Directors. The options are exercisable at times and increments as specified by the Board of Directors, and generally expire ten years from date of grant.

Activities under the 2002 Director Option Plan, the 2002 Stock Plan and the 1996 Plan, the ("Plans") are as follows:

	Shares Available for Grant	Options Outstanding: Number of Shares	Options Outstanding: Weighted Average Exercise Price
Balances, January 1, 2004	2,665,697	6,606,738	$ 7.96
Additional shares reserved	1,971,987	--	--
Options granted	(3,044,300)	3,044,300	24.29
Options exercised	--	(1,541,544)	4.13
Options cancelled	475,897	(475,897)	18.43
Balances, December 31, 2004	2,069,281	7,633,597	14.59
Additional shares reserved	2,123,774	--	--
Options granted	(2,042,800)	2,042,800	34.03
Options exercised	--	(2,173,882)	8.10
Options cancelled	424,103	(424,103)	21.72
Balances, December 31, 2005	2,574,358	7,078,412	21.78
Options granted	(1,883,275)	1,883,275	38.26
Options exercised	--	(875,248)	15.82
Options cancelled	423,578	(423,578)	29.89
Balances, December 31, 2006	1,114,661	7,662,861	$ 26.06

The options outstanding and exercisable at December 31, 2006 are as follows:

	Options Outstanding				Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
$0.05 - $3.00	566,852	3.86	$ 1.07	$ 22,292	566,852	$ 1.07	22,292
$6.95 - $10.43	270,180	6.09	8.52	8,613	210,885	8.42	6,745
$10.50 - $15.40	1,024,214	5.95	13.45	27,601	968,762	13.34	26,215
$19.40 - $27.66	2,737,552	7.51	24.02	44,838	1,496,103	23.79	24,857
$27.90 - $40.39	2,560,563	9.16	37.57	7,234	427,836	36.84	1,524
$40.50 - $45.34	503,500	8.85	41.74	--	114,630	41.50	--
	7,662,861	7.62	$ 26.06	$ 110,578	3,785,068	$ 18.87	81,633

The aggregate intrinsic value in the table above represents the total pretax intrinsic value, based on options with an exercise price less than the Company's closing stock price of $40.40 per share as of December 31, 2006, which would have been received by the option holders had those option holders exercised their options as of that date. The total number of in-the-money options exercisable as of December 31, 2006 was approximately 3,670,000. As of December 31, 2005, there were approximately 2,739,000 outstanding options exercisable, and the weighted-average exercise price was $14.40 per share.

The total intrinsic value of options exercised during the year ended December 31, 2006 was approximately $20,528,000. The total cash received from employees as a result of employee stock option exercises during the year ended December 31, 2006 was approximately $13,850,000. In connection with these exercises, the tax benefits realized by the Company for the year ended December 31, 2006 was approximately $6,798,000. For the year ended December 31, 2006, the Company recorded $7,557,000 of deferred tax assets associated with nonqualified stock options as a result of the adoption of SFAS No. 123(R).

The Company settles employee stock option exercises with newly issued common shares.

9. EMPLOYEE BENEFIT PLAN

The Company maintains a Section 401(k) Plan. The 401(k) Plan provides participating employees with an

opportunity to accumulate funds for retirement and hardship. Eligible participants may contribute up to 100% of their eligible earnings to the Plan Trust. Beginning in December 2006, eligible participants may contribute up to 50% of their eligible earnings to the Plan Trust. The Company started matching employees' contributions to the plan on March 15, 2003 at 25% of employee's individual 401(k) contributions up to a maximum matching contribution of $2,000 per calendar year. Beginning in January 2005, the Company match was adjusted to 50% of an employee's individual 401(K) contributions up to a maximum matching contribution of $2,000 per calendar year. Beginning in January 2006, the Company match was changed to 50% of the first 5% of compensation deferred to the 401(k) plan. In addition, if any employee receives less than a $2,000 match under the new formula, the Company will true-up the 401(k) matching contribution at year-end to 50% of an employee's 401(k) contributions up to a $2,000 matching contribution per calendar year. The Company's matching contributions totaled $1,858,000, $1,084,000 and $620,000 in 2006, 2005 and 2004, respectively.

10. INCOME TAXES

U.S. and international components of income before the provision for income taxes and the components of the provision for income taxes consisted of the following (in thousands):

	Year Ended December 31,		
	2006	**2005**	**2004**
U.S.	$ 72,448	$ 49,414	$ 35,153
International	(1,726)	(1,298)	464
Total income before income taxes	$ 70,722	$ 48,116	$ 35,617
Current			
Federal	$ 30,405	$ 15,576	$ 7,892
State	4,895	4,399	1,285
Foreign	1,446	595	216
Total current	36,746	20,570	9,393
Deferred			
Federal	(4,634)	(731)	4,286
State	45	(1,569)	433
Foreign	(1,167)	10	(212)
Total deferred	(5,756)	(2,290)	4,507
Total provision for income taxes	$ 30,990	$ 18,280	$ 13,900

At December 31, 2006, we had utilized all federal and state net operating loss carryforwards and federal research and development tax credit carryforwards.

At December 31, 2006, we had research and development tax credit carryforwards of approximately $2,784,000 for state income tax purposes. The state research and development tax credit can be carried forward indefinitely.

Temporary differences and carryforwards that give rise to the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2006	2005
Net operating loss carryforwards	$ --	$ 441
Research and development credit carryforwards	1,809	4,675
Capitalized research and development costs	321	397
Purchased research and development	11,007	11,122
Stock-based compensation	7,970	--
Intangibles	(3,910)	(4,367)
Foreign currency transaction gains	(131)	--
Other, accruals and reserves	3,961	4,969
Net deferred tax assets	21,027	17,237
Foreign currency transaction gains	(982)	--
Total	$ 20,045	$ 17,237

Deferred tax assets relating to tax benefits of employee stock option grants have been reduced to reflect the exercises in the year ended December 31, 2006. Certain exercises resulted in tax deductions in excess of previously recorded benefits based on the option value at the time of grant ("windfalls"). When the tax benefit reduces taxes payable, the Company will credit equity. At December 31, 2006, the Company recorded a credit to equity of $6,338,000.

Management periodically evaluates the recoverability of the deferred tax assets and recognizes the tax benefit only as reassessment demonstrates that they are more likely than not realizable. At December 31, 2006, and 2005, the Company did not provide a valuation allowance against its deferred tax assets because it believes it is more likely than not that all deferred tax assets will be realized in the foreseeable future.

The income tax provision differed from the provision computed at the U.S. statutory tax rate as follows:

	Year Ended December 31,		
	2006	2005	2004
Federal statutory rate	35.0 %	35.0 %	35.0 %
State, net of federal benefit	4.5	4.7	4.7
Tax reserves	0.5	0.4	(0.2)
Stock-based compensation and other permanent difference	5.8	1.4	4.0
Research and development tax credits	(2.0)	(3.5)	(4.5)
Total provision for income taxes	43.8 %	38.0 %	39.0 %

11. OPERATING SEGMENT AND GEOGRAPHIC INFORMATION

The Company operates in one segment, using one measurement of profitability to manage its business. Geographic area net sales and long-lived assets are summarized as follows:

	Net Sales			Long-Lived Assets		
	Year Ended December 31,			December 31,		
	2006	2005	2004	2006	2005	2004
United States	79 %	84 %	88 %	69 %	78 %	83 %
Germany	12	9	6	1	1	1
Switzerland	--	--	--	20	--	--
Other	9	7	6	10	21	16
	100 %	100 %	100 %	100 %	100 %	100 %

Net sales are attributed to countries based on the shipping location of the external customers. Long-lived assets are comprised of property and equipment, net.

12. QUARTERLY FINANCIAL DATA (UNAUDITED)

The following tables contain selected unaudited Consolidated Income Statement data for each quarter of 2006 and 2005 (in thousands, except per share amounts):

	Year 2006 Quarter Ended			
	Mar. 31,	Jun. 30,	Sep. 30,	Dec. 31,
Net sales	$ 91,428	$ 101,062	$ 102,678	$ 112,622
Gross profit	80,463	87,874	89,357	97,920
Net income	$ 8,493	$ 9,480	$ 9,531	$ 12,228
Net income per share:				
Basic	$ 0.19	$ 0.21	$ 0.21	$ 0.27
Diluted	$ 0.19	$ 0.21	$ 0.21	$ 0.26
Weighted-average shares outstanding:				
Basic	44,032	44,327	44,572	44,806
Diluted	45,882	46,221	46,305	46,680

	Year 2005 Quarter Ended			
	Mar. 31,	Jun. 30,	Sep. 30,	Dec. 31,
Net sales	$ 66,234	$ 75,026	$ 79,014	$ 85,808
Gross profit	58,309	66,532	69,558	75,840
Net income	$ 6,421	$ 7,936 (1)	$ 11,754	$ 3,725 (2)
Net income per share:				
Basic	$ 0.15	$ 0.19	$ 0.27	$ 0.09
Diluted	$ 0.15	$ 0.18	$ 0.26	$ 0.08
Weighted-average shares outstanding:				
Basic	41,843	42,512	43,195	43,637
Diluted	44,231	44,660	45,898	46,130

Note 1: Net income includes license agreement fees of $1,000,000.

Note 2: Net income includes license acquisition charges of $20,000,000.

KYPHON INC.
SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS
FOR THE YEARS ENDED DECEMBER 31, 2004, 2005 AND 2006
(in thousands)

Description	Balance at Beginning of Year	Charged to Costs and Expenses	Deductions	Balance at End of Year
Allowances for accounts receivable				
Fiscal year ended 2004	$ 500	737	183	$ 1,054
Fiscal year ended 2005	1,054	1,366	843	1,577
Fiscal year ended 2006	$ 1,577	714	427	$ 1,864
Allowance for inventories valuation:				
Fiscal year ended 2004	$ 625	158	254	$ 529
Fiscal year ended 2005	529	757	295	991
Fiscal year ended 2006	$ 991	2,136	2,266	$ 861

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Evaluation of disclosure controls and procedures. Our Chief Executive Officer, Richard W. Mott, and Chief Financial Officer, Maureen L. Lamb, evaluated the effectiveness of Kyphon's disclosure controls and procedures as of the end of the period covered by this report, and concluded that Kyphon's disclosure controls and procedures were effective to ensure that information Kyphon is required to disclose in the reports that we file or submit with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended (or the Exchange Act) is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms, and to ensure that information required to be disclosed by Kyphon in the reports that we file or submit under the Exchange Act is accumulated and communicated to Kyphon's management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Internal Control Over Financial Reporting

Management's annual report on internal control over financial reporting. Management's report on Kyphon's internal control over financial reporting is included on page 75 of Item 8 of this Annual Report on Form 10-K, and the attestation report of our independent registered public accounting firm on page 77 of Item 8 of the this Annual Report on Form 10-K is incorporated by reference to Item 8 of this Annual Report on Form 10-K.

Changes in internal control over financial reporting. During the quarter ended December 31, 2006, there were no changes in Kyphon's internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, Kyphon's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS; EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2007 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2006 fiscal year (the "2007 Proxy Statement").

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the 2007 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference to the 2007 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference to the 2007 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the 2007 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) The financial statements required by Item 15(a) are filed as Item 8 of this annual report.

(2) The financial statement schedules required by Item 15(a) are filed as Item 8 of this annual report.

(3) Exhibits

Number		Description
3.1	(1)	Amended and Restated Certificate of Incorporation of the registrant.
3.2	(2)	Amended and Restated Bylaws of the registrant.
4.1	(3)	Specimen common stock certificate of the registrant.
4.2	(4)	Indenture, dated as of February 6, 2007, between Kyphon Inc. and U.S. Bank National Association as trustee (including form of 1.00% Convertible Senior Note due 2012 and form of 1.25% Convertible Senior Note due 2014).
4.3	(4)	Registration Rights Agreement, dated as of February 6, 2007, among Kyphon Inc. and J.P. Morgan Securities Inc., Goldman, Sachs & Co. and Banc of America Securities LLC, for themselves and the other Initial Purchasers.
10.1*	(3)	Form of Indemnification Agreement for directors and executive officers.
10.2*	(3)	1996 Stock Option Plan, including form of option agreement.
10.3*	(3)	2002 Stock Plan, including form of option agreement.
10.4*		2002 Stock Plan form of stock purchase right grant notice and restricted stock purchase agreement.
10.5*	(1)	2002 Director Option Plan, including form of option agreement.
10.6*	(13)	2007 Employee Stock Purchase Plan, including form of employee stock purchase plan subscription agreement.
10.7	(3)	Lease dated January 27, 2000 for office space located at 1350 Bordeaux Drive, Sunnyvale, CA 94089 and Second Amendment to Lease dated November 29, 2001.
10.8	(3)	Third Amendment to Lease dated March 29, 2002 for office space located at 1350 Bordeaux Drive, Sunnyvale, CA 94089.
10.9*	(3)	Employment Agreement between the registrant and Gary L. Grenter dated July 16, 2001.
10.10	(3)	Promissory Note Secured by Deed of Trust between the registrant and Gary L. Grenter dated December 31, 2001.
10.11	(3)	Amended and Restated Stockholder Rights Agreement effective as of December 14, 1999, among the registrant and certain stockholders of the registrant.
10.12*	(5)	Employment Agreement between the registrant and Richard W. Mott dated September 3, 2002.
10.13†	(5)	Sublicense Agreement effective as of August 19, 2002, between the registrant and Bonutti Research, Inc.
10.14	(6)	Stock Purchase Agreement by and between Kyphon and the shareholders of Sanatis GmbH, dated February 15, 2003.
10.15	(7)	Lease dated September 18, 2003 for office spaces located at 1221 Crossman Avenue and 480 Java Drive, Sunnyvale, California.
10.16*	(8)	Form of Severance Agreement entered into by and between Kyphon Inc. and its executive officers.

10.17* (8)	Severance Agreement, dated January 28, 2005, entered into by and between Kyphon Inc. and Richard W. Mott.
10.18 (9)	First Amendment to Lease Agreement, made as of September 28, 2005, by and between Moffett Office Park Investors LLC, a Delaware limited liability company, and Kyphon Inc.
10.19 (10)	Real Estate Leasing Contract (English translation) by and between Kyphon Sarl and Credit Suisse, dated May 24, 2006.
10.20 (10)	Guaranty, by and between Kyphon Inc. and Credit Suisse, dated May 26, 2006.
10.21 (11)	Employment Letter by and between Kyphon and Maureen L. Lamb, Chief Financial Officer and Treasurer, dated September 1, 2006.
10.22 (11)	Severance Agreement by and between Kyphon and Maureen L. Lamb, Chief Financial Officer and Treasurer, dated September 20, 2006.
10.23 (12)	Agreement and Plan of Merger, dated December 4, 2006, by and among Kyphon, Neptune Acquisition Sub, Inc., St. Francis Medical Technologies, Inc., and Philip M. Young.
10.24 (12)	Credit Agreement, dated January 18, 2007, among Kyphon and certain subsidiaries as borrowers, Bank of America, N.A. as administrative agent, swingline lender and letter of credit issuer, and the other lenders and agents party thereto.
10.25	Form of Stockholder Support Agreement entered into by and between Kyphon and the stockholders of St. Francis Medical Technologies, Inc.
10.26†	Asset Purchase Agreement (Non-Vertebroplasty Assets), dated December 20, 2006, by and among Kyphon, Disc-O-Tech Medical Technologies Ltd., and Disc-O-Tech Orthopedic Technologies Inc.
10.27†	Asset Purchase Agreement (Vertebroplasty Assets), dated December 20, 2006, by and among Kyphon, Disc-O-Tech Medical Technologies Ltd., and Disc-O-Tech Orthopedic Technologies Inc.
21.1	Subsidiaries of the registrant.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference from our Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 3, 2006.
(2) Incorporated by reference from our Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on October 19, 2006.
(3) Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-83678), which was declared effective on May 16, 2002.
(4) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 12, 2007.
(5) Incorporated by reference from our Quarterly Report on Form 10-Q as filed with the Securities and Exchange Commission on November 13, 2002.
(6) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 7, 2003.
(7) Incorporated by reference from our Quarterly Report on Form 10-Q as filed with the Securities and Exchange Commission on November 14, 2003.
(8) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 1, 2005.
(9) Incorporated by reference from our Quarterly Report on Form 10-Q as filed with the Securities and Exchange Commission on November 1, 2005.
(10) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 31, 2006.
(11) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities and Exchange Commission on September 21, 2006.

(12) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 24, 2007.
(13) Incorporated by reference from our Definitive Proxy Statement on Schedule 14A as filed with the Securities and Exchange Commission on April 26, 2006.

* Management compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 15(c) of Form 10-K.

† Confidential treatment requested on portions of this exhibit. Unredacted versions of this exhibit have been filed separately with the Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on our behalf by the undersigned, thereunto duly authorized, in the City of Sunnyvale, State of California, on the 28th day of February, 2007.

Kyphon Inc.

By: /s/ Richard W. Mott

Richard W. Mott
President, Chief Executive Officer and Director
(Principal Executive Officer)

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Richard W. Mott and Maureen L. Lamb, his attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, or his or their substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of this registrant and in the capacities and on the dates indicated:

Signature	**Title**	**Date**
/s/ RICHARD W. MOTT **Richard W. Mott**	President, Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2007
/s/ MAUREEN L. LAMB **Maureen L. Lamb**	Vice President, Chief Financial Officer (Principal Accounting and Financial Officer)	February 28, 2007
/s/ JAMES T. TREACE **James T. Treace**	Chairman of the Board	February 28, 2007
/s/ STEPHEN M. CAMPE **Stephen M. Campe**	Director	February 28, 2007
/s/ DOUGLAS W. KOHRS **Douglas W. Kohrs**	Director	February 28, 2007
/s/ JACK W. LASERSOHN **Jack W. Lasersohn**	Director	February 28, 2007
/s/ LOUIS J. LAVIGNE, JR. **Louis J. Lavigne, Jr.**	Director	February 28, 2007
/s/ FRANK M. PHILLIPS, M.D. **Frank M. Phillips, M.D.**	Director	February 28, 2007
/s/ KAREN D. TALMADGE, PH.D. **Karen D. Talmadge, Ph.D.**	Executive Vice President, Co-Founder, Chief Science Officer and Director	February 28, 2007
/s/ ELIZABETH H. WEATHERMAN **Elizabeth H. Weatherman**	Director	February 28, 2007

Exhibit 21.1

SUBSIDIARIES OF KYPHON INC.

Subsidiaries of Registrant	State or Other Jurisdiction of Incorporation or Organization
Kyphon Canada Inc.	Canada
Kyphon Cayman Ltd.	Cayman Islands
Kyphon Europe B.V.B.A.	Belgium
Kyphon Ireland Research Holding Ltd.	Ireland
Kyphon Ireland Ltd.	Ireland
Kyphon Deutschland GmbH	Germany
Sanatis GmbH	Germany
Kyphon Austria GmbH	Austria
Kyphon Iberica S.L.	Spain
Kyphon Italia S.R.L.	Italy
Kyphon UK Ltd.	United Kingdom
Kyphon Nippon K.K.	Japan
Kyphon France SARL	France
Kyphon Australia Pty Ltd	Australia
Kyphon Sarl	Switzerland
Kyphon Switzerland GmbH	Switzerland
Kyphon South Africa (proprietary) Limited	South Africa
InnoSpine, Inc.	Delaware, USA

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (Nos. 333-122610, 333-89332, 333-104260, and 333-140716) of Kyphon Inc. of our report dated February 28, 2007 relating to the consolidated financial statements, financial statement schedule, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
PricewaterhouseCoopers LLP

San Jose, California
February 28, 2007

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard W. Mott certify that:

1. I have reviewed this Annual Report on Form 10-K of Kyphon Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as designed in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2007

By: /s/ Richard W. Mott

Richard W. Mott
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Maureen L. Lamb certify that:

1. I have reviewed this Annual Report on Form 10-K of Kyphon Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as designed in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2007

By: /s/ Maureen L. Lamb

Maureen L. Lamb
Vice President, Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard W. Mott, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Kyphon Inc. on Form 10-K for the fiscal year ended December 31, 2006 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Kyphon Inc.

Date: February 28, 2007 By: /s/ Richard W. Mott

Richard W. Mott
President, Chief Executive Officer and Director
(Principal Executive Officer)

I, Maureen L. Lamb, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Kyphon Inc. on Form 10-K for the fiscal year ended December 31, 2006 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Kyphon Inc.

Date: February 28, 2007 By: /s/ Maureen L. Lamb

Maureen L. Lamb
Vice President, Chief Financial Officer
(Principal Accounting and Financial Officer)