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, 2005 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 Ave
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:
None	N/A

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 par value
(Title of Class)

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, 2005 (which is the last business day of registrant's most recently completed second fiscal quarter), as reported on the NASDAQ National Market was approximately $1.1 billion. 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, 2006, the registrant had 44,059,289 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 2005 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; 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 using minimally invasive technology. Our devices are used primarily by spine specialists including orthopedic surgeons and neurosurgeons, interventional radiologists, and interventional neuroradiologists who repair spinal fractures caused by osteoporosis, trauma, cancer or benign lesions through performing minimally invasive surgery known as balloon kyphoplasty. Our commercial products consist of our *KyphX*® instruments, used to treat spinal fractures during balloon kyphoplasty, including our proprietary *KyphX* balloon technology and our proprietary brands of bone filler materials. Surgeons use these instruments to help repair spinal fractures during minimally invasive spine surgeries. Most alternative spinal fracture treatments are either highly invasive or are only pain management therapies.

We believe there are approximately 700,000 clinically-diagnosed spinal fractures in approximately 550,000 patients each year due to osteoporosis in the United States and Europe. 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 spinal 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 the United States and Europe, 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 the United States and Europe 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.

As of December 31, 2005, we had trained approximately 8,000 physicians in the United States, Europe and Asia-Pacific on the balloon kyphoplasty technique, and these physicians had used our instruments in approximately 187,000 patients and 220,000 spinal factures. To support these physicians, we have built a large and growing worldwide direct sales organization that numbered in excess of 425 professionals as of December 31, 2005. Balloon kyphoplasty treatment of spinal fractures results 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 anesthesia 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 May 2000, we commenced full commercial introduction of our *KyphX* instruments in the United States. We devote significant resources to product development, supporting our sales and marketing team, training and educating physicians and supporting reimbursement and clinical activities related to our products.

In February 2003, we acquired Sanatis GmbH, a privately held developer and manufacturer of orthopedic 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 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 December 2005, we entered into a definitive agreement to acquire InnoSpine, Inc., 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, which acquisition was completed in January 2006. 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 Functional Anesthetic Discography (FAD), 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, FAD is a unique, minimally invasive procedure that utilizes a catheter-based system anchored in the disc space to deliver mild anesthetic 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 anesthetic delivery to the degenerated disc, then the disc can be identified for further treatment.

We intend to pursue the research, development and commercialization of spine products arising from these acquisitions and from our licenses to various portfolios of patents we have acquired, including from Bonutti Research in August 2002 and Dr. J. Lee Berger in April 2005, as well as other product initiatives, to complement our existing *KyphX* instruments and to leverage our experienced sales force and expertise in spinal fracture treatments. The full commercialization of products from these acquisitions will require research, development, and regulatory approvals and/or clearances, and may require clinical studies prior to market launch. 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.

Anatomy of the Spine

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.

Consequences of Spinal 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.

Market Opportunity for the Treatment of Spinal Fractures

We believe that each year in the United States and Europe an estimated 700,000 clinically-diagnosed spinal fractures in 550,000 patients occur due to osteoporosis as well as 150,000 fractures in 50,000 patients due to cancer. In addition, we believe that minimally invasive fixation techniques are appropriate for as many as 100,000 vertebral body fractures annually that are caused by trauma. In the U.S. alone, we estimate there are an additional 440,000 osteoporotic fractures per year that go undiagnosed. The majority of the diagnosed fractures are managed in the hospital or at home, predominantly with conservative treatment options such as bed rest, pain medication and back braces. Approximately 150,000 people in the United States per year are hospitalized due to pain associated with spinal fractures caused by osteoporosis, resulting in annual costs estimated to be in excess of $1.6 billion. The number of fractures caused by osteoporosis is increasing more rapidly than the aging of the population, which has been assumed to be

related to increasingly sedentary lifestyles.

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. 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.

Alternative Means for the Treatment of Spinal Fractures

When treating a patient with a spinal fracture, an orthopedic 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 orthopedic 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.

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, 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 cancer-related fractures, and is used to treat only a portion of the trauma-related fractures.

Pain Management Therapies

Due to the limitations of conventional orthopedic surgery for patients with spinal fractures, the majority of these patients are treated with conservative pain management therapies. These methods do not involve surgical intervention and do not repair the fractured spine. These pain management 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 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.

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.

In vertebroplasty, a physician, typically an interventional radiologist, places one or two large needles into the fractured vertebra and injects bone filler material into the collapsed vertebral body. The bone filler most commonly used in vertebroplasty is bone cement. Because the vertebral body is in a collapsed position, this procedure requires the use of thin bone filler material that is injected under high pressure in order to effectively penetrate the inner spaces of the deteriorated bone. A non-viscous filler material injected under high pressure into the vertebral body can result in leakage, as documented in literature. Once injected, the bone filler material hardens and fixes the bone in its collapsed position.

The Kyphon Solution

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 surgeon 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 surgeon'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 8,000 physicians, including 3,000 overseas in the use of our *KyphX* instruments. We believe these physicians have used our instruments to treat approximately 187,000 patients and 220,000 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 897 patients treated with balloon kyphoplasty and 2,408 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.

The Use of *KyphX* Instruments during Minimally Invasive Balloon Kyphoplasty Spine Surgery

Spinal fracture surgeries using our *KyphX* instruments are minimally invasive and are generally performed by spine-focused orthopedic surgeons and neurosurgeons, although the number of interventional radiologists and interventional neuroradiologists using our products to perform balloon kyphoplasty is increasing. A surgeon first creates a working channel through the patient's back into the fractured vertebral body using one of our *KyphX* Bone Access Systems.

The surgeon 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. 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.

Our Strategy

Our goal is to become the recognized global leader in restoring spinal function through minimally invasive therapies. In particular, the key elements of our strategy 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 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 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, 2005, our direct spine sales organization included over 425 individuals in the U.S. 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 that data will begin to be available from this trial sometime during 2006. 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.

- *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.

- *Continue Revenue Growth Through New Product Development and Acquisition*. Our sales force is an important asset with the capacity to sell new products that complement our *KyphX* instruments, including *KyphX* product line extensions as well as new technologies that we develop or acquire from others. In August 2002, we acquired the rights to a series of patents, now numbering 26, owned by Bonutti Research and covering the use of inflatable devices in and around bone and tissue in the spine. In February 2003, we acquired Sanatis GmbH, a privately-held developer and manufacturer of orthopedic biomaterials based in Rosbach, Germany. In April 2005, we exclusively licensed rights to a series of patents covering inventions by J. Lee Berger, M.D., concerning devices and methods for creating voids within, or moving, tissue or bone, or materials or uses for same. In December 2005, we entered into a definitive agreement to acquire InnoSpine, Inc., a privately-held developer of innovative products for diagnosing axial low back pain due to disc degeneration, which acquisition was completed in January 2006. In January 2006, we entered into a consulting agreement with Dr. Harvinder S. Sandhu, covering various fields of minimally invasive spine diagnosis and therapy, including treatment of spinal disc disorders and diagnosis of various spine conditions. We intend to pursue the research, development and commercialization of spine products arising from one or more of these acquisitions, licenses, and relationships to complement our existing *KyphX* instruments and leverage our experienced sales force and expertise in spinal fracture treatments. The commercialization of products from one or more of these acquisitions and licenses as well as our own internal efforts to develop new products and product line extensions will require research, development, and regulatory approvals and/or clearances, and may require clinical studies prior to market launch. We intend to pursue other external business development opportunities as well to help us achieve our goals, which may include opportunities outside of the market for the treatment of spinal fractures as well as opportunities outside of the spine.

- *Other Business Initiatives.* With our acquisition of InnoSpine, Inc., we have moved beyond our original sole focus of spinal deformity correction, through treatment of vertebral compression fractures, to our second business focus, disc repair and regeneration. We have a variety of internal resources dedicated to supporting research and development in this area as well as potential business development opportunities. Our third 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 and when best to enter that initiative. We believe both additional business initiatives provide further opportunity to grow our company in the area of minimally invasive spine.

Our Products

With the acquisition of InnoSpine, Inc., we will have two product families, Spinal Deformity Correction and Disc Repair and Regeneration. Both product families will be sold and supported through our existing sales organization.

Spinal Deformity Correction. 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

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 orthopedic 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, or a mark that allows us to market a product throughout the European Union, 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.

Disc Repair and Regeneration. This product family is comprised currently of the products acquired from InnoSpine, Inc. These products are used in the diagnosis and potential treatment of axial low back pain due to degenerative disc disease. We believe that approximately 200,000 patients with persistent, severe axial back pain could be indicated for this diagnostic procedure each year in the U.S. alone, including the majority of patients undergoing spinal fusion at one or more levels. We intend to initiate full commercial launch during the second quarter of 2006. A single disposable product kit is comprised of an introducer needle, a spine needle, an inflatable balloon anchor and syringes. During the Functional Anesthetic Discography (FAD) diagnostic procedure, a short acting local anesthetic is delivered through the balloon catheter anchored in a spinal disc suspected to be the source of a patient's low back pain. The core balloon catheter technology was cleared by the FDA in April 2005 for delivery of local anesthetic, radiopaque contrast or saline solution to the intradiscal space.

Sales and Marketing

We market and sell our *KyphX* instruments through our direct sales force in the United States and Europe that numbers in excess of 425 professionals as of December 31, 2005. Our target customer base includes the approximately 21,000 physicians who perform spine surgery, including orthopedic spine surgeons, neurosurgeons, interventional radiologists and interventional neuroradiologists. No customer accounted for more than 10% of total net sales in 2005, 2004 or 2003.

As of December 31, 2005, our U.S. sales organization was comprised of 248 sales territories. Each territory is managed by a spine consultant who acts 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 also trained approximately 8,000 physicians in the U.S., Europe and Asia-Pacific to perform the balloon kyphoplasty procedure with our *KyphX* instruments.

We have operated mainly in the United States, and 84%, 88% and 90% of our sales were made in U.S. dollars in 2005, 2004 and 2003, 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 planning to establish an operational presence in Switzerland including manufacturing, distribution and certain research and development activities, to support the growth of our international business.

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 2006 we plan to sell our products in Brazil and Mexico through distributors, and anticipate establishing presences in certain additional Asian countries and Australia.

Reimbursement

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

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.

Approximately 90% of patients 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 departments). 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). 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.

As to 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 and 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. For 2006, CMS assigned the balloon kyphoplasty procedures using *KyphX* instruments, which are described by the new Category I CPT codes (discussed above), to APC 0052 (Level IV Musculoskeletal procedures except hand and foot) and to APC 274 (myelography). 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. Effective January 1, 2006, there are three new Category I CPT codes, or reimbursement codes, describing procedures in which our products are used: CPT codes 22523, 22524 and 22525. The first two codes describe performance of percutaneous

vertebral augmentation, including cavity creation (fracture reduction including biopsy when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty), for thoracic and lumbar procedures, respectively. The third code describes performance of the procedure on each additional thoracic or lumbar vertebral body. In addition, two existing radiologic codes, CPT codes 76012 and 76013, were modified. These codes now describe fluoroscopic and CT guidance, to include specific reference to vertebral augmentation including cavity creation.

Although the reimbursement levels associated with the reimbursement codes for kyphoplasty are greater than what physicians in some states previously received for such procedures, they are also less than what physicians in other states previously received which could make surgery with our products less attractive to some physicians. Physicians may believe or determine that the reimbursement available under these new codes is not sufficient to support continued use of our products to perform balloon kyphoplasty. As of now, it is not possible to assess whether the implementation of the new Category I CPT codes has had or will have any material impact on the behavior of clinicians with respect to their interest in performing the balloon kyphoplasty procedure. At this time, it is too early to predict with any degree of certainty the full impact of the new Category I CPT codes on our business, although we have not seen any significant impact in any geographic region to date.

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 has 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. We do not know whether these efforts will continue or will be effective or broad in application. We are also aware that some foreign governments, including Germany, are continuing to evaluate coverage and reimbursement for balloon kyphoplasty, which ultimately may increase or decrease the reimbursement available for procedures performed with our products. Our business could be harmed in countries where the level of reimbursement available is ultimately decreased. Notwithstanding all of these activities, we will continue to seek appropriate levels of reimbursement in those markets using appropriate measures.

Manufacturing

We believe our manufacturing operations are in compliance with regulations mandated by the FDA and the European Union. We have been an FDA-registered and California-licensed medical device manufacturer since 1998 and have had our CE Mark since February 2000. We had our annual TUV audit in January 2005 updating our facility to ISO 13485:2003 certified. TUV is our notified body and the audit is necessary for our European Community certification, which in turn permits us to acquire and maintain CE marks for our products. We are subject to unannounced inspections by the FDA, TUV 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. We have been inspected by the CDHS, the FDA 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 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 appropriately 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 creating new products, product extensions and improvements to existing products to address unmet patient and market needs 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, including but not necessarily limited to, diagnosis of discogenic pain, treatment of spinal fractures and other spinal deformities and disease states, dynamic stabilization initiatives, disc repair regeneration initiatives, and evaluating several opportunities within the cancer initiatives. In addition, we intend to further develop balloon and related technologies to treat various other bone disorders arising from trauma or cancer. Our expenditure for research and development totaled $46.4 million, $22.2 million and $16.0 million in 2005, 2004 and 2003, respectively. Research and development expense in 2005 included the license acquisition cost of $20.0 million and Berger license fee of $1.0 million. We are currently developing the following products:

- 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 biomaterials designed for spine surgery in patients with cancer in the spine; and
- instruments and biomaterials for the diagnosis and treatment of spinal disc disease.

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

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 interest by third parties in introducing into the marketplace 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 knock-offs of our products in some Asia-Pacific countries. These products are initially being marketed in the U.S., Europe and Asia as supposedly more 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.

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, efficacy 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, 2005, we had over 42 issued U.S. patents, 30 issued foreign patents, 70 pending U.S. patent applications, 100 pending foreign applications, including 26 patents that we exclusively licensed from Bonutti Research in August 2002, and 7 patents and patent applications 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 orthopedic 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 orthopedic biomaterials based in Rosbach, Germany. Sanatis has filed four patent applications covering inventions relating to calcium cement formulations and a cement delivery technology.

In April 2004, we filed two patent infringement suits against Disc-O-Tech Medical Technologies Ltd. , an Israel-based company doing business in the United States. This was the first time we enforced our patent rights against any entity. We filed suit in the United States District Court in Delaware and in the International Trade Commission (ITC) in Washington, D.C. In September 2004, the ITC entered an Order barring Disc-O-Tech from all further importation of its SKy Bone Expander device into the United States and from engaging in any further sales activities and uses of such imported products, thereby terminating the ITC proceeding in our favor. In June 2005, the Delaware District court entered a Consent Judgment permanently enjoining Disc-O-Tech from further infringing our patent rights with its SKy Bone Expander device or products not colorably different from the SKy Bone Expander, which took effect on July 22, 2005. This Judgement bars further importation or selling of Disc-O-Tech's SKy Bone Expander device or colorable variations of that device for performing kyphoplasty in the U.S. market. This concluded the litigation in our favor without the possibility of further trial or appeal. Disc-O-Tech, however, remains a competitor abroad, in other jurisdictions where we have not pursued them to date with our foreign patent rights, or may not be able to pursue them at all.

In January 2006, Kyphon and Dr. Harvinder Sandhu, a well-respected orthopaedic surgeon, formed an exclusive consulting relationship covering various fields of minimally invasive spine diagnosis and therapy,

including treatment of spinal disc disorders and diagnosis of various spine conditions. Previously, in November 2005, Dr. Sandhu agreed to exclusively license to Kyphon his early invention rights concerning a directional bone tamp for treating vertebral compression fractures for a cash payment of $5.0 million and a series of payments totaling up to an additional $15.0 million. The license also includes a typical provision for a capped royalty stream on any future developed product that practices Dr. Sandhu's technology. In November 2005, Dr. Sandhu and Kyphon filed suit in federal district court in Memphis, Tennessee against Medtronic Sofamor Danek 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, unjust enrichment, and correction of inventorship of several patents and patent applications presently owned by Sofamor Danek. The suit also requests, among other relief, that Sofamor Danek transfer to Dr. Sandhu ownership of the disputed patents and patent applications. The dispute concerns Dr. Sandhu's directional bone tamp inventions exclusively licensed to Kyphon. The complaint alleges that after receiving a confidential disclosure of Dr. Sandhu's inventions, Sofamor Danek 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* project without his permission. The litigation is in its early stages; no trial date has yet been set.

In December 2005, we entered into a definitive agreement to acquire InnoSpine, Inc., a privately held developer of a proprietary technology platform for the diagnosis and potential treatment of axial low back pain due to disc degeneration, which acquisition was completed in January 2006. InnoSpine has filed for patent protection on various aspects of the 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 noninfringing 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 noninfringing technologies could prevent us from manufacturing and selling our products, which in turn could adversely affect our business and our 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 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 and 11 Gauge Bone Access Needle are 510(k)-cleared products that we currently obtain from contract suppliers. We believe our *KyphX* Introducer Tool Kit, *Osteo Introducer* System, Advanced *Osteo Introducer* System, Bone Biopsy Device, *Latitude* Curette, and *KyphX* Bone Filler Device, when sold as manual orthopedic surgical instruments, are exempt from clearance or approval requirements. Our 510(k) clearances permit us to promote particular short and long-term benefits of balloon kyphoplasty, 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.

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 quality system regulations and may also conduct inspections of the clinical investigators' and study sponsors' sites. 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 elaborate testing, control, documentation and other quality assurance procedures during the manufacturing process;
- 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 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 2005, 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 healthcare 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 healthcare professionals comply with such safe harbors and have adopted codes of conduct to guide our activities in that regard. Conduct and business 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, healthcare professionals. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute. Some of these state laws apply to healthcare 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 healthcare companies to have to defend a False Claim action. Although we believe we are in substantial compliance with the healthcare laws relevant to our Company, we are aware that a complaint against us, which we believe is a *qui tam* complaint, was recently presented to a U.S. Attorney's Office for consideration (See Item 1A. Risk Factors – "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. If a subpoena, or an enforcement or other action results from this investigation, our business and financial condition could be adversely affected which could cause our stock price to decline").

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, includes at least two related federal statutes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare 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 healthcare benefits, items or services.

We have adopted corporate policies and codes of conduct to assist our employees in complying with these laws. We train our employees on how to engage appropriately with healthcare providers under these laws, and we have implemented a compliance program to enforce our policies. 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 healthcare 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 kyphoplasty performed on an out-patient basis has been and remains significantly less than reimbursement available for 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 sometimes influences 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 healthcare programs (including Medicare and Medicaid). Our activities could be subject to challenge 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 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 adopted numerous directives and standards regulating the design, manufacture, clinical trial, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout 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 may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body 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 designated manufacturing and quality requirements known as ISO requirements.

We have obtained CE Marking permitting us to commercialize our products currently being sold 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.

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, 2005, we had a total of 885 employees, with 121 people in operations, 89 people in research and development, 544 people in sales, marketing and professional education and 131 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 the ability to treat and restore spinal anatomy during balloon kyphoplasty. 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. 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 balloon kyphoplasty procedures using our *KyphX* instruments.

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 *KyphX* instruments are currently covered and reimbursed by the Medicare program and other governmental and private third-party payors. However, as a result of developments in both physician and hospital reimbursement, including the establishment of new reimbursement codes describing kyphoplasty, some physicians and hospitals in some states may believe that the level of reimbursement they receive is too low to support performing balloon kyphoplasty. Continued use of our *KyphX* instruments 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 recent reimbursement code changes has had or will have any material impact on the behavior of clinicians with respect to their interest in performing the balloon kyphoplasty procedure.

In addition, reimbursement for competing procedures, such as 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 balloon kyphoplasty 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 balloon kyphoplasty procedures, our ability to market and sell our *KyphX* instruments 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 balloon kyphoplasty procedures. 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 *KyphX* 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 balloon kyphoplasty procedures, such a development could significantly impact the willingness of hospitals, clinics and doctors to purchase and use our *KyphX* 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, and some could involve 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 *KyphX* instruments, harm our business and reduce our revenues.

The absence of prospective, randomized, controlled clinical trial data as support for the economic differentiation of balloon kyphoplasty over vertebroplasty is causing some influential physicians in positions of authority to speak out against adoption of balloon kyphoplasty, which may ultimately adversely affect our business and our financial condition, which could cause our stock price to decline.

Over the past year or so, a handful of vocal physicians have begun 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. On more than one occasion, certain speakers, including a few physicians of authority in various institutions and 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. We do not yet know what clinical outcomes that trial will

reveal, or whether the trial's results, once available, will demonstrate the benefits of treatment of vertebral compression fractures with balloon kyphoplasty. We also cannot predict how the current 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 *KyphX* products to perform balloon kyphoplasty, 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 *KyphX* instruments as an alternative to conventional spinal fracture treatment and conservative pain management therapies. We believe primary care is an important source of patient referral, and, therefore, it is important to educate them about our products and the clinical outcome of the balloon kyphoplasty procedure. We believe that primary care physicians and spine specialists may not widely adopt our products unless they determine, based on experience, clinical data and published, peer-reviewed journal articles, that our products provide benefits or an attractive alternative to conventional treatments of spinal fractures. In addition, we believe that recommendations and support of our products by influential practitioners are essential for market acceptance and adoption of our products. If we are unable to have continued referrals from primary care physicians, then our future growth will be harmed and our business may decline.

If we are unable to successfully integrate into our business InnoSpine, Inc. or any other acquisitions we may choose to make, we could encounter difficulties that harm our business.

We recently acquired InnoSpine, Inc. and a technology that we have not dealt with before. We may also acquire other companies, products or technologies that we believe to be complementary to the present or future direction of our business. We may have difficulty integrating the acquired personnel, financials, operations, products or technologies into our existing business. Acquisitions and the resulting integration 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.

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 *KyphX* instruments may decline.

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 may already be introducing 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. Some of these competitors' products may be successful as a result of greater efficacy, less expensive alternatives to our products, or another advantage that makes 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. 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 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 for diagnosis and treatment of spinal conditions. 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.

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.

Our failure to maintain necessary regulatory clearances or approvals, or to obtain additional regulatory clearances or approvals, in the U.S. and abroad could hurt our ability to commercially distribute and market our *KyphX* instruments.

Our *KyphX* instruments and bone cement and our *KyphOs* calcium phosphate 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. 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) 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, or in new geographic jurisdictions for us, such as Japan. 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.

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.

Modifications to our marketed devices may require new 510(k) clearances or premarket approvals or the FDA may require us to cease marketing or recall the modified devices until clearances are obtained.

Any modification to a 510(k)-cleared device 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, possibly, premarket approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA can review any manufacturer's decision. We have modified aspects of our *KyphX* instruments without seeking new 510(k) clearances because we believe that the modifications do not significantly affect the product's safety or effectiveness. The FDA may not agree with any of our decisions not to seek new clearances or approvals. If the FDA requires us to seek 510(k) clearance or premarket approval for any of these modifications to a previously cleared device, we may be required to cease marketing or to recall the modified device until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

If we are unable to expand our 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 2006 and 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 and *KyphX HV-R* 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.

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 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 *KyphOs* calcium phosphate, and we have had to publicly report that information through filing a Medical Device Report to the FDA or Vigilance Reports in Europe. 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 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. If a subpoena, or an enforcement or other action ultimately results from this investigation, our business and financial condition could be adversely affected which could cause our stock price to decline.

We have learned that sometime 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 reimbursement practices. Although no subpoena has been issued to us, the USAO in connection with this complaint is investigating our sales and marketing practices, including those relating to Medicare reimbursement available to our customer hospitals, based on site-of-service, for using Kyphon's products in surgery, and has informally asked about some of our documentation that may be relevant to the investigation. We believe we are in substantial compliance with the healthcare laws relevant to our Company. Even though we have not received a subpoena regarding the complaint or its allegations, we are voluntarily cooperating 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, although timing on that decision is uncertain. At this time, we do not know whether the outcome of the investigation will have a material adverse impact to our business, and cannot assure you regarding any future path USAO or any related lawsuit may take. If an enforcement or other action results from the ongoing investigation, our business and financial condition could be adversely affected which could cause our stock price to decline.

We derive a significant portion of our operating results from non-U.S. sales, 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 $48.5

million, or approximately 16% of total net sales in 2005. 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.

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 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 recently terminated our relationship with distributors in several foreign jurisdictions and are in the process of establishing, or have already established, new relationships in those and other geographic regions. 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.

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.

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 *KyphX* instruments or generate significant revenue growth.

Our world-wide direct sales organization has increased from approximately 31 employees in October 2000 to over 425 employees in December 2005, 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 880 employees in December 2005. 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.

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, 2005, we had $76.1 million of cash and cash equivalents and $118.3 million of short-term investments. We currently believe that our current cash, cash equivalents, investments, and cash generated from operations will be sufficient to meet our anticipated cash needs for at least the next 12 months. If existing cash, cash equivalents, and cash generated from operations are insufficient to satisfy our cash requirements, whether as a result of possible investment in new markets or businesses through both internal or external business development, expansion of product lines, increased capital expenditures, additional clinical trials, expansion of product lines 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 or obtain a credit facility. The sale of additional equity or the sale of 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.

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 auditor's, conclusions after December 31, 2005 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 for the years ending on and after December 31, 2004. 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, 2005 with respect to the effectiveness of our internal control over financial reporting. Although we received unqualified opinions as of December 31, 2005, 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.

Recent changes in the required accounting treatment for stock options will have a material negative impact on our financial statements and may affect our stock price.

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 123(R), pursuant to which we must measure all stock-based compensation awards, including grants of employee stock options, using a fair value-based method and record such expense in our consolidated financial statements. We are required to expense employee stock-based compensation awards beginning January 1, 2006. Currently, we disclose such expenses on a pro forma basis in the notes to our consolidated financial statements, but we do not record a charge for employee stock option expense in the financial statements. Once we begin to comply with SFAS No. 123(R) as of the beginning of fiscal year 2006, our reported earnings will decrease, which may affect our stock price. In addition, our reported earnings may have increased volatility due to the tax impact and timing of employee stock option exercises.

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.

A significant amount of our United States revenue is dependent on business from areas prone to hurricanes, and the occurrence of one or more significant hurricanes or other natural disasters in those geographic areas could substantially adversely impact many of our customers' operations, which would harm our financial condition and our revenues.

Many of our customers in the southeastern United States and the Gulf Coast region have been adversely affected by one or more major hurricanes during the past several years, and may be so affected in the future. Such catastrophic storm activity has in the past adversely affected our revenues from, and business activities in, those regions, and could in the future similarly adversely affect our revenues and operations, due to our customers' decreased ability to continue their operations without significant disruption. We may also be entering a historic period of increased hurricane activity. If any disaster of this sort were to occur in the future, our United States revenues could be significantly impacted.

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 feet 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 feet 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 most 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 feet 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. We anticipate the larger facility should be available in 2007, and are currently evaluating financing options for it. 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 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, unjust enrichment, and correction of inventorship of several patents and patent applications presently owned by Sofamor Danek, including U.S. Patent No. 6,676,665. The suit also requests, among other relief, that Sofamor Danek 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 Sofamor Danek. The complaint alleges that Sofamor Danek 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* project without his permission. The litigation is in its early stages; no trial date has yet been set.

From time to time, Kyphon may become involved in litigation relating to additional claims arising from the ordinary course of business. Management does not know whether the final disposition of any such litigation matters will have a material adverse affect on Kyphon.

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 National 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 National Market:

	Common Stock	
	High	Low
Fiscal Year 2004		
First quarter	$ 30.28	$ 20.83
Second quarter	$ 29.37	$ 22.38
Third quarter	$ 28.51	$ 22.22
Fourth quarter	$ 26.55	$ 22.93
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

We had 98 stockholders of record as of February 15, 2006. Since many holders’ shares are listed under their brokerage firm’s name, we believe the actual number of stockholders is greater than 98.

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 and do not anticipate paying any cash dividends in the foreseeable future.

We did not sell any unregistered securities during the period covered by this Annual Report on Form 10-K.

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, 2005, 2004 and 2003, and the consolidated balance sheet data as of December 31, 2005 and 2004 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, 2002 and 2001, and the consolidated balance sheet data as of December 31, 2003, 2002 and 2001 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.

	Year Ended December 31,				
	2005	2004	2003	2002	2001
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Net sales	$ 306,082	$ 213,414	$ 131,028	$ 76,316	$ 36,073
Cost of goods sold	35,843	24,734	16,794	10,416	8,108
Gross profit	270,239	188,680	114,234	65,900	27,965
Operating expenses:					
Research and development	46,383	22,238	16,031	22,512	7,978
Sales and marketing	144,768	106,103	69,538	44,083	28,360
General and administrative	34,951	25,972	16,328	11,849	9,132
Total operating expenses	226,102	154,313	101,897	78,444	45,470
Income (loss) from operations	44,137	34,367	12,337	(12,544)	(17,505)
Interest income (expense) and other, net	3,979	1,250	986	(2,794)	(309)
Income (loss) before income taxes	48,116	35,617	13,323	(15,338)	(17,814)
Provision (benefit) for income taxes	18,280	13,900	(14,000)	--	--
Net income (loss)	$ 29,836	$ 21,717	$ 27,323	$ (15,338)	$ (17,814)
Net income (loss) per share:					
Basic	$ 0.70	$ 0.54	$ 0.71	$ (0.63)	$ (9.06)
Diluted	$ 0.66	$ 0.50	$ 0.65	$ (0.63)	$ (9.06)
Weighted-average shares outstanding:					
Basic	42,803	40,449	38,433	24,405	1,967
Diluted	45,336	43,670	42,090	24,405	1,967

	As of December 31,				
	2005	2004	2003	2002	2001
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 194,473	$ 115,799	$ 85,479	$ 74,303	$ 3,352
Working capital (deficit)	216,504	153,926	86,564	83,504	(5,623)
Total assets	316,632	213,389	154,480	101,524	18,287
Convertible promissory notes	--	--	--	--	12,000
Long-term debt	--	--	--	--	43
Redeemable convertible preferred stock	--	--	--	--	38,024
Deferred stock-based compensation	116	2,113	6,435	11,947	16,082
Total stockholders' equity (deficit)	$ 250,056	$ 179,635	$ 134,250	$ 91,514	$ (37,667)

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, 2005.

- *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 using minimally invasive technology. Our devices are 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 known as balloon kyphoplasty procedures. Our commercial products 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. Most alternative treatments for these types of spinal fractures are either highly invasive or are only pain management therapies.

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 and in Canada. In November 2005, we leased a facility which serves as a temporary facility for us to conduct administrative and distribution activities for our international business while we build a larger facility in Neuchâtel, Switzerland. We anticipate the larger facility should be available in

2007, and are currently evaluating financing options for it. We plan to conduct manufacturing, distribution, administrative and certain research and development activities in this facility to support the growth of our international business. Our global distribution network consists of a direct sales organization in excess of 425 individuals who market our products in the U.S., many of the major countries in Europe and in Canada and 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 we recently enrolled our sixth patient in our Japanese clinical trial.

Products and Significant Business Trends. Our net sales consist 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).

During 2005, our business experienced significant growth. Net sales in 2005 increased to $306.1 million, compared to $213.4 million in 2004, representing growth of 43%. We trained over 2,200 physicians during 2005, primarily in the United States and in Europe. In the U.S., we added approximately 286 new hospitals to our customer base during 2005.

In April 2005, we entered into an agreement to exclusively license, in the field of orthopaedics including all spinal applications, Dr. J. Lee Berger's portfolio of patents concerning medical devices and methods for creating voids in, or moving, tissue or bone, including platform cannulae for expandable bodies. We made an up-front payment of $1.0 million in April 2005 and have agreed to provide a lifetime-capped royalty stream on any products that may be developed that practice the licensed patent rights.

In January 2006, we formed an exclusive consulting relationship with Dr. Harvinder Sandhu, a well-respected orthopaedic surgeon, covering various fields of minimally invasive spine diagnosis and therapy, including treatment of spinal disc disorders and diagnosis of various spine conditions. In November 2005, Dr. Sandhu had previously agreed to exclusively license to Kyphon his early invention rights concerning a directional bone tamp for treating vertebral compression fractures for a cash payment of $5.0 million and a series of payments totaling up to an additional $15.0 million. The license also includes a capped royalty stream on any future developed product that practices Dr. Sandhu's technology.

On December 30, 2005, we entered into a definitive agreement to acquire 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. We recorded $11.0 million to developed technology as a result of this acquistion which we expect to amortize on a straight line basis over the next 10 years. We intend to initiate full commercial launch of the InnoSpine product during the second quarter of 2006. We expect that sales of the InnoSpine product will largely offset the associated impact of increased operating expenses.

With our acquisition of InnoSpine, we have moved beyond only our original sole focus of spinal deformity correction, through treatment of vertebral compression fractures, to our second business focus, disc repair and regeneration. We have a variety of internal resources dedicated to supporting research and development in this area as well as potential business development opportunities. Our third 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 and when best to enter that initiative. We believe both additional business initiatives provide further opportunity to grow our company in the area of minimally invasive spinal diagnosis and therapies.

We will continue to evaluate other additional potential opportunities for growth in our business by evaluating external products and technologies. While our primary focus will remain on our core business and the opportunities the osteoporosis, cancer and trauma vertebral fracture markets present, we may choose to pursue one or more business development opportunities which we believe are appropriate initiatives for our business, even if such opportunities are outside of the field for the treatment of spinal fractures or disease, or outside of the spine itself. 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. And until such time, if ever, that Kyphon succeeds in diversifying its business through internal development or external business development activities, Kyphon will remain dependent on the single opportunity of treating vertebral compression fractures with balloon kyphoplasty with its products and bear the traditional risks to its business of being a company whose revenues are principally derived from one procedure.

On February 6, 2006, Mr. Frank P. Grillo joined the Company as our Vice President, Strategy and Business Development, a newly established position. Mr. Grillo most recently comes from ten years at Boston Scientific Corporation where he most recently held the position of Vice President, Marketing, Women's Health, Urology/Gynecology Division. Prior to his role in Marketing, Mr. Grillo spent four years as Director of New Business Development for the cardiology and drug delivery groups at Boston Scientific. Mr. Grillo has an MBA from the J.L. Kellogg Graduate School of Business at Northwestern University and a Bachelor of Science in Chemical Engineering from Tufts University. In his role, Mr. Grillo will report to Mr. Richard W. Mott, our President & Chief Executive Officer.

Effective February 15, 2006, Arthur T. Taylor, the Company's Vice President, Chief Financial Officer and Treasurer (CFO) since August 2004, was promoted to assume the responsibility of Chief Operating Officer (COO), a newly established position, for the Company. Mr. Taylor will also continue to serve as CFO in the interim until an appropriate successor is hired. As our COO, Mr. Taylor will continue to report to Mr. Mott, and will oversee our manufacturing, quality, research and development, reimbursement, product marketing, clinical and regulatory, and information systems and technology departments.

Also effective February 15, 2006, Ms. Elizabeth A. Rothwell, who previously served as our Vice President, Operations and Quality from February 2003 until March 2005, and who temporarily assumed the role of Vice President, Research and Development in April 2005, will now reassume the role of Vice President, Quality, and Mr. Rick S. Kline, who has served as our Vice President, Operations and Quality since April 2005, will continue to serve as our Vice President, Operations. Both Ms. Rothwell and Mr. Kline will report to Mr. Taylor as COO. The Company intends to promptly begin a search to fill the roles of Vice President, Research and Development, and Vice President and CFO.

Over the past year, a handful of vocal physicians have begun 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 to justify the effectiveness of balloon kyphoplasty and the perceived economic differentiation between balloon kyphoplasty and vertebroplasty. On more than one occasion, certain speakers, including a few physicians of authority in various institutions and professional societies, have publicly stated their opposition to both balloon kyphoplasty and Kyphon based on a lack of perceived justification for the cost or economics of the procedure. While we are in the process of conducting a randomized, controlled trial in Europe comparing balloon kyphoplasty versus non-surgical management, enrollment of which recently concluded, we do not yet know what clinical outcomes that trial will reveal, or whether the trial's results, once available, will be beneficial to making a case for treatment of vertebral compression fractures with balloon kyphoplasty, or how this public negative criticism to adoption of our products for treating patients ultimately may affect our business or our revenues.

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 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 2006. Data from this trial, in addition to clinical data obtained from studies previously completed in the US and Europe, will be used to support regulatory approval in Japan for balloon kyphoplasty. If approved, we could begin commercialization in Japan in the 2009 timeframe.

- In 2005 we also initiated patient enrollment for our cancer patient fracture evaluation study as well as the pulmonary function pilot study. Both studies are in the early stages of patient enrollment.

- We will be initiating a randomized controlled trial comparing balloon kyphoplasty and vertebroplasty. 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, with enrollment beginning in the fourth quarter of 2006 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.

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, 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 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, 2005, 2004 and 2003.

Our accounts receivable balance was $55.5 million and $42.3 million, net of allowances of $1.6 million and $1.1 million at December 31, 2005 and 2004, 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 $991,000 and $529,000 at December 31, 2005 and 2004, 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.

In the fourth quarter of 2003, we released our valuation allowance because based upon our recurring level of profitability; we believed that it was more likely than not that we would be able to utilize our deferred tax assets before they expire. Prior to the fourth quarter of 2003 we had provided a full valuation

allowance against our deferred tax assets, due to uncertainties related to our ability to utilize our deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire.

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, 2005 and 2004, 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 and have 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. 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. The annual goodwill impairment test for our Sanatis acquisition was completed in the first quarter of fiscal 2005, and it was determined that there was no impairment of goodwill at that time. 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 current 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.

As of January 1, 2006, using the modified prospective method, we adopted Statement of Financial Accounting Standards (SFAS) No. 123(R), which requires the expensing of our stock compensation programs. The adoption of SFAS No. 123 (R) is expected to increase our cost of goods sold and operating expenses by approximately $30.0 million in 2006 based upon employee stock options outstanding as of December 31, 2005 and estimated 2006 option grants to employees. Had we been required to expense employee stock options in 2005, our cost of goods sold and operating expenses would have increased by approximately $25.3 million.

Results of Operations

Comparison of years ended December 31, 2005, 2004 and 2003

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,					
	2005		2004		2003	
	Amount	% of Net sales	Amount	% of Net sales	Amount	% of Net sales
U.S. net sales	$ 257,558	84 %	$ 187,526	88 %	$ 118,422	90 %
International net sales	48,524	16 %	25,888	12 %	12,606	10 %
Net sales	306,082	100 %	213,414	100 %	131,028	100 %
Cost of goods sold	35,843	12 %	24,734	12 %	16,794	13 %
Gross profit	270,239	88 %	188,680	88 %	114,234	87 %
Operating expenses:						
Research and development	46,383	15 %	22,238	10 %	16,031	13 %
Sales and marketing	144,768	47 %	106,103	50 %	69,538	53 %
General and administrative	34,951	12 %	25,972	12 %	16,328	12 %
Total operating expenses	226,102	74 %	154,313	72 %	101,897	78 %
Income from operations	44,137	14 %	34,367	16 %	12,337	9 %
Interest income and other, net	3,979	2 %	1,250	1 %	986	1 %
Income before income taxes	48,116	16 %	35,617	17 %	13,323	10 %
Provision (benefit) for income taxes	18,280	6 %	13,900	7 %	(14,000)	(11)%
Net income	$ 29,836	10 %	$ 21,717	10 %	$ 27,323	21 %

***Net Sales*.** Net sales increased $92.7 million, or 43%, in 2005 compared to 2004, and increased $82.4 million, or 63%, in 2004 compared to 2003. The increases in net sales in 2005 primarily resulted from an increase in the number of physicians trained in the use of our *KyphX* instruments as well as an 18% increase in the number of procedures performed by trained physicians per month compared to 2004. During 2005 approximately 2,200 physicians were trained in the use of our *KyphX* instruments. The increases in net sales in 2004 primarily resulted from the 1,700 more physicians trained in the use of our *KyphX* instruments during 2004 as well as a 17% increase in the number of procedures performed by trained physicians per month compared to 2003. Domestic sales increased $70.0 million, or 37% in 2005 compared to 2004 and $69.1 million, or 58% in 2004 compared to 2003. International sales increased $22.6 million, or 87% in 2005 compared to 2004 and $13.3 million, or 105% in 2004 compared to 2003. International sales also reflected the unfavorable currency impact of $0.5 million in 2005 and a favorable currency impact of $2.6 million in 2004 based on prior year's average Euro rates. No customer accounted

for more than 10% of total net sales in 2005, 2004 or 2003. As of December 31, 2005, we had trained approximately 5,000 spine specialists in the U.S. and approximately 3,000 clinicians in other parts of the world, primarily Europe. These physicians have used our *KyphX* instruments in approximately 187,000 patients and 220,000 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. We have targeted a range of $383 million to $398 million in net sales for 2006.

Cost of Goods Sold. Cost of goods sold consists of material, labor, subcontract, and overhead costs. Cost of goods sold increased $11.1 million, or 45%, in 2005 compared to 2004, and increased $7.9 million, or 47%, in 2004 compared to 2003. The absolute increase in cost of goods sold over the years from 2003 to 2005 resulted primarily from increased material, labor, subcontract and overhead costs in relation to the increased sales volume of our products in addition to an increase in our inventory provisions in fiscal 2005 and 2003 due to planned new generation product transition. The cost of goods sold as a percentage of net sales decreased from 2003 to 2004 primarily as a result of fixed overhead costs being spread over increased production volume. 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. As a percentage of net sales, we expect cost of goods sold to be in the range of 12% to 13% for 2006.

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 increased $24.1 million, or 109%, in 2005 compared to 2004. Research and development expenses increased $6.2 million, or 39%, in 2004 compared to 2003. The increase in 2005 from 2004 was primarily attributable to the license acquisition charges of $20.0 million to Dr. Harvinder Sandhu and $1.0 million to Dr. Lee Berger. 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. The increase in 2004 from 2003 was primarily attributable to increased personnel costs of $3.4 million, increased clinical studies expense of $2.3 million, increased research and development consulting fees of $926,000 and increased facilities costs of $655,000, offset by a decrease in amortization of deferred stock-based compensation expense of $1.1 million. We expect to continue to make substantial investments in research and development and anticipate that research and development expenses in 2006 will increase in absolute dollars excluding the license acquisition charges due largely to the 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 percentage of net sales, we anticipate our research and development expenses to be in the range of 10% to 11% for 2006.

Sales and Marketing. Sales and marketing expenses consist of costs for personnel, physician training programs and marketing activities. Sales and marketing expenses increased $38.7 million, or 36%, in 2005 compared to 2004. Sales and marketing expenses increased $36.6 million, or 53%, in 2004 compared to 2003. 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. The increase in 2004 from 2003 related primarily to a $25.0 million increase in the costs of hiring, training and compensating additional direct selling representatives and expansion of the Spine Education Specialist (SES) sales force, increased sales travel expenses of $3.8 million, increased expenditures for surgeon training and professional education of $2.1 million and increased outside professional service fees and consulting expenses of $1.2 million. In 2005, we largely completed the consolidation of the SES sales force with the rest of the sales force. As we continue to commercialize our *KyphX* instruments on a global basis, we expect to significantly increase our sales and marketing efforts and expenditures in absolute dollars while maintaining our sales and marketing expenses as a percentage of

net sales at 47% to 48% for 2006.

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 $9.0 million, or 35%, in 2005 compared to 2004. General and administrative expenses increased $9.6 million, or 59%, in 2004 compared to 2003. 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. The increase in 2004 from 2003 was primarily attributable to increased personnel costs of $4.2 million, increased litigation costs of $2.6 million and increased consulting and outside professional service fees of $2.0 million. The increases in expenses were offset partially by decreased amortization of deferred stock-based compensation of $213,000. We expect general and administrative expenses to increase in the future as we add personnel, 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. As a percentage of net sales, we expect that our general and administrative expenses will be approximately 14% to 15% in 2006.

Interest Income and Other, Net. Interest income and other, net, increased $2.7 million in 2005 compared to 2004. Interest income and other, net, increased $264,000 in 2004 compared to 2003. The increase in 2005 compared to 2004, and the increase in 2004 compared to 2003 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 $194.5 million, $115.8 million, and $85.5 million as of December 31, 2005, 2004, and 2003, respectively.

***Provision (Benefit) for Income Taxes*.** 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 lower effective tax rate for 2005 is primarily due to a one time tax benefit related to revised estimates of our research and development credits and to manufacturing deductions. The benefit for income taxes of $14.0 million in 2003 resulted primarily from the release of the valuation allowance against our deferred tax assets in the fourth quarter of 2003. We believe that in 2006 our effective tax rate will be approximately 42% of income before taxes, with the actual amount of taxes paid potentially reduced by the utilization of net operating loss and research and development tax credit carryforwards as well as deductions due to stock option activities.

At December 31, 2005, we had approximately $500,000 and $4.8 million in federal and state net operating loss carryforwards, respectively, to reduce future taxable income. The federal and state carryforwards have expiration dates beginning in 2023 and 2010, respectively, in each case if not utilized.

At December 31, 2005, we had research and development tax credit carryforwards of approximately $2.2 million and $3.6 million for federal and state income tax purposes, respectively. If not utilized, the federal research and development tax credit carryforwards will expire beginning in 2018. The state research and development tax credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. Ownership changes for the Company, as defined, occurred on August 8, 1996, December 14, 1999 and May 17, 2002. In addition, we entered into a definitive agreement to acquire InnoSpine on December 30, 2005. Ownership changes for InnoSpine as defined, occurred on March 16, 2004 and December 30, 2005. In accordance with Internal Revenue Code Section 382, utilization of the carryforwards is subject to annual limitation. The annual limitation is not expected to result in the expiration of net operating losses prior to utilization.

Stock-Based Compensation

We recorded deferred stock-based compensation on options issued prior to our initial public offering as the

difference between the exercise price of options granted to employees and the deemed fair value of our common stock at the time of grant. Deferred stock-based compensation is amortized to cost of goods sold, research and development expense, sales and marketing expense and general and administrative expense as the options vest, generally over four years. Deferred stock-based compensation for employee stock options recorded through December 31, 2005 was $18.3 million, with accumulated amortization of $18.2 million. The remaining amount will be fully amortized by May 2006. All option amounts are being amortized using the straight-line method.

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 $1.3 million, $929,000 and $1.9 million in 2005, 2004 and 2003, respectively.

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

As of December 31, 2005, we had $76.1 million of cash and cash equivalents, $118.3 million of short-term investments, and working capital of $216.5 million. Our cash and cash equivalents and investments increased by $78.7 million during 2005.

***Cash Provided by Operating Activities*.** Our operating cash flow in 2005 was primarily the result of our operational profitability. Net cash provided by operations was $67.9 million attributable primarily to net income of $29.8 million and adjustments for non-cash charges related to the provision for deferred taxes including tax benefits from stock options of $14.8 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 the provision for deferred taxes including tax benefits from stock options of $12.8 million. Net cash provided by operations in 2003 was $13.0 million primarily attributable to net income of $27.3 million and offset by the net release of the valuation allowance against our deferred tax assets of $18.1 million.

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 $16.4 million, $17.6 million and $11.1 million during 2005, 2004, and 2003, respectively, due to increases in our net sales. Inventories decreased by $552,000 in 2005 due to improved inventory management. Inventories increased by $5.1 million and $2.4 million during 2004 and 2003, respectively, to meet the increased demand for our products. Accrued liabilities increased by $25.5 million, $9.0 million, and $7.0 million during 2005, 2004, and 2003, respectively, due to our increased operating expenses and income taxes. In 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 $100.9 million, $11.2 million and $13.3 million in 2005, 2004 and 2003, respectively. Cash used in investing activities reflected purchases of property and equipment for all periods. 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. During 2003, cash used in investing activities reflected the net purchases of

investments of $4.5 million, and payment of $4.9 million in connection with the Sanatis acquisition. We expect our purchases of property and equipment in 2006 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 $22.3 million, $9.8 million and $6.6 million in 2005, 2004 and 2003, respectively. Cash provided 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. Cash provided during 2003 was attributable to proceeds from the issuance of common stock under the employee stock purchase plan of $1.4 million, exercise of stock options of $2.6 million and repayment of related party notes receivable of $2.5 million.

Contractual Cash Obligations. At December 31, 2005 we had contractual cash obligations as follows (in thousands):

	Payment Due by Periods				
	Total	**2006**	**2007-2008**	**2009-2010**	**After 2010**
Operating leases	$ 24,439	$ 3,178	$ 6,140	$ 5,629	$ 9,492
Consulting agreement	200	75	125	--	--
License agreement	15,000	5,000	10,000	--	--
Purchase commitments with contract manufactures and suppliers	6,697	6,697	--	--	--
Purchase obligations	7,470	7,470	--	--	--
Asset retirement obligation	441	--	--	--	441
Total commitments	$ 54,247	$ 22,420	$ 16,265	$ 5,629	$ 9,933

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, 2005. These future payments are subject to foreign currency exchange rate risk.

We are obligated to make a series of annual payments totaling up to $15.0 million related to the license acquisition agreement with Dr. Sandhu. 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 amount has been classified as current liability as of December 31, 2005.

On December 30, 2005, we entered into a definitive agreement to acquire InnoSpine, Inc. 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.

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, 2005. 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 current cash, cash equivalents, investments and cash generated from operations will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. 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 costs of these trials will be significant. If existing cash, cash equivalents, and cash generated from operations are insufficient to satisfy our liquidity requirements, whether as a result of investment in new markets or businesses through both internal or external business development, expansion of product lines, additional clinical trials, possible increased capital expenditures, or for other reasons related to our business, we may seek to sell additional equity securities or obtain a credit facility. The sale of additional equity or 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. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or eliminate certain of our business expansion activities.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 151, "Inventory Costs, an amendment of Accounting Principles Board (APB) Opinion No. 43, Chapter 4." SFAS No. 151 amends APB No. 43, Chapter 4, to clarify those abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges. In addition, SFAS No. 151 requires that allocation of fixed production overhead to the cost of conversion be based on the normal capacity of the production facilities. The provisions of SFAS No. 151 are effective for fiscal years beginning after June 15, 2005. Accordingly, the provisions of SFAS No. 151 will be effective January 1, 2006 for us. The adoption of SFAS No. 151 is not expected to have a material impact on our consolidated financial statements.

In December 2004, the FASB originally issued SFAS No. 123(R). SFAS No. 123(R) will require companies to measure all stock-based compensation awards using a fair value-based method and record such expense in their financial statements, including grants of employee stock options. In addition, the adoption of SFAS No. 123(R) will require additional accounting related to the income tax effects and

additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R), as amended, is effective for public companies for the first annual period beginning after June 15, 2005. Accordingly, the provisions of SFAS No. 123(R) will be effective January 1, 2006 for us. In March 2005, the SEC issued Staff Accounting Bulletin (SAB) No. 107, "TOPIC 14: Share-based payment." SAB No. 107 addresses the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides views regarding the valuation of share-based payment arrangements for public companies. SAB No. 107 was effective immediately.

We plan to adopt SFAS No. 123(R) using the modified prospective method, under which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No.123(R) for all share-based payments granted after the effective date and (b) based on the previous requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS No. 123(R) that remain unvested on the effective date. The amounts disclosed within our consolidated financial statement footnotes are not necessarily indicative of the amounts that will be expensed upon the adoption of SFAS No. 123(R). Compensation expense calculated under SFAS No. 123(R) may differ from amounts currently disclosed within our consolidated financial statement footnotes based on changes in the fair value of our common stock, changes in the number of options granted or the terms of such options, the treatment of tax benefits and changes in interest rates or other factors. The adoption of SFAS No. 123 (R) is expected to increase our cost of goods sold and operating expenses by approximately $30.0 million in 2006 based upon employee stock options outstanding as of December 31, 2005 and estimated 2006 option grants to employees. We expect the adoption of SFAS 123 (R) to have a significant impact on our consolidated income statements and the presentation of the consolidated statements of cash flows.

In March 2005, the FASB issued FASB Interpretation No. 47 (FIN No. 47), "Accounting for Conditional Retirement Obligations-an interpretation of SFAS No. 143." FIN No. 47 clarifies the timing of when a liability should be recognized for legal obligations associated with the retirement of a tangible long-lived asset. In addition, FIN No. 47 clarifies the treatment when there is insufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN No. 47 is effective no later than December 31, 2005. Retrospective application for interim financial information is permitted but is not required. The adoption of FIN No. 47 did not have a material impact on our consolidated financial statements.

In June 2005, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 05-6 (EITF No. 05-6), "Determining the Amortization Period for Leasehold Improvements Purchased after Lease Inception or Acquired in a Business Combination." EITF No. 05-6 clarifies that the amortization period for leasehold improvements acquired in a business combination or placed in service significantly after and not contemplated at or near the beginning of the lease term should be amortized over the shorter of the useful life of the assets or a term that includes the required lease periods and renewals that are reasonably assured of exercise at the time of the acquisition. EITF No. 05-6 is to be applied prospectively to leasehold improvements purchased or acquired in reporting periods beginning after June 29, 2005. The adoption of EITF No. 05-6 did not have a material impact on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest rate risk at December 31, 2005 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 84%, 88%, and 90% of our sales were made in U.S. dollars in 2005, 2004, and 2003, 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, 2005, 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, 2005. Management's assessment of the effectiveness of Kyphon's internal control over financial reporting as of December 31, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

KYPHON INC.
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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 2005 and 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2005, and an audit of its 2003 consolidated financial statements 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, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule 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.

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, 2005 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, 2005, 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, 2006

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

	Year Ended December 31,		
	2005	**2004**	**2003**
Net sales	$ 306,082	$ 213,414	$ 131,028
Cost of goods sold	35,843	24,734	16,794
Gross profit	270,239	188,680	114,234
Operating expenses:			
Research and development	46,383	22,238	16,031
Sales and marketing	144,768	106,103	69,538
General and administrative	34,951	25,972	16,328
Total operating expenses	226,102	154,313	101,897
Income from operations	44,137	34,367	12,337
Interest income	3,998	1,314	1,067
Other expense, net	(19)	(64)	(81)
Income before income taxes	48,116	35,617	13,323
Provision (benefit) for income taxes	18,280	13,900	(14,000)
Net income	$ 29,836	$ 21,717	$ 27,323
Net income per share:			
Basic	$ 0.70	$ 0.54	$ 0.71
Diluted	$ 0.66	$ 0.50	$ 0.65
Weighted-average shares outstanding:			
Basic	42,803	40,449	38,433
Diluted	45,336	43,670	42,090

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, 2005	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 76,149	$ 87,236
Investments	118,324	24,421
Accounts receivable, net of allowances of $1,577 in 2005 and $1,054 in 2004	55,480	42,347
Inventories	9,265	11,457
Prepaid expenses and other current assets	5,899	4,521
Deferred tax assets	10,488	13,537
Total current assets	275,605	183,519
Investments	--	4,142
Property and equipment, net	15,977	12,728
Goodwill and other intangible assets, less accumulated amortization of $88 in 2005 and $65 in 2004	15,377	5,039
Deferred tax assets	6,749	4,009
Other assets	2,924	3,952
Total assets	$ 316,632	$ 213,389
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,308	$ 5,544
Accrued liabilities	49,793	24,049
Total current liabilities	59,101	29,593
Deferred rent and other	4,051	4,161
Contingent purchase price	3,424	--
Total liabilities	66,576	33,754
Commitments and contingencies (Notes 4 and 6)		
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: 43,843 shares in 2005 and 41,355 shares in 2004		
Outstanding: 43,813 shares in 2005 and 41,325 shares in 2004	44	41
Additional paid-in capital	231,312	189,410
Treasury stock, at cost: 30 shares in 2005 and 2004	(201)	(201)
Deferred stock-based compensation	(116)	(2,113)
Accumulated other comprehensive income	172	3,489
Retained earnings (accumulated deficit)	18,845	(10,991)
Total stockholders' equity	250,056	179,635
Total liabilities and stockholders' equity	$ 316,632	$ 213,389

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,		
	2005	**2004**	**2003**
Cash flows from operating activities:			
Net income	$ 29,836	$ 21,717	$ 27,323
Adjustments to reconcile net income to net cash provided by operating activities:			
Provision for accounts receivable allowances	1,366	737	404
Provision for excess and obsolete inventories	757	158	550
Depreciation and amortization	4,274	2,817	2,237
Provision for deferred taxes	14,753	12,821	(18,129)
Loss on disposal of property and equipment	182	93	47
Stock-based compensation	3,091	3,852	5,966
Write-off of in-process research and development	--	--	636
Changes in operating assets and liabilities, net of effect of acquisition:			
Accounts receivable	(16,408)	(17,581)	(11,086)
Inventories	552	(5,127)	(2,373)
Prepaid expenses and other current assets	(1,270)	343	(1,452)
Other assets	939	(1,975)	(1,182)
Accounts payable	3,898	(40)	3,013
Accrued liabilities	25,540	9,030	7,031
Deferred rent and other	366	4,156	--
Net cash provided by operating activities	67,876	31,001	12,985
Cash flows from investing activities:			
Acquisition of property and equipment	(8,025)	(9,650)	(3,961)
Maturities and sales of investments	38,600	19,945	30,023
Purchases of investments	(129,030)	(21,523)	(34,537)
Payment for acquisition, net of cash	(2,448)	--	(4,850)
Net cash used in investing activities	(100,903)	(11,228)	(13,325)
Cash flows from financing activities:			
Proceeds from issuance of common stock	4,697	3,421	1,417
Proceeds from exercise of stock options	17,597	6,361	2,640
Proceeds from payment of related party note receivable	--	--	2,510
Net cash provided by financing activities	22,294	9,782	6,567
Effect of foreign exchange rate changes on cash	(354)	187	1,400
Net increase (decrease) in cash and cash equivalents	(11,087)	29,742	7,627
Cash and cash equivalents at beginning of year	87,236	57,494	49,867
Cash and cash equivalents at end of year	$ 76,149	$ 87,236	$ 57,494
Supplementary disclosure of non-cash investing and financing activities:			
Write-off of fully depreciated property and equipment	$ 847	$ 187	$ 84
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ --	$ --	$ 23
Cash paid during the year for income taxes	$ 1,696	$ 400	$ 43

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, 2003	37,330	$ 37	$ 163,354	$ (201)	$ (11,947)	$ 302	$ (60,031)	$ 91,514
Exercise of stock options	1,875	2	2,638	--	--	--	--	2,640
Issuance of common stock under employee stock purchase plan	176	--	1,417	--	--	--	--	1,417
Issuance of common stock upon exercise of warrants	59	--	--	--	--	--	--	--
Tax benefits from exercise of common stock options	--	--	3,496	--	--	--	--	3,496
Deferred stock-based compensation, net of cancellations	--	--	454	--	(454)	--	--	--
Amortization of deferred stock-based compensation	--	--	--	--	4,079	--	--	4,079
Non-employee stock-based compensation	--	--	--	--	1,887	--	--	1,887
Components of other comprehensive income:								
Changes in unrealized gains (losses) on available-for sale investments, net of taxes	--	--	--	--	--	(40)	--	(40)
Cumulative translation adjustments	--	--	--	--	--	1,934	--	1,934
Net income	--	--	--	--	--	--	27,323	27,323
Total comprehensive income								29,217
Balance at December 31, 2003	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

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 the United States, 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 of the major countries in Europe, and has subsidiaries in Canada, in Japan and in Australia.

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 of America dollar is the functional currency, are included in operations.

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 $7,251,000 and none, for the years ended December 31, 2005 and 2004, respectively. Cash equivalents are classified as available-for-sale and therefore are carried at fair market value. Related unrealized gains and losses were insignificant for the year ended December 31, 2005.

Investments

Restricted Cash. Under the terms of its facility lease, as amended, 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, and $1,000,000 which was classified as an other asset as of December 31, 2005 and 2004, respectively.

Available-for-Sale. All 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, 2005, 2004 and 2003. All of the Company's investments as of December 31, 2005 have maturities of one year or less. The Company's available-for-sale investments are summarized as follows (in thousands):

	December 31,	
	2005	2004
Asset-backed securities	$ 29,441	$ --
U.S. government and agency securities	6,506	4,494
Corporate debt secruities	82,377	19,927
Total short-term investments	$ 118,324	$ 24,421
Asset-backed securities	$ --	$ 747
Corporate debt securities	--	3,395
Total long-term investments	$ --	$ 4,142

	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
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
December 31, 2004				
U.S. government and agency securities	$ 4,507	$ --	$ (13)	$ 4,494
Corporate debt securities	19,992	--	(65)	19,927
Total short-term investments	$ 24,499	$ --	$ (78)	$ 24,421
Asset-backed securities	$ 747	$ --	$ --	$ 747
Corporate debt securities	3,400	--	(5)	3,395
Total long-term investments	$ 4,147	$ --	$ (5)	$ 4,142

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 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 one 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 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 Brussels, Belgium, and Sunnyvale, California to original condition upon lease termination. The Company estimated that gross expected future cash flows of approximately $662,000 would be required to fulfill these obligations.

As of December 31, 2005, the Company has recorded asset retirement obligations of approximately $441,000 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, 2005. The leasehold improvements are being amortized to depreciation expense over the term of the lease. Related amortization expense was approximately $61,000, $39,000 and none for the years ended December 31, 2005, 2004 and 2003, 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 for the Sanatis GmbH ("Sanatis") acquisition was completed in the first quarter of 2005, and it was determined that there was no impairment of goodwill at that time. There have been no events or changes in circumstances subsequent to the Company's annual test 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. Predicting future cash flows attributable to a particular asset is difficult, and requires the use of significant judgment.. 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, 2005, there have been no such impairments.

Concentrations of Credit Risk and Other Risks and Uncertainties

The Company's cash and cash equivalents are deposited with two major financial institutions in the United States and in some major financial institutions in European cities, Canada and Japan. Deposits in those institutions may exceed the amount of insurance provided on such deposits.

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's accounts receivable are derived from net sales earned from customers located in the United States and Europe. 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, 2005, 2004 and 2003. No customer accounted for more than 10% of total accounts receivable at December 31, 2005 and 2004.

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 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 are included in net sales and were approximately $1,151,000, $766,000 and $400,000 for the years ended December 31, 2005, 2004 and 2003, 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 $4,934,000, $3,515,000 and $3,552,000 for the years ended December 31, 2005, 2004 and 2003, 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,	
	2005	2004
Unrealized losses on available-for-sale investments, net of taxes	$ (137)	$ (47)
Translation adjustments	309	3,536
	$ 172	$ 3,489

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 options and common stock subject to repurchase. 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,		
	2005	2004	2003
Net income	$ 29,836	$ 21,717	$ 27,323
Weighted-average shares outstanding	42,803	40,451	38,461
Less: weighted-average shares subject to repurchase	--	(2)	(28)
Basic weighted-average shares outstanding	42,803	40,449	38,433
Dilutive effect of:			
Options to purchase common stock	2,533	3,218	3,610
Warrants	--	3	47
Diluted weighted-average shares outstanding	45,336	43,670	42,090
Net income per share:			
Basic	$ 0.70	$ 0.54	$ 0.71
Diluted	$ 0.66	$ 0.50	$ 0.65

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,		
	2005	2004	2003
Options to purchase common stock	575	509	146
Common stock subject to repurchase	--	--	13

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, 2005 and 2004, the Company held 30,000 shares of treasury stock. Treasury stock is accounted for using the cost method.

Accounting for Stock-Based Compensation

The Company has issued to certain employees options under the 1996 Plan and shares of common stock under stock purchase agreements, some of which contained repurchase provisions, with exercise prices below the deemed fair market value of the Company's common stock at the date of grant. The Company's right to repurchase shares of restricted common stock lapsed as these shares became vested to the employee. The Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock options or restricted common stock and the deemed fair market value of the Company's stock at the date of grant. This deferred stock-based compensation is amortized to expense on a straight line basis, over the period during which the Company's right to repurchase the restricted common stock lapses or the options become exercisable, generally four years.

The Company uses the intrinsic value method in accounting for its employee stock options, and presents disclosure of pro forma information as if the Company had accounted for stock based compensation using the fair value method. The following table, using the effective annual tax rates, provides a reconciliation of net income and net income per share to pro forma net income and pro forma net income per share had compensation cost for the Company's stock option grants to employees been determined based on the fair value of each option on the date of grant (in thousands, except per share amounts):

	Year Ended December 31,		
	2005	2004	2003
Net income, as reported	$ 29,836	$ 21,717	$ 27,323
Add: Stock-based employee compensation expense included in reported net income, net of taxes	1,136	1,784	2,447
Deduct: Total stock-based employee compensation expense, determined under fair value based method for all awards, net of taxes	(15,698)	(9,897)	(6,291)
Pro forma net income	$ 15,274	$ 13,604	$ 23,479
Net income per share			
Basic:			
As reported	$ 0.70	$ 0.54	$ 0.71
Pro forma	$ 0.36	$ 0.34	$ 0.61
Diluted:			
As reported	$ 0.66	$ 0.50	$ 0.65
Pro forma	$ 0.34	$ 0.31	$ 0.56

The weighted-average assumptions used are as follows:

	Year Ended December 31,		
	Employee Stock Options		
	2005	2004	2003
Risk-free interest rate	3.97%	3.04%	2.58%
Expected volatility	51%	62%	70%
Expected life (in years)	3.6	4.0	4.0
Dividend yield	--	--	--

	Employee Stock Purchase Plan		
	2005	2004	2003
Risk-free interest rate	3.21%	1.22%	1.15%
Expected volatility	58%	66%	66%
Expected life (in years)	1.3	1.5	0.7
Dividend yield	--	--	--

The weighted-average grant date fair value per share of options granted during the years ended December 31, 2005, 2004 and 2003 was $12.36, $12.61 and $8.84, respectively. The weighted average fair value for shares purchased through the employee stock purchase plan during the years ended December 31, 2005, 2004 and 2003 were $11.96, $6.80 and $3.96 per share, respectively.

In December 2004, the Financial Accounting Standards Board ("FASB") issued a Statement, "Share-Based Payment, an amendment of FASB Statements Nos. 123 and 95" ("SFAS No. 123(R)") that addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for either equity instruments of the company or liabilities that are based on the fair value of the company's equity instruments or that may be settled by the issuance of such equity instruments. Additional discussion regarding SFAS No. 123(R) is included in "Recent Accounting Pronouncements" below.

The Company accounts for equity instruments issued to non-employees at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. 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, and the vested portion of these options was remeasured at each vesting date. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. The fair value of the stock options granted were revalued at

each reporting date using the Black-Scholes option pricing model using the following weighted-average assumptions:

	Year Ended December 31,		
	2005	2004	2003
Risk-free interest rate	3.86%	4.21%	3.92%
Expected volatility	52%	65%	74%
Expected life (in years)	1.9	4.2	3.2
Dividend yield	--	--	--

The Company recognized stock-based compensation expense related to employee and non-employee options as follows (in thousands):

	Year Ended December 31,		
	2005	2004	2003
Cost of goods sold	$ 124	$ 317	$ 467
Research and development	949	1,134	2,232
Sales and marketing	1,416	1,360	2,012
General and administrative	602	1,041	1,255
	$ 3,091	$ 3,852	$ 5,966

Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4." SFAS No. 151 amends APB No. 43, Chapter 4, to clarify those abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges. In addition, SFAS No. 151 requires that allocation of fixed production overhead to the cost of conversion be based on the normal capacity of the production facilities. The provisions of SFAS No. 151 are effective for fiscal years beginning after June 15, 2005. Accordingly, the provisions of SFAS No. 151 will be effective January 1, 2006 for the Company. The adoption of SFAS No. 151 is not expected to have a material impact on the Company's consolidated financial statements.

In December 2004, the FASB originally issued SFAS No. 123(R). SFAS No. 123(R) will require companies to measure all stock-based compensation awards using a fair value-based method and record such expense in their financial statements, including grants of employee stock options. In addition, the adoption of SFAS No. 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R), as amended, is effective for public companies for the first annual period beginning after June 15, 2005. Accordingly, the provisions of SFAS No. 123(R) will be effective January 1, 2006 for the Company. In March 2005, the SEC issued Staff Accounting Bulletin ("SAB") No. 107, "TOPIC 14: Share-based payment." SAB No. 107 addresses the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides views regarding the valuation of share-based payment arrangements for public companies. SAB No. 107 was effective immediately.

The Company adopted SFAS No. 123(R) during the first quarter of 2006 using the modified prospective method. The amounts disclosed within the Company's footnotes are not necessarily indicative of the amounts that will be expensed upon the adoption of SFAS No. 123(R). Compensation expense calculated under SFAS No. 123(R) may differ from amounts currently disclosed within the Company's consolidated financial statement footnotes based on changes in the fair value of the Company's common stock, changes in the number of options granted or the terms of such options, the treatment of tax benefits and changes in interest rates or other factors. The adoption of SFAS No. 123(R) is expected to increase cost of goods sold and operating expenses by approximately $30,000,000 in the year ending December 31, 2006 based upon employee stock options outstanding as of December 31, 2005 and estimated 2006 option grants to employees. The Company expects the adoption of SFAS No. 123(R) to have a significant impact on the consolidated income statements and the presentation of the consolidated statements of cash flows.

In March 2005, the FASB issued FASB Interpretation No. 47 ("FIN No. 47"), "Accounting for Conditional Retirement Obligations-an interpretation of SFAS No. 143." FIN No. 47 clarifies the timing of when a liability should be recognized for legal obligations associated with the retirement of a tangible long-lived asset. In addition, FIN No. 47 clarifies the treatment when there is insufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN No. 47 is effective no later than December 31, 2005. Retrospective application for

interim financial information is permitted but is not required. The adoption of FIN No. 47 did not have a material impact on the Company's consolidated financial statements.

In June 2005, the EITF reached a consensus on Issue No. 05-6 ("EITF No. 05-6"), "Determining the Amortization Period for Leasehold Improvements Purchased after Lease Inception or Acquired in a Business Combination." EITF No. 05-6 clarifies that the amortization period for leasehold improvements acquired in a business combination or placed in service significantly after and not contemplated at or near the beginning of the lease term should be amortized over the shorter of the useful life of the assets or a term that includes the required lease periods and renewals that are reasonably assured of exercise at the time of the acquisition. EITF No. 05-6 is to be applied prospectively to leasehold improvements purchased or acquired in reporting periods beginning after June 29, 2005. The adoption of EITF No. 05-6 did not have a material impact on the Company's consolidated financial statements.

3. BALANCE SHEET COMPONENTS

Inventories (in thousands):

	December 31,	
	2005	**2004**
Raw materials	$ 4,331	$ 5,715
Work-in-process	1,656	1,042
Finished goods	3,278	4,700
	$ 9,265	$ 11,457

Property and Equipment (in thousands):

	December 31,	
	2005	**2004**
Furniture and fixtures	$ 2,405	$ 2,782
Computer software and hardware	8,194	4,929
Laboratory and manufacturing equipment	5,327	4,665
Leasehold improvements	6,366	5,943
	22,292	18,319
Less: Accumulated depreciation and amortization	(8,871)	(6,158)
Plus: Construction-in-progress	2,556	567
	$ 15,977	$ 12,728

Depreciation and amortization expense relating to the Company's property and equipment was approximately $4,216,000, $2,931,000 and $2,211,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Goodwill and Intangible Assets:

Changes in the carrying amount of goodwill during the years ended December 31, 2004 and 2005 are as follows (in thousands):

Goodwill at January 1, 2004	$ 4,584
Foreign currency translation	343
Goodwill at December 31, 2004	4,927
Foreign currency translation	(617)
Goodwill at December 31, 2005	$ 4,310

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

	December 31, 2005				
	Gross Carrying Amount	Foreign Currency Translation	Accumulative 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	

	December 31, 2004				
	Gross Carrying Amount	Foreign Currency Translation	Accumulative Amortization	Net	Amortization Period
Patent	$ 142	$ 35	$ (65)	$ 112	5 years
Total intangibles	$ 142	$ 35	$ (65)	$ 112	

Amortization expense for the Company's intangible assets was approximately $35,000, $39,000 and $26,000 for the years ended December 31, 2005, 2004 and 2003, respectively. Based on the intangible assets held at December 31, 2005, and exchange rates in effect as of the balance sheet date, the Company expects to recognize amortization expense of approximately $1,131,000 each in years 2006 and 2007, approximately $1,105,000 in 2008, and approximately $1,100,000 from 2009 to 2015.

Accrued Liabilities (in thousands):

	December 31,	
	2005	2004
Payroll and related expenses	$ 19,665	$ 13,052
License acquisition	15,000	--
Accrued income taxes	6,213	4,616
Legal, accounting and professional fees	2,367	1,620
Clinical studies	1,165	1,404
Travel and entertainment	1,184	466
Professional training courses	206	666
Other	3,993	2,225
	$ 49,793	$ 24,049

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.

In November 2005, the Company entered into an agreement with Dr. Harvinder Sandhu ("Dr. Sandhu"), a well-respected 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 and is obligated to make a series of payments totaling up to an additional $15,000,000. Based on management judgment, ability and intent, this amount has been classified as a current liability as of December 31, 2005. 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

Sanatis GmbH

In February 2003, the Company purchased all of the outstanding stock of Sanatis, a privately-held developer and manufacturer of orthopedic biomaterials based in Rosbach, Germany. The acquisition was made to add Sanatis' experience developing and manufacturing orthopedic biomaterials and to complement the Company's existing patent portfolio with Sanatis' intellectual property surrounding calcium-based biomaterials and delivery technologies. The total purchase consideration for Sanatis consisted of $4,492,000 in cash, and other acquisition costs of $201,000. In December 2003, the Company paid an additional $157,000 in cash to settle a contract Sanatis had with a third party prior to its acquisition and recorded this amount as additional allocation of the purchase price to goodwill.

The acquisition of Sanatis was accounted for using the purchase method of accounting and, accordingly, the results of operations of Sanatis have been included in the Company's consolidated financial statements subsequent to February 25, 2003. 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. The excess of the purchase price over the fair value of the net identifiable assets was allocated to goodwill. The purchase price was allocated as follows (in thousands):

Accounts receivable, net	$	16
Other current assets		17
Property and equipment, net		76
Other assets		67
Assumed liabilities		(176)
Purchased in-process research and development		636
Goodwill		4,072
Patents		142
	$	4,850

The fair value of the identifiable assets, including the portion of the purchase price attributed to the patents and purchased in-process research and development was determined by management. The income approach was used to value Sanatis' patents and purchased in-process research and development, 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 25% for the patent and purchased in-process research and development. No amount of goodwill is expected to be deductible for tax purposes.

The in-process projects related primarily to the development of resorbable calcium phosphate cements that are used for application as bone replacement materials. At the time of the purchase, the purchased in-process technology was not considered to have reached technological feasibility and it had no alternative future use. Accordingly, it was recorded as a component of operating expense. The revenues, expenses, cash flows and other assumptions underlying the estimated fair value of the purchased in-process research and development involve significant risks and uncertainties. The risks and uncertainties associated with completing the purchased in-process projects include retaining key personnel and being able to successfully and profitably produce, market and sell related products. Consistent with the expected timeline for approval of products in development at the time of the acquisition, in December 2003, the Company obtained a CE Mark for its *KyphOs* resorbable calcium phosphate bone filler material. The CE Mark cleared the product for sale in Europe.

InnoSpine, Inc.

On December 30, 2005, the Company entered into a definitive agreement to acquire 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

acquisition was made to allow the Company to expand its focus on spinal deformity correction 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.

The acquisition of InnoSpine was accounted for using the purchase method of accounting. The results of operations of InnoSpine will be 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 $3,516,000 has been included in the Company's determination of the total purchase price, of which $3,424,000 has been classified as a non-current liability. The remaining balance of approximately $92,000 has been classified within accrued liabilities. The total purchase consideration was allocated as follows (in thousands):

Developed technology	$ 11,000
Assumed liabilities	(267)
Contingent purchase price	(3,516)
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, Sanatis and InnoSpine. The unaudited pro forma financial information reflects the consolidated results of operations as if the acquisition of Sanatis and InnoSpine occurred at the beginning of 2003 and includes the amortization of the resulting other intangible assets. The pro forma data includes a non-recurring charge, consisting of in-process research and development of $636,000 in 2003. The unaudited pro forma financial data presented are not necessarily indicative of the Company's results of operations that might have occurred had the transaction been completed at the beginning of 2003, 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	2003
		(unaudited)	
Pro forma net sales	$ 306,082	$ 213,414	$ 131,028
Pro forma net income	$ 29,653	$ 21,552	$ 27,286
Pro forma net income per share:			
Basic	$ 0.69	$ 0.53	$ 0.71
Diluted	$ 0.65	$ 0.49	$ 0.65
Weighted-average shares outstanding:			
Basic	42,803	40,449	38,433
Diluted	45,336	43,670	42,090

6. 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 most of the major countries in Europe as well as Japan 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, 2005 and 2004, deferred rent of approximately $3,814,000 and $3,923,000, respectively, had been recorded. In 2004, the Company received cash incentives of $3,200,000 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 $2,423,000, $2,658,000 and $1,400,000 during 2005, 2004 and 2003, respectively.

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

Fiscal year ending December 31,	
2006	$ 3,178
2007	3,293
2008	2,847
2009	2,804
2010	2,825
Thereafter through 2014	9,492
Total	$ 24,439

Portions of the Company's payments for facility leases are denominated in foreign currencies and were translated in the tables above based their respective U.S. dollar exchange rates at December 31, 2005. These future payments are subject to foreign currency exchange rate risk.

In December 2003, the Company entered into a lease termination agreement to terminate its facility lease in May 2004 which was due to expire in March 2005. A lease termination charge of $1,200,000 was recorded in the year ended December 31, 2003 as a general and administrative expense. In addition, the amortization of the remaining leasehold improvements at that facility were accelerated and were fully amortized by the second quarter of 2004.

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).

Indemnification Agreements

From time to time, the Company enters into standard indemnification arrangements in the ordinary course of business with its business partners or customers. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for any future losses suffered or incurred by the indemnified party in connection with any intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual anytime after the execution of the agreement.

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 April 2004, the Company filed two patent infringement suits against Disc-O-Tech Medical Technologies Ltd., an Israel-based company doing business in the United States as Disc Orthopaedic Technologies Inc. ("Disc-O-Tech"). The Company filed suit in the United States District Court in Delaware and in the International Trade Commission ("ITC") in Washington, D.C. In the ITC proceeding in September 2004, the ITC entered an Order barring Disc-O-Tech from all further importation of its SKy Bone Expander device into the United States and from engaging in any further sales activities and uses of such imported products, thereby terminating the ITC proceeding in the Company's favor. In June 2005, the Delaware District court entered a Consent Judgment permanently enjoining Disc-O-Tech from further infringing the Company's patent rights with its SKy Bone Expander device or products not colorably different from the SKy Bone Expander, which took effect on July 22, 2005. This Consent Judgement bars further importation or selling of Disc-O-Tech's SKy Bone Expander device or colorable variations of that device for performing kyphoplasty in the US market. This concluded the litigation in the Company's favor without the possibility of further trial or appeal.

In November 2005, Dr. Harvinder Sandhu, a well-respected orthopaedic surgeon, and the Company filed suit in federal district court in Memphis, Tennessee against Medtronic Sofamor Danek 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, unjust enrichment, and correction of inventorship of several patents and patent applications presently owned by Sofamor Danek, including U.S. Patent No. 6,676,665. The suit also requests, among other relief, that Sofamor Danek 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 1990s and which he confidentially disclosed and discussed with Sofamor Danek. The complaint alleges that Sofamor Danek 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* project without his permission (see Note 4). The litigation is in its early stages; no trial date has yet been set. No provision for any liability that may result upon the 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.

7. 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, 2005.

Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan ("ESPP"), under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. The ESPP contains consecutive, overlapping twenty-four month offering periods. Each offering period includes four six-month purchase periods. 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 Company issued approximately 314,000, 338,000 and 176,000 shares of common stock in 2005, 2004, and 2003, respectively. At December 31, 2005, approximately 969,000 shares of common stock remained reserved for future issuance under the ESPP.

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 were 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, 2005, 155,000 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:

		Options Outstanding			
		Employees		Non-Employees	
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Balances, January 1, 2003	2,453,538	6,211,881	$ 3.79	614,064	$ 1.04
Additional shares reserved	1,867,817	--	--	--	--
Options granted	(2,150,500)	2,113,500	15.68	37,000	9.92
Options exercised	--	(1,453,406)	17.03	(421,459)	15.16
Options cancelled	494,842	(489,842)	4.56	(5,000)	3.00
Balances, December 31, 2003	2,665,697	6,382,133	8.14	224,605	2.27
Additional shares reserved	1,971,987	--	--	--	--
Options granted	(3,044,300)	3,044,300	24.29	--	--
Options exercised	--	(1,441,228)	4.33	(100,316)	1.25
Options cancelled	475,897	(475,897)	18.43	--	--
Balances, December 31, 2004	2,069,281	7,509,308	14.77	124,289	3.09
Additional shares reserved	2,123,774	--	--	--	--
Options granted	(2,042,800)	2,042,800	34.03	--	--
Options exercised	--	(2,115,910)	8.22	(57,972)	3.38
Options cancelled	424,103	(424,103)	21.72	--	--
Balances, December 31, 2005	2,574,358	7,012,095	$ 21.95	66,317	$ 2.84

The options outstanding and exercisable at December 31, 2005 are as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price
$0.05	100,000	2.81	$ 0.05	100,000	$ 0.05
$0.13	2,000	3.22	0.13	2,000	0.13
$0.31	25,700	4.10	0.31	25,700	0.31
$0.77	50,625	4.23	0.77	50,625	0.77
$1.00	445,741	5.23	1.00	445,321	1.00
$3.00	133,650	6.17	3.00	123,193	3.00
$6.95 - $9.50	394,951	7.07	8.64	150,473	8.68
$9.98 - $15.40	1,180,492	6.98	13.42	772,063	13.30
$19.40 - $23.86	876,436	8.23	21.63	316,064	21.19
$23.87 - $34.56	2,635,494	8.65	25.44	654,396	25.24
$35.32 - $45.34	1,233,323	9.60	38.90	98,744	38.20
	7,078,412	8.00	$ 21.78	2,738,579	$ 14.40
Employees	7,012,095	8.03	$ 21.95	2,678,929	$ 14.67
Non-employees	66,317	5.42	2.84	59,650	2.16
	7,078,412	8.00	$ 21.78	2,738,579	$ 14.40

At December 31, 2004, there were 2,802,620 options outstanding granted to employees and 112,205 options outstanding granted to non-employees which were exercisable.

8. 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. 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 $1,084,000, $620,000 and $372,000 in 2005, 2004 and 2003, respectively.

9. RELATED PARTY TRANSACTIONS

In August 1996, the Company entered into two consulting agreements with consultants who are stockholders of the Company, one of whom was formerly a member of the Board of Directors. Aggregate amounts paid for services for the years ended December 31, 2005, 2004 and 2003 were $207,000, $216,000 and $216,000, respectively.

10. INCOME TAXES

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

	Year Ended December 31,		
	2005	2004	2003
U.S.	$ 49,414	$ 35,153	$ 14,636
International	(1,298)	464	(1,313)
Total income before income taxes	$ 48,116	$ 35,617	$ 13,323
Current			
Federal	$ 15,576	$ 7,892	$ 4,152
State	4,399	1,285	907
Foreign	595	216	500
Total current	20,570	9,393	5,559
Deferred			
Federal	(731)	4,286	(15,803)
State	(1,569)	433	(3,336)
Foreign	10	(212)	(420)
Total deferred	(2,290)	4,507	(19,559)
Total provision (benefit) for income taxes	$ 18,280	$ 13,900	$ (14,000)

At December 31, 2005, the Company had approximately $500,000 and $4,800,000 in federal and state net operating loss carryforwards, respectively, to reduce future taxable income. The federal and state carryforwards have expiration dates beginning in 2023 and 2010, respectively, if not utilized.

At December 31, 2005, the Company had research and development tax credit carryforwards of approximately $2,236,000 and $3,564,000 for federal and state income tax purposes, respectively. If not utilized, the federal research and development tax credit carryforwards will expire beginning in 2018. The state research and development tax credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. Ownership changes for the Company, as defined, occurred on August 8, 1996, December 14, 1999 and May 17, 2002. In addition, the Company entered into a definitive agreement to acquire InnoSpine in December 2005. Ownership changes for InnoSpine, as defined, occurred on March 16, 2004 and December 30, 2005. In accordance with Internal Revenue Code Section 382, utilization of the carryforwards is subject to annual limitation. The annual limitation is not expected to result in the expiration of net operating losses prior to utilization.

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

	December 31,	
	2005	2004
Net operating loss carryforwards	$ 441	$ 5,507
Research and development credit carryforwards	4,675	3,638
Capitalized research and development costs	397	479
Purchased research and development	11,122	3,451
Other, accruals and reserves	4,910	4,471
Total deferred income tax assets	21,545	17,546
Intangibles	(4,367)	--
Total deferred income tax liabilities	(4,367)	--
Net deferred income tax liabilities	$ 17,178	$ 17,546

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, 2005, and 2004, the Company did not provide a valuation allowance against its deferred tax asset 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 (benefit) differed from the provision (benefit) computed at the U.S. statutory tax rate as follows:

	Year Ended December 31,		
	2005	2004	2003
Federal statutory rate	35.0 %	35.0 %	34.0 %
State, net of federal benefit	4.7	4.7	5.8
Deferred stock-based compensation	--	--	(35.7)
Tax reserves	0.4	(0.2)	30.6
Other permanent difference	1.4	4.0	1.6
Change in valuation allowance	--	--	(142.0)
Research and development tax credits	(3.5)	(4.5)	--
Total provision (benefit) for income taxes	38.0 %	39.0 %	(105.7)%

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,		
	2005	2004	2003	2005	2004	2003
United States	84 %	88 %	90 %	78 %	83 %	86 %
Germany	9	6	3	1	1	1
Other	7	6	7	21	16	13
	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 2005 and 2004 (in thousands, except per share amounts):

	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

	Year 2004 Quarter Ended			
	Mar. 31,	Jun. 30,	Sep. 30,	Dec. 31,
Net sales	$ 44,433	$ 50,745	$ 55,811	$ 62,425
Gross profit	39,516	44,745	49,564	54,855
Net income	$ 4,813	$ 4,703	$ 6,132	$ 6,069
Net income per share:				
Basic	$ 0.12	$ 0.12	$ 0.15	$ 0.15
Diluted	$ 0.11	$ 0.11	$ 0.14	$ 0.14
Weighted-average shares outstanding:				
Basic	39,761	40,145	40,733	41,147
Diluted	43,332	43,452	43,734	43,938

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, 2003, 2004 AND 2005
(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 2003	$ 100	404	4	$ 500
Fiscal year ended 2004	500	737	183	1,054
Fiscal year ended 2005	$ 1,054	1,366	843	$ 1,577
Allowance for inventories valuation:				
Fiscal year ended 2003	$ 607	550	532	$ 625
Fiscal year ended 2004	625	158	254	529
Fiscal year ended 2005	$ 529	757	295	$ 991
Valuation allowance for deferred tax assets:				
Fiscal year ended 2003	$ 20,398	--	20,398	$ --
Fiscal year ended 2004	--	--	--	--
Fiscal year ended 2005	$ --	--	--	$ --

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. The Chief Executive Officer, Richard W. Mott, and Chief Operating Officer, Arthur T. Taylor, 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 it files or submits with the Securities and Exchange Commission under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, and to ensure that information required to be disclosed by Kyphon in the reports that it files or submits under the Exchange Act is accumulated and communicated to Kyphon's management, including its 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 Kyhon's internal control over financial reporting is included on page 51 of Item 8 of this Annual Report on Form 10-K, and the attestation report of our independent registered public accounting firm on page 53 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, 2005, 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 AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2006 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2005 fiscal year (the “2006 Proxy Statement”).

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the 2006 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 2006 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item is incorporated by reference to the 2006 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the 2006 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
3.2	Amended and Restated Certificate of Incorporation of the registrant.
3.4	Amended and Restated Bylaws of the registrant.
4.1 (1)	Specimen common stock certificate of the registrant.
10.1* (1)	Form of Indemnification Agreement for directors and executive officers.
10.2* (1)	1996 Stock Option Plan, including form of option agreement.
10.3* (1)	2002 Stock Plan, including form of option agreement.
10.4* (1)	2002 Employee Stock Purchase Plan, including form of employee stock purchase plan subscription agreement.
10.5* (1)	2002 Director Option Plan, including form of option agreement.
10.8 (1)	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.
10.8.1 (1)	Third Amendment to Lease dated March 29, 2002 for office space located at 1350 Bordeaux Drive, Sunnyvale, CA 94089.
10.9* (1)	Employment Agreement between the registrant and Gary L. Grenter dated July 16, 2001.
10.10 (1)	Promissory Note Secured by Deed of Trust between the registrant and Gary L. Grenter dated December 31, 2001.
10.11 (1)	Amended and Restated Stockholder Rights Agreement effective as of December 14, 1999, among the registrant and certain stockholders of the registrant.
10.12* (2)	Employment Agreement between the registrant and Richard W. Mott dated September 3, 2002.
10.13†(2)	Sublicense Agreement effective as of August 19, 2002, between the registrant and Bonutti Research, Inc.
10.14 (3)	Stock Purchase Agreement by and between Kyphon and the shareholders of Sanatis GmbH, dated February 15, 2003.
10.15 (4)	Lease dated September 18, 2003 for office spaces located at 1221 Crossman Avenue and 480 Java Drive, Sunnyvale, California.
10.16* (5)	Form of Severance Agreement entered into by and between Kyphon Inc. and its executive officers.
10.17* (5)	Severance Agreement, dated January 28, 2005, entered into by and between Kyphon Inc. and Richard W. Mott.
10.18 (6)	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.
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 Registration Statement on Form S-1 (Registration No. 333-83678), which was declared effective on May 16, 2002.
(2) Incorporated by reference from our Quarterly Report on Form 10-Q as filed with the Securities Exchange Commission on November 13, 2002.
(3) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities Exchange Commission on March 7, 2003.
(4) Incorporated by reference from our Quarterly Report on Form 10-Q as filed with the Securities Exchange Commission on November 14, 2003.
(5) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities Exchange Commission on February 1, 2005.
(6) Incorporated by reference from our Quarterly Report on Form 10-Q as filed with the Securities Exchange Commission on November 1, 2005.

* 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 2nd day of March, 2006.

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 Arthur T. Taylor, 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)	March 2, 2006
/s/ ARTHUR T. TAYLOR **Arthur T. Taylor**	Vice President, Chief Operating Officer (Principal Accounting and Financial Officer)	March 2, 2006
/s/ JAMES T. TREACE **James T. Treace**	Chairman of the Board	March 2, 2006
/s/ STEPHEN M. CAMPE **Stephen M. Campe**	Director	March 2, 2006
/s/ DOUGLAS W. KOHRS **Douglas W. Kohrs**	Director	March 2, 2006
/s/ JACK W. LASERSOHN **Jack W. Lasersohn**	Director	March 2, 2006
/s/ LOUIS J. LAVIGNE, JR. **Louis J. Lavigne, Jr.**	Director	March 2, 2006
/s/ KAREN D. TALMADGE, PH.D. **Karen D. Talmadge, Ph.D.**	Executive Vice President, Co-Founder, Chief Science Officer and Director	March 2, 2006
/s/ ELIZABETH H. WEATHERMAN **Elizabeth H. Weatherman**	Director	March 2, 2006