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, 2004 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 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 check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). YES [X] NO [ ]

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, 2004 (which is the last business day of registrant's most recently completed second fiscal quarter), as reported on the NASDAQ National Market was approximately $628.8 million. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 15, 2005, the Registrant had 41,812,166 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 2004 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 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations – Factors Affecting Future Operating Results" section of this Form 10-K. The reader is cautioned 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

We are 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 kyphoplasty. Our commercial products consist of our *KyphX*® instruments, used to treat spine fractures during 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 spine fracture treatments are either highly invasive or are only pain management therapies.

We believe there are approximately 700,000 clinically-diagnosed spine 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, 2004, we had trained more than 5,600 physicians in the United States, Europe and Asia Pacific on the kyphoplasty technique, and these physicians had used our instruments in over 110,000 spine surgeries. To support these physicians, we have built a large and growing worldwide direct sales organization that numbered in excess of 350 professionals as of December 31, 2004. 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, 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 GmbH, our *KyphOs*™ calcium phosphate cement, in December 2003, and we are now authorized to sell this material in Europe.

We intend to pursue the research, development and commercialization of spine products arising from this acquisition and from our license to a portfolio of patents we acquired from Bonutti Research in August 2002, 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-spine 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 spine fractures include trauma, cancerous and benign tumors and infection.

Unrepaired spine 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 spine 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 spine 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 spine 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 spine 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*. Spine fractures can cause prolonged or permanent disability, reducing mobility and impairing other physical functions. Patients with spine 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 spine 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 spine fracture increased the risk of subsequent spine fractures by five times compared to the risk of someone suffering a first fracture. The presence of two or more spine fractures increased the risk of additional spine 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 spine fractures increased the risk of hip fracture by 4.5 times, while the presence of two or more spine fractures increased the risk of hip fracture by 7.2 times.

- *Emotional Effects*. Studies have demonstrated that the physical deformity caused by spine 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 Spine 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 believe 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 spine 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 Spine Fractures

When treating a patient with a spine 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 spine 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 spine 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 spine 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 health care;
- 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 spine 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 kyphoplasty. Our instruments have also been used in open surgical procedures. We generally refer to our instruments as the *KyphX* instruments.

Minimally invasive spine fracture surgeries using our *KyphX* instruments typically involve the insertion of two of our disposable proprietary balloon devices into the fractured bone, although only one balloon may be used occasionally. 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 Food and Drug Administration ("FDA") in the U.S. for kyphoplasty.

We have trained more than 5,600 physicians, including approximately 1,700 overseas in the use of our *KyphX* instruments. We believe these physicians have used our instruments in over 110,000 kyphoplasty surgeries involving spine fractures.

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 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 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 kyphoplasty and 2,408 patients treated with vertebroplasty. The data in the published literature demonstrates that 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

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 Kyphoplasty Spine Surgery

Spine 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 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 Kyphoplasty Surgery Using Our KyphX Instruments as the Standard of Care for Spine Fracture Repair.* We intend to support clinical trial efforts to establish that treating spine fractures with 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 Spine 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, 2004, our direct spine sales organization included over 350 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 with our Spine Educational Field Force.* 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 kyphoplasty procedure as an alternative to conventional spine fracture treatment and conservative pain management therapies. During 2003, we deployed an independently managed sales team to call on primary care physicians to educate them about the use of our *KyphX* instruments in minimally invasive spine surgery. As of December 31, 2004, we had expanded the number of our sales force personnel involved in this program to approximately 60 individuals in the United States. We have also initiated various marketing programs aimed at raising the awareness about the clinical outcomes of 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 kyphoplasty procedures, as well as the short- and long-term outcomes associated with the use of our products in kyphoplasty. In Europe, we have initiated a post-marketing clinical study comparing 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 kyphoplasty procedure. We expect to complete patient enrollment during 2005, and we will continue to monitor these patients for two years of follow-up evaluations. 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 Physician Reimbursement in the United States*. In all 50 states and in the District of Columbia, Medicare reimburses 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 trials and support from leading physicians who are familiar with the *KyphX* instruments to continue to support further appropriate levels of physician reimbursement, including through the American Medical Association's ("AMA") Current Procedure Terminology ("CPT") process.

- *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 kyphoplasty procedures. We will invest significant resources in our efforts to enter the Japanese market, including initiating a local clinical trial during 2005, 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. We intend to pursue the research, development and commercialization of spine products arising from these acquisitions to complement our existing *KyphX* instruments and leverage our experienced sales force and expertise in spinal fracture treatments. The commercialization of products from these acquisitions 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 spine fractures as well as opportunities outside of the spine.

Our Products

We currently sell the following instruments, as well as our proprietary brands of bone filler materials which are used in spine 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 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. Products introduced during 2004 include the *KyphX Elevate* Inflatable Bone Tamp, the *KyphX Exact* Inflatable Bone Tamp, and the *KyphX Express* Inflatable Bone Tamp, all of which are variations of the basic *KyphX Xpander* Inflatable Bone Tamp.

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 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 kyphoplasty in April 2004 and began immediate commercialization in the U.S.

We obtained a CE Mark for our first product from our acquisition of Sanatis GmbH, our *KyphOs* calcium phosphate cement, in December 2003, and started selling this bone filler material in Europe during 2004.

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 350 professionals as of December 31, 2004. Our target customer base includes the approximately 6,000 to 7,000 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 2004, 2003 or 2002.

Our U.S. sales organization is currently comprised of 168 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. In 2003, we initiated a spine education specialist program whereby selected sales representatives call on primary care physicians to educate them about our *KyphX* instruments. As of December 31, 2004, we had expanded the number of our U.S. sales force personnel involved in this program to approximately 60 individuals in the United States. We have also trained more than 5,600 physicians in the U.S., Europe and Asia Pacific to perform the kyphoplasty procedure with our *KyphX* instruments.

We have operated mainly in the United States, and 88%, 90% and 93% of our sales were made in U.S. dollars in 2004, 2003 and 2002, respectively. The majority of our international sales are derived from European Union countries. Our European operations are 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 still in the very 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 also formed our Canadian subsidiary and have begun to sell our products in Canada through a direct sales force. In 2005, we plan to begin selling our products in Brazil and Mexico through distributors, and to investigate other selected South American and Asia-Pacific countries regarding potential product selling activities.

Reimbursement

Establishing reimbursement for any new medical technology is a challenge in the current environment of cost containment, managed care and Medicare. To successfully establish reimbursement coverage, we must prove that our technology improves health outcomes, such as quality of life or functional ability, and does so in a cost-effective manner.

Payment for patient care in the United States is generally made by private insurers. These insurers act on their own behalf or under contract with the U.S. government to administer the Medicare program. Medicare covers most of the medical expenses of individuals ages 65 and over. Approximately 90% of patients with spine fractures caused by osteoporosis are covered by Medicare, while the rest are covered primarily by private insurers. Private insurers often follow the coverage and payment policies of Medicare. Most patients with spine fractures caused by cancer and trauma are covered by private insurers.

For inpatient and outpatient spine fracture reduction procedures, the Center for Medicare and Medicaid Services (“CMS”), reimburses hospitals for a prospectively determined amount, regardless of the actual cost for such treatment, based primarily on the patient's diagnosis and the nature of the care provided during the hospital stay. We receive payment directly from the hospital for our instruments, and Medicare reimburses the hospital for its costs of admitting (for inpatient procedures) and treating the patient, whether inpatient or outpatient, including the purchase of our instruments, under existing applicable codes. The physician who performs the procedure is reimbursed under a different system that is based on procedure codes, called current procedural terminology, or CPT, codes. Government imposed limits on reimbursement of hospitals and other health care providers have significantly impacted the willingness of hospitals, clinics and doctors to utilize technologies and procedures that are not eligible for appropriate levels of Medicare reimbursement.

In all 50 states and in the District of Columbia, Medicare reimburses physicians at varying payment levels for their services when they perform procedures using our *KyphX* instruments. Currently, Medicare reimburses physicians who use our *KyphX* instruments on a state-by-state basis. This form of reimbursement is not uniform across all states because there is presently no national CPT code or associated national payment rate relating to procedures using our instruments, and a national CPT code may not exist for some time. As a result, unless a state has a published policy regarding reimbursement, physicians must report procedures using our instruments under an unlisted CPT code, submit their bills for review and request payment based on the time, work and risk involved in the procedure. We intend to continue to use the results of future clinical studies, peer-reviewed physician journal articles, and support from leading physicians who are familiar with our *KyphX* instruments to further support physician reimbursement for procedures using our instruments. In addition, in 2004, medical societies familiar with the kyphoplasty procedure applied for the establishment of a national payment rate through a CPT code. In the fourth quarter of 2004, the AMA CPT Editorial Panel considered multiple applications for a national CPT code for spine specialist reimbursement for kyphoplasty, which is the initial step in the CPT process. We have learned that the AMA CPT Editorial Panel has decided to support the establishment of a national CPT code for kyphoplasty. We also understand that the relative value survey process involving input from the medical community regarding the kyphoplasty procedure, may begin in the first or second quarter of 2005. We understand that upon conclusion of the survey process and determination of the appropriate

reimbursement level, the results may be publicly communicated in the fourth quarter of 2005 in the Federal Register. Despite these developments, we cannot be certain that a CPT code for kyphoplasty with an associated value ultimately would become effective in 2006, or at all. We also cannot assure you that the establishment of a national CPT code, if any, would be beneficial to our business since the reimbursement level associated with the national CPT code could be less than what physicians in some states are presently receiving and may not be deemed sufficient by physicians to justify the use of our products to perform kyphoplasty.

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 April 2004 with no non-compliance reports issued, continuing our facility as ISO 13485:1996 certified. In January 2005, we received ISO 13485:2003 certification of our manufacturing facilities. 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 significant 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, treatment of spinal fractures and other spinal deformities and disease states. 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 $22.0 million, $15.2 million and $10.1 million in 2004, 2003 and 2002, respectively. 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 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 spine 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 kyphoplasty. Competition is likely to increase the awareness and frequency of alternative procedures to kyphoplasty. We are also beginning to see introduction by competitors of instruments designed to achieve both void creation and fracture reduction. Particularly in Europe, these products are initially being marketed as more effective and less expensive than our *KyphX* products although limited entry into the U.S. market has also begun for some of these 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 spine 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, 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 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 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, 2004, we had 37 issued U.S. patents, 28 issued foreign patents, 51 pending U.S. patent applications, 114 pending foreign applications and 26 patents that we exclusively licensed from Bonutti Research in August 2002.

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.

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.

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 would have a material adverse effect on our business, results of operations and financial condition.

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 a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance. 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 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 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 the 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, and manufacturing 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 most 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 relatively low number of MDRs for our products; more may be required as the number of procedures performed with our products increases. Through 2004, 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.

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 15 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.

Employees

As of December 31, 2004, we had a total of 706 employees, with 108 people in operations, 65 people in research and development, 433 people in sales, marketing and professional education and 100 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 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 possible after they are filed with the SEC.

ITEM 2. PROPERTIES

Our United States operations and our corporate headquarters are located in an approximately 107,000 square foot facility in Sunnyvale, California, where we conduct our manufacturing, warehousing, research, regulatory and administrative activities. The facility is leased through August 2014. Under the terms of the lease agreement, we have the option to rent an adjacent existing facility as well as an option to have additional square footage built and leased to us in the same surrounding campus.

Our European operations are located in an approximately 22,000 square foot facility in Brussels, Belgium, where we conduct sales, clinical, regulatory and administrative activities. The facility is leased through December 2011 and includes offices, storage and warehouse facilities. We also have a leased research facility located in Rosbach, Germany through January 2008. In addition, we have leased individual sales offices in most of the major countries in Europe and offices in Japan and Canada, expiring at various dates through 2013.

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 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 as Disc Orthopaedic Technologies Inc. ("Disc-O-Tech"). 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, which thereby terminated the ITC proceeding in our favor. An enforcement proceeding against Disc-O-Tech in the ITC may later be initiated if it is determined that Disc-O-Tech is not complying fully with the ITC Order. In Delaware, our complaint presently alleges, among other things, that by importing, manufacturing, distributing and promoting its SKy Bone Expander device and related tools for use in kyphoplasty procedures, Disc-O-Tech is willfully infringing five of our U.S. patents, all of which generally concern the use of various medical devices to repair spinal compression fractures, and seeks enhanced damages and a permanent injunction for its willful infringement. Trial is set for June 2005. We are using the information discovered during the ITC proceeding about Disc-O-Tech's business activities to prosecute our case against Disc-O-Tech in Delaware and will continue to do so vigorously. Costs related to this litigation will be dilutive to our earnings.

We are presently party to no other material litigation.

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 2003		
First quarter	$ 11.00	$ 7.64
Second quarter	$ 14.87	$ 8.10
Third quarter	$ 25.85	$ 15.14
Fourth quarter	$ 29.40	$ 20.56
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

We had 139 stockholders of record as of February 15, 2005.

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.

The information required by this item regarding securities authorized for issuance under equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

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

On May 17, 2002, we completed our initial public offering, including exercise of the underwriters' over-allotment option, of 6,900,000 shares at an initial public offering price of $15.00 per share, for aggregate cash proceeds of approximately $103.4 million. Our managing underwriters for the offering were U.S. Bancorp Piper Jaffray Inc., Banc of America Securities LLC and Bear, Stearns & Co. Inc. In connection with the offering, we paid approximately $7.2 million in underwriting discounts and commissions and approximately $1.3 million in other offering costs. After deducting the underwriting discounts and commissions and the offering costs, our net proceeds from the offering, including the over-allotment option, were approximately $94.9 million. As of December 31, 2004, all proceeds from the offering had been utilized.

Our Board of Directors approved a stock repurchase program on November 7, 2002 pursuant to which up to 2,000,000 shares of our outstanding common stock may be repurchased from time to time. 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. No shares were repurchased under this program in 2004 or 2003. In 2002, we repurchased 30,000 shares pursuant to this repurchase program.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following tables reflect 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, 2004, 2003 and 2002, and the consolidated balance sheet data as of December 31, 2004 and 2003 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, 2001 and 2000, and the consolidated balance sheet data as of December 31, 2002, 2001 and 2000 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 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.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Net sales	$ 213,414	$ 131,028	$ 76,316	$ 36,073	$ 6,076
Cost of goods sold	24,734	16,794	10,416	8,108	3,606
Gross profit	188,680	114,234	65,900	27,965	2,470
Operating expenses:					
Research and development	22,043	15,237	10,145	7,859	4,516
Sales and marketing	104,299	68,676	43,509	27,891	11,399
General and administrative	27,971	17,348	12,540	9,720	5,343
Purchased in-process research and development	--	636	12,250	--	--
Total operating expenses	154,313	101,897	78,444	45,470	21,258
Income (loss) from operations	34,367	12,337	(12,544)	(17,505)	(18,788)
Interest income (expense) and other, net	1,250	986	(2,794)	(309)	1,086
Net income (loss) before income taxes	35,617	13,323	(15,338)	(17,814)	(17,702)
Provision (benefit) for income taxes	13,900	(14,000)	--	--	--
Net income (loss)	$ 21,717	$ 27,323	$ (15,338)	$ (17,814)	$ (17,702)
Net income (loss) per share:					
Basic	$ 0.54	$ 0.71	$ (0.63)	$ (9.06)	$ (15.55)
Diluted	$ 0.50	$ 0.65	$ (0.63)	$ (9.06)	$ (15.55)
Weighted-average shares outstanding:					
Basic	40,449	38,433	24,405	1,967	1,139
Diluted	43,670	42,090	24,405	1,967	1,139

	As of December 31,				
	2004	2003	2002	2001	2000
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 115,799	$ 85,479	$ 74,303	$ 3,352	$ 8,898
Working capital (deficit)	153,926	86,564	83,504	(5,623)	10,213
Total assets	213,389	154,480	101,524	18,287	15,195
Convertible promissory notes	--	--	--	12,000	--
Long-term debt	--	--	--	43	132
Redeemable convertible preferred stock	--	--	--	38,024	38,024
Deferred stock-based compensation, net	(2,113)	(6,435)	(11,947)	(16,082)	(6,781)
Total stockholders' equity (deficit)	$ 179,635	$ 134,250	$ 91,514	$ (37,667)	$ (25,134)

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

Introduction

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 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. In some cases, forward-looking statements can be identified by the use of forward-looking terminology such as “believe,” “estimate,” “may,” “can,” “will,” “intend,” “objective,” “plan,” “expect” or “anticipate” or the negative of these terms or other comparable terminology. 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 “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors Affecting Future Operating Results”, (“MD&A”) section of this report. The reader is cautioned not to place undue reliance on these forward looking statements, which reflect management’s analysis only as of the date of this Annual Report on 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. MD&A 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.

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

- *Deferred and stock-based compensation.* This section provides the method and financial reporting of our accounting for stock options granted to employees prior to our initial public offering and grants to 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, 2004.

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

- *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.

- *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 MD&A 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 orthopedic 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 kyphoplasty procedures. Our commercial products consist of our *KyphX* instruments used to treat spine fractures during kyphoplasty, including our proprietary *KyphX* balloon technology and our proprietary brands of bone filler materials. Surgeons use these instruments and bone filler materials to help repair fractures during kyphoplasty procedures. Most alternative spine fracture treatments are either highly invasive or are only pain management therapies.

Our corporate headquarters and U.S. operations are located in Sunnyvale, California, where we conduct our manufacturing, warehousing, research, regulatory and administrative activities. Outside the U.S., we operate sales, clinical, regulatory and administrative facilities in Brussels, Belgium, research and biomaterial manufacturing facilities in Rosbach, Germany, a clinical, regulatory and administrative facility in Japan, and we have direct selling operations in most of the major countries in Europe and in Canada. Our global distribution network consists of a direct sales force in excess of 350 individuals who market our products in the U.S., most of the major countries in Europe, Canada and Japan and distributors and sales agents in other countries in which we do not have a direct sales force.

We moved our U.S. headquarters at the end of the first quarter of 2004 to our present location from our prior location which was also in Sunnyvale, California. The move of our manufacturing facility was completed during the second quarter of 2004.

Effective August 11, 2004, Arthur T. Taylor assumed the role as our Vice President, Chief Financial Officer and Treasurer. Mr. Taylor most recently was Chief Financial Officer for Terayon Communication Systems, Inc. of Santa Clara, California.

Effective October 1, 2004, Louis J. Lavigne, Jr., Executive Vice President and Chief Financial Officer of Genentech, Inc., was appointed to our Board of Directors as Chairman of the Audit Committee and a member of the Board's Nominating and Corporate Governance Committee.

In the fourth quarter of 2004, we adjusted the responsibilities of some of our executive team to better serve our needs. Bert Vandervelde took over responsibility for all of our activities outside of the U.S., as Vice President and General Manager, International. Elizabeth A. Rothwell, Vice President, Operations, assumed responsibility for our research and development activities, to permit Avram A. Edidin to focus on external development opportunities as Vice President, Emerging Technologies. Bradley W. Paddock, employed by us for over five years in various sales capacities and intimately familiar with our sales strategies and objectives, assumed the position of Vice President, U.S. Sales, following the resignation of Anthony J. Recupero to pursue other business opportunities, effective December 31, 2004. Mr. Recupero remains a consultant to Kyphon through June 2006. We may make further adjustments to the responsibilities and reporting structure of our executive team as we continue to grow.

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 and *KyphX* Bone Biopsy Device, as well as our recently cleared *KyphX HV-R* Bone Cement and our CE-Marked *KyphOs* calcium phosphate from our acquisition of Sanatis GmbH.

During 2004, our business experienced significant growth. Net sales in 2004 increased to $213.4 million, compared to $131.0 million in 2003, representing growth of 63%. We trained approximately 1,700 physicians to use our products during 2004 in the United States and Europe. In the U.S., we added over 350 new hospitals to our customer base during that same period. We continued a program whereby additional spine education specialists were hired with a primary role of educating referring primary care physicians and other medical advisors on kyphoplasty as an alternative to conventional spine fracture treatment and conservative pain management therapies.

In April 2004, we received 510(k) clearance from the FDA to market our *KyphX HV-R* Bone Cement for the fixation of osteoporosis-related pathological fractures of the vertebral body during kyphoplasty. In July 2004, we received FDA clearance to expand the indications for use for our bone cement to also include fixation of pathological fractures due to cancer or benign lesions during kyphoplasty, as well as specific clearance of our *KyphX* Inflatable Bone Tamps for fracture reduction or void creation during kyphoplasty. These clearances allow us to promote numerous short and long-term benefits associated with kyphoplasty procedures.

Recently, we concluded an extensive review of the published clinical literature describing the results for 897 patients treated with kyphoplasty and 2,408 patients treated with vertebroplasty. The data in the published literature demonstrates that 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. As a result, we have now introduced the corresponding comparative claims into our educational and marketing materials.

In April 2004, we filed two patent infringement suits against Disc-O-Tech, an Israel-based company doing business in the United States. We filed suit in the United States District Court in Delaware and in the 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, which thereby terminated the ITC proceeding in our favor. An enforcement proceeding against Disc-O-Tech in the ITC may later be initiated if it is determined that Disc-O-Tech is not complying fully with the ITC Order. In Delaware, our complaint presently alleges, among other things, that by importing, manufacturing, distributing and promoting its SKy Bone Expander device and related tools for use in kyphoplasty procedures, Disc-O-Tech is willfully infringing five of our U.S. patents, all of which generally concern the use of various medical devices to repair spinal compression fractures, and seeks enhanced damages and a permanent injunction for its willful infringement. Trial is set for June 2005. We are using the information discovered during the ITC proceeding about Disc-O-Tech's business activities to prosecute our case against Disc-O-Tech in Delaware and will continue to do so vigorously. Costs related to this litigation will be dilutive to our earnings.

In addition to Disc-O-Tech, several other companies either have already introduced one or more products into the U.S. and/or foreign markets to compete with our *KyphX* instruments for treating vertebral fractures or may be on the verge of doing so. To the extent any competing products infringe our patents; we will consider how best to protect our market space as well as whether to take action against any potentially infringing activities. As a result, we may decide that litigation or other legal activity to seek to protect and enforce our rights, in addition to our ongoing actions against Disc-O-Tech, would be appropriate. Regardless of if we do so, however, we likely will have to compete with these competitive products for some period of time and may ultimately not succeed in enforcing our rights. We may not have the ability to prevent those products from remaining on the market in at least some geographic locations, and we may lose market share or have our growth impeded as a result.

We have had several recent encouraging developments related to reimbursement for our products. First, in May 2004, the Centers for Medicare and Medicaid Services ("CMS") ICD-9 Coordination and Maintenance Committee issued and published a recommendation for a specific ICD-9-CM in-patient procedure code for the kyphoplasty procedure. On August 11, 2004, this rule was approved and the kyphoplasty procedure was assigned ICD-9-CM code 81.66 to go into effect on October 1, 2004. This code was assigned to the following five diagnosis related groups ("DRG") codes: 233, 234, 442, 443 and 486. DRG codes establish the payment levels that hospitals can claim reimbursement from Medicare and Medicaid and are in turn, key factors in determining reimbursement levels and ultimately the quantity of products used in procedures such as kyphoplasty. At this time it is not yet clear how each of these codes will be applied, especially 442, 443 and 486, which are new. We anticipate increased clarification as more information becomes available from CMS in the next few months.

Second, in November 2004, CMS published the Final Rule on the Medical Hospital Outpatient Prospective System ("HOPPS") and created new and distinct hospital outpatient procedure codes for kyphoplasty, C9718 and C9719. These new C-codes are assigned to APC 51 and are effective January 1, 2005. At the

reimbursement level presently in effect, we do not anticipate that many kyphoplasty procedures will be performed on an outpatient basis.

On a national level, the Healthcare Common Procedure Coding System ("HCPCS") National Editorial Panel established two new HCPCS "S" codes for kyphoplasty effective January 1, 2004. These S codes are intended for use by private payors, such as the Blue Cross Blue Shield Association and the Health Insurance Association of America, although no payment level is associated with these codes. In addition, policy and/or bulletin coverage is now established in 40 states, with the remaining states providing coverage on a case-by-case basis. The private payor community has also shown significant interest in establishing reimbursement policies for kyphoplasty. Specifically, Blue Cross Blue Shield has now adopted policy coverage for kyphoplasty in 31 states, and a number of private payors nationwide have also adopted policy coverage. However, there are some private payors that may continue to perceive the procedure which uses our products as experimental and thus not subject to reimbursement. Another challenge we face is to achieve consistent and/or increased payment levels among the different insurers. We continue to focus on addressing these issues.

There was also progress in surgeon reimbursement during 2004. Presently, no national CPT code exists for spine specialist reimbursement under Medicare for performing kyphoplasty, and a CPT code may not exist for some time. Physicians presently must report procedures using our instruments under an unlisted CPT code. In the fourth quarter of 2004, the AMA CPT Editorial Panel considered multiple applications for a national CPT code for spine specialist reimbursement for kyphoplasty, which is the initial step in the CPT process. We have learned that the AMA CPT Editorial Panel has decided to support the establishment of a national CPT code for kyphoplasty. We also understand that the relative value survey process involving input from the medical community regarding the kyphoplasty procedure may begin in the first or second quarter of 2005. We understand that upon conclusion of the survey process and determination of the appropriate reimbursement level, the results may be publicly communicated in the fourth quarter of 2005 in the Federal Register. Despite these developments, we cannot be certain that a CPT code for kyphoplasty with an associated value ultimately will become effective in 2006 or at all. While we perceive this AMA CPT Editorial Panel support for the establishment of a national CPT code for kyphoplasty to be significant progress, we cannot be certain what action will ultimately be taken, or how any action taken may affect our marketplace or our business, or whether any CPT code ultimately would increase or decrease any of the spine specialist reimbursement already available. Any CPT code has at least the potential to be detrimental to spine specialist reimbursement, and thus to our revenues.

In Europe, kyphoplasty was assigned a code in the newly 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 one or more competitors is attempting 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 for our products in those markets. We do not know whether these efforts will continue, be effective or broad in application. Notwithstanding these activities, we will continue to seek appropriate levels of reimbursement in those markets using appropriate measures.

We frequently evaluate 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 large 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 outside of the field for the treatment of spinal fractures or outside of the spine itself. Some of the opportunities we are presently investigating include technologies and products that address degenerative disc disease and various cancers associated with our core market. These efforts may require us to seek additional funding and may be dilutive to our earnings.

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 clearance 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, primarily by the FDA. Failure to comply with regulatory requirements could have a material adverse effect on our business. Additionally, our industry is highly competitive and our success depends on our ability to compete successfully against our competitors. We devote significant resources to assessing and analyzing competitive, regulatory and economic risks and opportunities. A detailed discussion of these and other factors is provided in the "Factors Affecting Future Operating Results" section of our MD&A.

Results of Operations

Changes to Previously Announced Fiscal 2004 Fourth Quarter and Annual Results

On February 7, 2005, we announced our fiscal 2004 fourth quarter and annual results. On February 8, 2005, the SEC issued additional guidance regarding accounting for incentives associated with operating leases. In light of this guidance, we concluded that reflecting an additional $2.9 million in long-term liabilities and a corresponding $2.9 million of additional property and equipment was appropriate. This adjustment related to a reimbursement received from our lessor in 2004 in conjunction with the lease of our headquarters in Sunnyvale, California. In conjunction with this lease, we received cash incentives from our landlord to be used for leasehold improvements. These amounts have now been reflected as additional deferred rent and additional property and equipment and are being amortized to rent expense and depreciation expense over the term of our operating lease, respectively.

There was no change to our fiscal 2004 fourth quarter and annual net income or earnings per share as previously announced.

Comparison of years ended December 31, 2004, 2003 and 2002

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,					
	2004		2003		2002	
	Amount	% of Net sales	Amount	% of Net sales	Amount	% of Net sales
U.S. net sales	$ 187,526	88 %	$ 118,422	90 %	$ 70,850	93 %
International net sales	25,888	12 %	12,606	10 %	5,466	7 %
Net sales	213,414	100 %	131,028	100 %	76,316	100 %
Cost of goods sold	24,734	12 %	16,794	13 %	10,416	14 %
Gross profit	188,680	88 %	114,234	87 %	65,900	86 %
Operating expenses:						
Research and development	22,043	10 %	15,237	12 %	10,145	13 %
Sales and marketing	104,299	49 %	68,676	52 %	43,509	57 %
General and administrative	27,971	13 %	17,348	13 %	12,540	17 %
Purchased in-process research and development	--	-- %	636	1 %	12,250	16 %
Total operating expenses	154,313	72 %	101,897	78 %	78,444	103 %
Income (loss) from operations	34,367	16 %	12,337	9 %	(12,544)	(16)%
Other and interest income (expense), net	1,250	1 %	986	1 %	(2,794)	(4)%
Net income (loss) before income taxes	35,617	17 %	13,323	10 %	(15,338)	(20)%
Provision (benefit) for income taxes	13,900	7 %	(14,000)	(11)%	--	-- %
Net income (loss)	$ 21,717	10 %	$ 27,323	21 %	$ (15,338)	(20)%

Net Sales. Net sales increased $82.4 million, or 63%, in 2004 compared to 2003, and increased $54.7 million, or 72%, in 2003 compared to 2002. The increases in net sales primarily resulted from an increase in the number of physicians trained in the use of our *KyphX* instruments as well as an increase in the number of procedures performed by trained physicians. In addition, net sales increased due to the introduction of new products and to a much lesser extent selected product price increases. Domestic sales increased $69.1 million, or 58% in 2004 compared to 2003 and $47.6 million, or 67% in 2003 compared to 2002. International sales increased $13.3 million, or 105% in 2004 compared to 2003 and $7.1 million, or 131% in 2003 compared to 2002. The increase in international sales also reflected the currency impact of $2.6 million and $1.9 million in 2004 and 2003, respectively, as the Euro exchange rate continued to strengthen against the U.S. dollar. No customer accounted for more than 10% of total net sales in 2004, 2003 or 2002. As of December 31, 2004, we had trained approximately 3,900 spine specialists in the U.S. and approximately 1,700 clinicians in other parts of the world, primarily Europe. These physicians have used our *KyphX* instruments in over 110,000 spine surgeries since we first introduced our products. We believe the total number of potential physicians who may perform kyphoplasty procedures using our products is approximately 5,000 to 5,500 in the U.S. The number of physicians in Europe is less defined at this time, but we believe them to be more than 3,000. We have targeted a range of $280 million to $295 million in net sales for 2005.

Cost of Goods Sold. Cost of goods sold consists of material, labor, subcontract, and overhead costs. Cost of goods sold increased $7.9 million, or 47%, in 2004 compared to 2003, and increased $6.4 million, or 61%, in 2003 compared to 2002. However, cost of goods sold as a percentage of net sales continued to decrease primarily as a result of fixed overhead costs being spread over increased production volume. The absolute increase in cost of goods sold over the years from 2002 to 2004 resulted primarily from increased material, labor, subcontract, overhead costs and inventory provisions in relation to the increased sales volume of our products. 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.

Research and Development. Research and development expenses consist of costs for product research, product development, regulatory and clinical functions and personnel. Research and development expenses increased $6.8 million, or 45%, in 2004 compared to 2003. Research and development expenses increased $5.1 million, or 50%, in 2003 compared to 2002. 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 $618,000, offset by a decrease in amortization of deferred stock-based compensation expense of $1.1 million. The increase in 2003 from 2002 was primarily attributable to increased personnel costs of $1.7 million, increased research and development consulting fees of $858,000, increased product testing and development expenditures of $831,000, and increased basic and applied research funding of $582,000. We expect to continue to make substantial investments in research and development and anticipate that research and development expenses in 2005 will increase in absolute dollars due largely to the commencement of clinical studies. As a percentage of targeted net sales, we anticipate our research and development expenses to be in the range of 10% to 11% for 2005.

Sales and Marketing. Sales and marketing expenses consist of costs for personnel, physician training programs and marketing activities. Sales and marketing expenses increased $35.6 million, or 52%, in 2004 compared to 2003. Sales and marketing expenses increased $25.2 million, or 58%, in 2003 compared to 2002. 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 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. The increase in 2003 from 2002 related primarily to a $17.1 million increase in the costs of hiring, training and compensating additional direct selling representatives, increased expenditures related to advertising, promotion, trade shows and market research activities of $4.0 million, increased sales travel expenses of $2.0 million, and increased consulting expenses of $1.3 million. As we continue to commercialize our *KyphX* instruments on a global basis during 2005, 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 targeted net sales at 48% to 49% for the year.

General and Administrative. General and administrative expenses consist of personnel costs, professional service fees, expenses related to intellectual property rights, Sarbanes-Oxley compliance initiatives and general corporate expenses. General and administrative expenses increased $10.6 million, or 61%, in 2004 compared to 2003. General and administrative expenses increased $4.8 million, or 38%, in 2003 compared to 2002. 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. The increase in 2003 from 2002 resulted primarily from increased personnel costs of $1.5 million, increased facility expenses of $587,000, increased licenses and insurance expenditures of $581,000, increased travel and entertainment expenses of $552,000, and facility expense of $1.2 million due to an early lease termination as a result of our decision to move to a larger facility. 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. Therefore, we anticipate that our general and administrative expenses will increase in absolute dollars as we expand our infrastructure. As a percentage of targeted net sales, we expect that our general and administrative expenses will be approximately 12% to 13% in 2005.

Purchased In-Process Research and Development. We did not purchase additional in-process research and development in 2004. In February 2003, we purchased Sanatis GmbH, for approximately $4.7 million in cash and acquisition costs of $201,000. Sanatis is 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 our existing patent portfolio with Sanatis' intellectual property surrounding calcium-based biomaterials and delivery technologies. The impact to our financial operating results during 2003 was an increase in research and development of

approximately $624,000. We have recorded the transaction using the purchase method of accounting. At the time of this transaction, we recorded an expense associated with the purchase of in-process research and development expenses of $636,000, and we capitalized net tangible assets of $176,000, intangible assets of $142,000 and goodwill of $4.1 million. We are amortizing the intangible assets on a straight line basis over a five-year period. No amortization of goodwill has been recorded. Instead, we perform an assessment for impairment by applying a fair-value based test annually, or more frequently, if changes in circumstances or the occurrence of events suggests the remaining value is not recoverable. The annual goodwill impairment test was completed in the first quarter of fiscal 2004, and it was determined that there was no impairment of goodwill at that time.

In August 2002, we entered into a patent license agreement with Bonutti Research Inc. for the rights to a series of patents issued to Dr. Peter Bonutti and other related patent rights and applications as defined in the agreement. Under the terms of the agreement, we acquired the exclusive right to develop any of the claimed inventions, including expandable balloons and related products, for use within bone, and for use within joints, ligaments, tendons, or cartilage in the spine and the co-exclusive right to develop any of the claimed inventions, including expandable balloons and related products, for orthopedic use in treating or diagnosing injuries of the joints, ligaments, cartilage, nerves or tendons outside of the spine. We paid $12.3 million in cash for the rights, all of which was immediately expensed to purchased in-process research and development. At the time of the acquisition, the acquisition cost was immediately expensed to operations as it was determined that the technology acquired may be used to develop products that have not been approved for sale by regulatory authorities, and the in-process projects to which the patents may apply had not yet reached technological feasibility and had no alternative future uses.

Other and Interest Income (Expense), Net. Other and interest income (expense), net, increased $264,000 in 2004 compared to 2003. Other and interest income (expense), net, increased $3.8 million in 2003 compared to 2002. The increase in 2004 compared to 2003 resulted primarily from an increase in interest income due to higher cash, cash equivalents and investment balances. The increase in 2003 from 2002 resulted from interest income from higher cash, cash equivalent and investment balances resulting from the proceeds of our initial public offering in May 2002 as well as decreased interest expense from repaid convertible promissory notes, also in May 2002.

Provision (benefit) for Income Taxes. The provision for income taxes in 2004 was $13.9 million at an effective tax rate of 39% for the year. The benefit for income taxes of $14.0 million for 2003 resulted primarily from a tax provision offset by the release of the valuation allowance against our deferred tax assets in the fourth quarter of 2003. Our deferred tax assets arose from federal and state net operating loss carryforwards, federal and state tax credit carryforwards as well as from other timing differences. Historically, these deferred tax assets had been offset in total by a valuation allowance due to the uncertainty surrounding the realization of our deferred tax assets. The release of the valuation allowance and the resulting recognition of a deferred tax benefit in 2003 was based on management's belief that it is more likely than not that these deferred tax assets would be realized. We believe that in 2005 our effective tax rate will be approximately 40% 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, 2004, we had approximately $14.4 million and $10.0 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 2021 and 2007, respectively, in each case if not utilized.

At December 31, 2004, we had research and development tax credit carryforwards of approximately $2.2 million and $2.2 million for federal and state income tax purposes, respectively. If not utilized, the federal research and development tax credit carryforwards will expire beginning in 2012. 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, as defined, occurred on August 8, 1996, December 14, 1999 and May 17, 2002. 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.

Deferred and Stock-Based Compensation

We recorded deferred stock-based compensation for financial reporting purposes 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. Deferred stock-based compensation recorded through December 31, 2004 was $24.8 million, with accumulated amortization of $22.7 million. The remaining $2.1 million will be amortized over the remaining vesting periods of the options. The options are generally subject to a four-year total vesting schedule from the date of grant. All deferred stock-based compensation amounts are being amortized using a straight-line method. We expect to record amortization expense for deferred stock-based compensation as follows:

Year	Amount
2005	$2.0 million
2006	$0.1 million

Stock-based compensation expense related to 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 $929,000, $1.9 million and $1.1 million in 2004, 2003 and 2002, 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, 2004, we had $87.2 million of cash and cash equivalents, $28.6 million of investments (short and long-term), and working capital of $153.9 million. Our cash and cash equivalents increased during the year ended December 31, 2004 by $29.7 million over the corresponding amount of cash and cash equivalents as of December 31, 2003.

Cash Provided by Operating Activities. Our operating cash flow in 2004 was primarily the result of our operational profitability. Net cash provided by operations was approximately $31.0 million in 2004 attributable primarily to net income of $21.7 million and adjustments for non-cash charges related to the amortization of deferred stock-based compensation of $3.9 million, changes in deferred tax assets of $4.1 million and tax benefits from stock options of $8.7 million. Accrued liabilities increased by $9.0 million due to our increased operating expenses and deferred rent and other increased by $4.2 million. This was partially offset by increases in inventory balances of $5.1 million and increases in accounts receivable of $17.6 million as we increased our net sales. Net cash provided by operations in 2003 was approximately $13.0 million primarily attributable to net income of $27.3 million and adjustments for non-cash charges related to the amortization of deferred stock-based compensation of $6.0 million, increases in accrued liabilities of $7.0 million and accounts payable of $3.0 million as we accrued for income taxes and increased our operating expenses offset partially by the release of the valuation allowance of the deferred tax asset of $21.6 million and increases in inventory balances of $2.4 million and increases in accounts receivable of $11.1 million as we increased our net sales. Our net cash flow from operations in 2002 reflected a near balance of operational cash inflow versus growing working capital needs. Net cash

provided by operating activities was $937,000 in 2002 attributable primarily to the add back of $12.3 million write-off of in-process research and development charge, non-cash charges related to $6.3 million amortization of deferred stock-based compensation, and $3.1 million of non-cash interest expense offset partially by net loss of $15.3 million, and increases in accounts receivable and inventories due to increased sales.

Cash Used in Investing Activities. Net cash used in investing activities was $11.2 million, $13.3 million and $39.5 million in 2004, 2003 and 2002, respectively. Cash used in investing activities reflected purchases of property and equipment for all periods. 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. During 2002, cash used for investing activities reflected the purchases of investments of $24.7 million and payment of $12.3 million in connection with the patent sublicense agreement.

Cash Provided by Financing Activities. Net cash provided by financing activities was $9.8 million, $6.6 million and $85.0 million in 2004, 2003 and 2002, respectively. 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. Cash provided during 2002 was attributable primarily from proceeds of $94.9 million from issuing common stock in our initial public offering partially offset by repayment of convertible promissory notes of $13.3 million.

Contractual Cash Obligations. At December 31, 2004 we had contractual cash obligations as follows (in thousands):

	Payment Due by Periods				
	Total	**2005**	**2006-2007**	**2008-2009**	**After 2009**
Operating leases	$ 20,428	$ 2,260	$ 4,292	$ 4,328	$ 9,548
Asset retirement obligation	256	--	--	--	256
Total commitments	$ 20,684	$ 2,260	$ 4,292	$ 4,328	$ 9,804

The amounts reflected in the table above for operating leases represent aggregate future minimum lease payments and asset retirement obligations under noncancellable facility leases. Portions of these payments are denominated in foreign currencies and were translated in the tables above based on their respective U.S. dollar exchange rates at December 31, 2004. These future payments are subject to foreign currency exchange rate risk.

Purchase orders or contracts for the purchase of raw materials and other goods and services are not included in the table above. We are not able to determine the aggregate amount of such purchase orders that represent contractual obligations, as purchase orders may represent authorizations to purchase rather than binding agreements. Although we also entered into contracts for outsourced services, the obligations under these contracts were not significant and the contracts generally contain clauses allowing for cancellation without significant penalty.

Stock Repurchase. Our Board of Directors approved a stock repurchase program on November 7, 2002 pursuant to which up to 2,000,000 shares of our outstanding common stock may be repurchased. 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 did not repurchase any of our common stock during 2004 or 2003.

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. If existing cash, cash equivalents, and cash generated from operations are insufficient to satisfy our liquidity requirements, 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 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 this additional financing, we may be required to reduce the scope of our planned product development and marketing efforts.

We expect to increase capital expenditures consistent with our anticipated growth in manufacturing, infrastructure and personnel as well as revisions and upgrades to our new facility. We also may increase our capital expenditures as we expand our product lines or invest in new markets.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share-Based Payment" (revised 2004), ("SFAS No. 123(R)"). SFAS No. 123(R) would require companies to measure all stock-based compensation awards using a fair value method and record such expense in the consolidated 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) is effective for public companies for interim and annual periods beginning after June 15, 2005. Adoption of SFAS No. 123(R), which is effective as of July 1, 2005, will have a material adverse impact on our earnings.

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 estimate allowances for doubtful accounts and for product returns. Specifically, we make estimates on the collectibility of customer accounts and sales returns and allowances 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 specific 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, 2004, 2003 and 2002.

Our accounts receivable balance was $42.3 million and $24.6 million, net of allowances of $1.1 million and $500,000 at December 31, 2004 and 2003, respectively.

Excess and obsolete inventories. We value our inventory at the lower of the cost (principally standard cost, which approximates actual cost on a first-in, first-out basis) or market value. 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 $529,000 and $625,000 at December 31, 2004 and 2003, respectively.

Accounting for income taxes. We account for income taxes under the provisions of SFAS No. 109, "Accounting for Income Taxes." Under this method, 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, respectively, a difference between the tax basis of an asset or a liability and its reported amount in the balance sheet will result in a taxable or a deductible amount in some future years when the related liabilities are settled or the reported amounts of the assets are recovered, hence giving rise to a deferred tax asset or liability. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and to the extent we believe that recovery is not likely, we must establish a valuation allowance.

As of December 31, 2002, we had provided a full valuation allowance of $20.4 million 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. 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.

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes. This process involves estimating 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 management estimates of taxable income and the period over which our deferred tax assets would be recoverable. As of December 31, 2004 and 2003, 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. 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 accepted valuation methods. For purchased in-process research and development, these methodologies include consideration of the risk of the project not achieving commercial feasibility.

Impairment of long-lived assets. We account for the impairment of long-lived assets in accordance SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", or in the case of goodwill, in accordance with SFAS No. 142, "Goodwill and Other Intangible Assets". We evaluate the carrying value of our long-lived assets and goodwill whenever certain events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable or at least on an annual basis for goodwill. Such events or circumstances include, but are not limited to, a significant decline in our market value or significant reductions in projected future cash flows. The annual goodwill impairment test was completed in the first quarter of fiscal 2004, and it was determined that there was no impairment of goodwill at that time.

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.

Factors Affecting Future Operating Results

If domestic and international payors adversely change third party coverage and reimbursement policies for kyphoplasty procedures, or if reimbursement for kyphoplasty procedures becomes difficult to obtain or is not available in sufficient amounts, our ability to market and sell our *KyphX* instruments would be adversely impacted, which would harm our business and our future growth.

Our success is dependent upon the availability of adequate reimbursement within prevailing health care payment systems in the United States and abroad, for physicians and hospitals for their services when they perform kyphoplasty procedures using our *KyphX* instruments. Medicare currently provides reimbursement at varying payment levels when kyphoplasty is performed using our *KyphX* instruments in all 50 states and in the District of Columbia. In a small number of cases, physicians performing a procedure using our instruments have not been reimbursed, either adequately or at all. In addition, some physicians in some states believe that the level of reimbursement they receive is too low. 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 kyphoplasty procedures using our products are performed.

Medicare, as well as private health maintenance organizations and insurance plans, may institute adverse changes in payors' policies toward reimbursement of kyphoplasty procedures. Medicare and private insurance payors are developing increasingly sophisticated methods of controlling health care costs through limitation on reimbursable procedures and the exploration of more cost-effective methods of delivering health care. New limits on coverage and reimbursement of hospitals and other health care providers may significantly impact the willingness of hospitals, clinics and doctors to purchase and use our *KyphX* instruments. Reimbursement and health care payment systems in international markets vary significantly by country and include both government-sponsored health care and private insurance. In addition, health care 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 sell our instruments, and these efforts are expected to continue in both the United States and abroad. Future adverse changes in insurance coverage and reimbursement policies in the United States or other nations would impact our ability to market and sell our *KyphX* instruments, harm our business and reduce our revenues.

Currently, Medicare reimburses physicians who use our *KyphX* instruments on a state-by-state basis. This form of reimbursement is not uniform across all states because there is presently no national CPT code or associated national payment rate relating to kyphoplasty procedures using our instruments. In the fourth quarter of 2004, the AMA CPT Editorial Panel considered multiple applications for a national CPT code for spine specialist reimbursement for kyphoplasty, which is the initial step in the CPT process. We have learned that the AMA CPT Editorial Panel has decided to support the establishment of a national CPT code for kyphoplasty. We also understand that the relative value survey process involving input from the medical community regarding the kyphoplasty procedure may begin in the first or second quarter of 2005. We understand that upon conclusion of the survey process and determination of the appropriate reimbursement level, the results may be publicly communicated in the fourth quarter of 2005 in the Federal Register. Despite these developments, we cannot be certain that a CPT code for kyphoplasty with an associated value ultimately will become effective in 2006 or at all. We also cannot assure you that establishment of a national CPT code, if any, would not adversely affect our business since the reimbursement level associated with the national CPT code could be less than what physicians in some states are presently receiving and thus could make surgery with our products less attractive, which would harm our revenues. Continued adoption of our *KyphX* instruments by the medical community may be adversely impacted if physicians perceive they do not receive sufficient reimbursement from payors for their services in performing the procedures using our instruments. If physicians or hospitals are unable to obtain adequate reimbursement for procedures in which our *KyphX* instruments are used, we may be unable to sell our instruments and our business could suffer.

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 orthopedic surgeons and neurosurgeons, interventional radiologists, and interventional neuroradiologists the ability treat and restore spinal anatomy during kyphoplasty. We cannot assure you that the market for the treatment of spine fractures will continue to generate significant of 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 approval of, manufacture and market new products. We must successfully sell and achieve market acceptance of new products, product extensions and enhanced versions of 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 third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. Our ability to market and sell new products, product extensions and enhanced versions of existing products may also be subject to government regulation, including clearance/approval by the United States Food and Drug Administration, or FDA, and foreign government agencies. Any failure in our ability to successfully develop and introduce new products, product extensions or enhanced versions of existing products and achieve market acceptance of new products and product extensions could have a material

adverse effect on our operating results and our business.

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 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 already introducing products to directly compete with ours in similar procedures, both in the United States and abroad. Some of these competitors' products may be successful in our market as a result of greater efficacy, less expensive alternatives to our products, or some other 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 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 that address patient and surgeon requirements. We compete with many larger companies that enjoy several competitive advantages, including:

- longer-standing distribution networks, and relationships with health care 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; and
- greater resources for product development, sales and marketing and patent litigation.

At any time, other companies may develop additional competitive products. 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 but which are presently in litigation and so far untested, expire no later than 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. If our intellectual property rights are not adequately protected or enforced, we may be unable to keep other companies from competing directly with us, which could result in a decrease in our market share. To protect our rights, we may in the future initiate other claims or litigation against third parties for infringement of our proprietary rights, in order to protect our rights or further determine the scope and validity of our intellectual property protection. We may also begin one or more patent proceedings in various administrative agencies, such as the world's various 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.

We have initiated patent infringement litigation against Disc-O-Tech Medical Technologies Ltd. that will be costly to us and may hurt our competitive position if we do not prevail.

In April 2004, we filed two patent infringement suits against Disc-O-Tech. One has been resolved in our favor; one remains pending. While we believe our allegations have merit, we cannot assure you that we will prevail in our suits against Disc-O-Tech. Regardless of whether we prevail, these suits will be costly to us and will divert management's attention and resources away from our business. If we do not prevail, some or all of our asserted proprietary rights may be damaged or invalidated, which may harm our valuation and our ability to protect our business from competition. In addition, our stock price may decline as a result of the impact of the litigation, including the financial impact of the cost of the litigation, public announcements of intermediate results, the inability or unwillingness of the company to discuss its internal litigation strategies publicly, and rulings on various motions, and/or the public's perception of the litigations' progression.

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 an instrument 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. 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/or royalties and/or issue a preliminary or permanent injunction that would prohibit us from making, using and selling essential technologies unless we could design around the patents, which we may be unable to do. 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 would do substantial harm to our business.

If primary care physicians are unwilling or unable to refer a larger number of patients to trained clinicians that use our products to perform 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 spine fracture treatment and conservative pain management therapies. In 2003, we initiated a pilot program whereby selected sales representatives call on primary care physicians to educate them about our products. 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 spine 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 convince a significant number of primary care physicians and spine specialists to accept and use our products, then our ability to commercialize our *KyphX* instruments will be negatively affected, our future growth will be harmed and our business may decline.

Our failure to maintain necessary regulatory clearances or approvals, or to obtain additional regulatory clearances or approvals, 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 do 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 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 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 kyphoplasty procedures. These clearances allow us to promote numerous short- and long-term clinical benefits associated with kyphoplasty procedures. Nevertheless, our 510(k) clearances can be revoked if safety or effectiveness problems develop. We also will be required to obtain 510(k) clearance or premarket approval to market additional products, such as new biomaterials for use in kyphoplasty, which will likely require clinical data, and to market our existing products for new indications, such as treatment of fractures caused by trauma. If the clinical data gathered are not supportive, then applications will not be filed. If we choose to seek additional clearances or approvals by filing one or more applications, we cannot be certain that we would obtain any further 510(k) clearances or premarket approvals in a timely manner or at all, and delays in obtaining clearances or approvals may adversely affect our revenue growth and future profitability.

If regulatory authorities abroad do not modify or retract their prior pronouncements concerning the use of bone cement in the spine or if they issue new pronouncements, our ability to promote and sell our instruments in those geographies may be harmed.

In July 2003, the Medicines and Healthcare Products Regulatory Agency ("MHRA") of the United Kingdom issued a Medical Device Alert entitled, "Injectable polymeric cements in percutaneous vertebroplasty, kyphoplasty and pedicle screw augmentation procedures." The United Kingdom MHRA has received reports of bone cement leaking during vertebroplasty and pedicle screw augmentation procedures leading to patient complications. The Alert noted that there have been no complications reported to MHRA from balloon kyphoplasty procedures, but stated that it was including balloon kyphoplasty procedures in the Alert due to similarities the MHRA perceived exist between balloon kyphoplasty procedures and the other procedures it identified in its Alert. We believe the MHRA's Alert concerning balloon kyphoplasty pertains directly to our *KyphX* products, since our products are the only balloons presently available in Europe to perform kyphoplasty. The notification asks physicians to consider alternatives before performing procedures using bone cement in the spine, to use the manufacturer's instructions in preparing bone cements for use in the spine, and to take specific precautions before and during those procedures. So far, despite the FDA's April 2004 clearance of our bone cement and other cements for use in kyphoplasty procedures in the United States and the FDA's subsequent modification of its own Web Notification concerning the use of bone cement in the spine to acknowledge its clearance of our bone cement, the MHRA has declined to update its own notification. If the MHRA notification is not modified or retracted in light of the FDA's clearance of our proprietary *KyphX HV-R* Bone Cement for specific use in the spine, then the notification may raise concerns with our customers, potential customers and reimbursement organizations, which could negatively impact our ability to sell and promote our instruments in geographic markets that follow MHRA's guidance. In addition, an increase in reports of deaths or serious injuries could lead the FDA or foreign regulatory agencies to issue safety alerts,

health advisories, or mandated labeling changes restricting use of our instruments, including new warnings regarding their use or contraindicating their use with bone cement, which could also harm our business and cause our revenues to decline.

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 will 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 devote significant resources to expand our manufacturing capacity at this facility. We could experience difficulties and disruptions in the manufacture of our *KyphX* instruments. We could also face the inability to procure and install the necessary manufacturing equipment, a shortage of components we use in our products, a lack of availability of qualified manufacturing personnel to work in our Sunnyvale facility, difficulties in achieving consistent quality control from new manufacturing lines 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. 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 kyphoplasty, involves risk of serious complications, including cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, and death. 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 kyphoplasty could expose us to increased risk of product liability litigation, and our current insurance coverage limits may not be adequate. 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.

Our non-U.S. sales present special risks.

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. Non-U.S. sales are subject to a number of special risks. For example:

- 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 of these events could harm our foreign operations.

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 350 employees in December 2004, which we believe represents very 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 700 employees in December 2004. We intend to continue to grow 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 attract and retain other qualified personnel or advisors could have a material adverse effect on or results of operations and financial condition.

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 the larger countries in Europe and in Canada, 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 Mexico and Korea and are in the process of establishing new relationships in those 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.

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 have a material adverse effect on us. We could incur material expenses in the future realting 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.

If we choose to make acquisitions or divestitures, we could encounter difficulties that harm our business.

We may acquire companies, products or technologies that we believe to be complementary to our present or future direction of our business. We do not know if we will be able to successfully complete any future acquisitions. If we do so, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees and increase our expenses, which could harm our business.

That our principal stockholders have significant voting power and stock ownership may not be in the best interests of our other stockholders.

Our officers, directors and principal stockholders together control approximately 39% of our outstanding common stock as of February 15, 2005. If these stockholders act together, they will be able to control our management and affairs in all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders. In addition, our other stockholders may not perceive that one or more actions taken

by this concentrated group of stockholders is in our or the remaining stockholders' best interests, which could harm our valuation and our stock price may decline.

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.

Recently enacted and proposed changes in securities and corporate governance laws and regulations will increase our costs.

The Sarbanes-Oxley Act of 2002 that became law in July 2002, as well as new rules and regulations subsequently implemented by the SEC and the NASDAQ exchange on which we are listed, have required changes to some of our corporate governance practices. The Act also requires the SEC to promulgate additional new rules on a variety of subjects. We expect all of these new rules and regulations to increase our legal and financial compliance costs, to make some activities more difficult, time consuming and/or costly, and to make it more difficult and more expensive for us to obtain director and officer 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 can provide no assurance regarding our, or our independent auditor's, conclusions after December 31, 2004 with respect to the effectiveness of our internal controls 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 are expending significant resources in developing the necessary documentation and testing procedures required by Section 404, given the risks inherent in the design and operation of internal controls over financial reporting, we can provide no assurance as to our, or our independent auditor's, conclusions after December 31, 2004 with respect to the effectiveness of our internal controls over financial reporting. If we are unable to comply 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, 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 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 method and record such expense in our consolidated financial statements. This requirement to expense stock-based compensation awards is set to take effect for public companies for interim and annual periods beginning after June 15, 2005. Currently, Kyphon discloses such expenses on a pro forma basis in the notes to our annual financial statements, but does not record a charge for employee stock option expense in the reported financial statements. Once Kyphon begins to comply with SFAS No. 123(R) as of the beginning of the third quarter of 2005, our reported earnings will decrease, which may affect our stock price.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest rate risk at December 31, 2004 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 88%, 90%, and 93% of our sales were made in U.S. dollars in 2004, 2003, and 2002, respectively. The majority of our European 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 Statement of Operations, as applicable.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL INFORMATION

We are responsible for the preparation and integrity of the consolidated financial statements appearing in our Annual Report. The consolidated financial statements were prepared in conformity with United States generally accepted accounting principles and include amounts based on management's estimates and judgments. All other financial information in this report has been presented on a basis consistent with the information included in the financial statements.

Our control environment is the foundation for our system of internal controls over financial reporting and is embodied in our Code of Business Conduct and Ethics. It sets the tone of our organization and includes factors such as integrity and ethical values. Our internal controls over financial reporting are supported by formal policies and procedures which are reviewed, modified and improved as changes occur in business conditions and operations.

The Audit Committee of the Board of Directors, which is composed solely of outside directors, meets periodically with members of management and the independent registered public accounting firm to review and discuss internal controls over financial reporting and accounting and financial reporting matters. The independent registered public accounting firm reports to the Audit Committee and accordingly has full and free access to the Audit Committee at any time.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

We are responsible for establishing and maintaining adequate internal control over financial reporting. We maintain a system of internal controls that is designed to provide reasonable assurance as to the fair and reliable preparation and presentation of the consolidated financial statements, as well as to safeguard our assets from unauthorized use or disposition.

We conducted an evaluation of the effectiveness of our internal controls over financial reporting based on the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. This evaluation included review of the documentation of controls, evaluation of the design effectiveness of controls, testing of the operating effectiveness of the controls and a conclusion on this evaluation. 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. Based on our evaluation, we have concluded that our internal control over financial reporting was effective as of December 31, 2004.

PricewaterhouseCoopers LLP, an independent registered public accounting firm, has audited management's assessment of the effectiveness of the internal control over financial reporting as of December 31, 2004 as stated in their report, which is included herein.

KYPHON INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

We have completed an integrated audit of Kyphon Inc.'s 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 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, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 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, 2004 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, 2004, 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
March 2, 2005

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

	Year Ended December 31,		
	2004	**2003**	**2002**
Net sales	$ 213,414	$ 131,028	$ 76,316
Cost of goods sold	24,734	16,794	10,416
Gross profit	188,680	114,234	65,900
Operating expenses:			
Research and development	22,043	15,237	10,145
Sales and marketing	104,299	68,676	43,509
General and administrative	27,971	17,348	12,540
Purchased in-process research and development	--	636	12,250
Total operating expenses	154,313	101,897	78,444
Income (loss) from operations	34,367	12,337	(12,544)
Interest income	1,314	1,067	929
Interest expense	--	(23)	(3,672)
Other expense, net	(64)	(58)	(51)
Net income (loss) before income taxes	35,617	13,323	(15,338)
Provision (benefit) for income taxes	13,900	(14,000)	--
Net income (loss)	$ 21,717	$ 27,323	$ (15,338)
Net income (loss) per share:			
Basic	$ 0.54	$ 0.71	$ (0.63)
Diluted	$ 0.50	$ 0.65	$ (0.63)
Weighted-average shares outstanding:			
Basic	40,449	38,433	24,405
Diluted	43,670	42,090	24,405

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, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 87,236	$ 57,494
Investments	24,421	13,456
Accounts receivable, net of allowances of $1,054 in 2004 and $500 in 2003	42,347	24,632
Inventories	11,457	6,239
Prepaid expenses and other current assets	4,521	3,810
Deferred tax assets	13,537	1,163
Total current assets	183,519	106,794
Investments	4,142	14,529
Property and equipment, net	12,728	6,044
Goodwill and other intangible assets, less accumulated amortization of $65 in 2004 and $26 in 2003	5,039	4,722
Deferred tax assets	4,009	20,462
Other assets	3,952	1,929
Total assets	$ 213,389	$ 154,480
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,544	$ 5,531
Accrued liabilities	24,049	14,699
Total current liabilities	29,593	20,230
Deferred rent and other	4,161	--
Total liabilities	33,754	20,230
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, par value: $0.001		
Authorized: 5,000 shares; none issued and outstanding	--	--
Common stock, par value: $0.001		
Authorized: 120,000 shares		
Issued: 41,355 shares in 2004 and 39,470 shares in 2003		
Outstanding: 41,325 shares in 2004 and 39,440 shares in 2003	41	39
Additional paid-in capital	189,410	171,359
Treasury stock, at cost: 30 shares in 2004 and 2003	(201)	(201)
Deferred stock-based compensation, net	(2,113)	(6,435)
Accumulated other comprehensive income	3,489	2,196
Accumulated deficit	(10,991)	(32,708)
Total stockholders' equity	179,635	134,250
Total liabilities and stockholders' equity	$ 213,389	$ 154,480

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,		
	2004	2003	2002
Cash flows from operating activities:			
Net income (loss)	$ 21,717	$ 27,323	$ (15,338)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Provision for accounts receivable allowances	737	404	3
Provision for excess and obsolete inventories	158	550	470
Depreciation and amortization	2,817	2,237	1,298
Deferred tax assets	4,080	(21,625)	--
Tax benefit from stock options	8,741	3,496	--
Loss on disposal of property and equipment	93	47	60
Non-cash interest expense	--	--	3,081
Amortization of deferred stock-based compensation	3,852	5,966	6,328
Write-off of in-process research and development	--	636	12,250
Changes in operating assets and liabilities, net of effect of acquisition:			
Accounts receivable	(17,581)	(11,086)	(8,358)
Inventories	(5,127)	(2,373)	(2,493)
Prepaid expenses and other current assets	343	(1,452)	(1,739)
Other assets	(1,975)	(1,182)	1,100
Accounts payable	(40)	3,013	518
Accrued liabilities	9,030	7,031	3,757
Deferred rent and other	4,156	--	--
Net cash provided by operating activities	31,001	12,985	937
Cash flows from investing activities:			
Acquisition of property and equipment	(9,650)	(3,961)	(2,571)
Proceeds from disposal of property and equipment	--	--	20
Maturities and sales of investments	19,945	30,023	--
Purchases of investments	(21,523)	(34,537)	(24,663)
Payment for acquisition	--	(4,850)	(12,250)
Net cash used in investing activities	(11,228)	(13,325)	(39,464)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	3,421	1,417	94,925
Repurchase of common stock	--	--	(23)
Proceeds from exercise of warrants	--	--	77
Proceeds from exercise of stock options	6,361	2,640	1,254
Proceeds from payment of related party note receivable	--	2,510	379
Acquisition of treasury stock	--	--	(201)
Proceeds from convertible promissory notes	--	--	2,000
Repayment of convertible promissory notes	--	--	(13,300)
Repayment of notes payable	--	--	(159)
Net cash provided by financing activities	9,782	6,567	84,952
Effect of foreign exchange rate changes on cash	187	1,400	90
Net increase in cash and cash equivalents	29,742	7,627	46,515
Cash and cash equivalents at beginning of year	57,494	49,867	3,352
Cash and cash equivalents at end of year	$ 87,236	$ 57,494	$ 49,867
Supplementary disclosure of noncash financing activities:			
Deferred stock-based compensation, net of cancellations	$ (470)	$ 454	$ 2,193
Issuance of warrants	$ --	$ --	$ 1,540
Conversion of redeemable convertible preferred stock to common stock	$ --	$ --	$ 38,024
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ --	$ 23	$ 854
Cash paid during the year for income taxes	$ 400	$ 43	$ --

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

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

	Common Stock		Additional Paid-In	Treasury	Deferred Stock-Based	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Stock	Compensation	Income (Loss)	Deficit	Equity (Deficit)
Balance at January 1, 2002	2,330	$ 2	$ 23,122	$ --	$ (16,082)	$ (16)	$ (44,693)	$ (37,667)
Exercise of stock options	1,742	2	1,252	--	--	--	--	1,254
Repurchase of common stock	(30)	--	(23)	--	--	--	--	(23)
Issuance of common stock upon filing of initial public offering, net of issuance costs of $1,330	6,900	7	94,918	--	--	--	--	94,925
Conversion of redeemable convertible preferred stock	26,291	26	37,998	--	--	--	--	38,024
Issuance of common stock upon exercise of warrants	78	--	77	--	--	--	--	77
Conversion of promissory note	49	--	736	--	--	--	--	736
Warrants issued in connection with promissory note	--	--	1,540	--	--	--	--	1,540
Beneficial conversion feature associated with promissory notes	--	--	1,541	--	--	--	--	1,541
Acquisition of treasury stock	(30)	--	--	(201)	--	--	--	(201)
Cumulative translation adjustments	--	--	--	--	--	252	--	252
Unrealized gain on available-for-sale investments, net of tax	--	--	--	--	--	66	--	66
Deferred stock-based compensation, net of cancellations	--	--	2,193	--	(2,193)	--	--	--
Amortization of deferred stock-based compensation	--	--	--	--	6,328	--	--	6,328
Net loss	--	--	--	--	--	--	(15,338)	(15,338)
Balance at December 31, 2002	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
Cumulative translation adjustments	--	--	--	--	--	1,934	--	1,934
Changes in unrealized gains (losses) on available-for sale investments, net of tax	--	--	--	--	--	(40)	--	(40)
Deferred stock-based compensation, net of cancellations	--	--	454	--	(454)	--	--	--
Amortization of deferred stock-based compensation	--	--	--	--	5,966	--	--	5,966
Net income							27,323	27,323
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
Cumulative translation adjustments	--	--	--	--	--	1,366	--	1,366
Changes in unrealized gains (losses) on available-for sale investments, net of tax	--	--	--	--	--	(73)	--	(73)
Deferred stock-based compensation, net of cancellations	--	--	(470)	--	470	--	--	--
Amortization of deferred stock-based compensation	--	--	--	--	3,852	--	--	3,852
Net income	--	--	--	--	--	--	21,717	21,717
Balance at December 31, 2004	41,325	$ 41	$ 189,410	$ (201)	$ (2,113)	$ 3,489	$ (10,991)	$ 179,635

The accompanying notes are an integral part of these 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 for surgeons and their patients for the 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.

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 as necessary. 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 a separate component of stockholders' equity (deficit), or to the Statement of Operations, as applicable.

Use of Estimates

In accordance with accounting principles generally accepted in the United States of America, management utilizes certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The primary estimates underlying the Company's financial statements include the allowance for doubtful accounts receivable, allowance for sales returns, reserves for obsolete and slow moving inventory, asset retirement obligations, income taxes and accrual for other liabilities. 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, certificates of deposit, and commercial paper.

Restricted Cash

Under the terms of its facility lease, the Company issued an irrevocable standby letter of credit of $1,000,000 to the lessor for the term of the facility lease. The letter of credit is secured by a certificate of deposit of $1,000,000 which was classified as other assets as of December 31, 2004 and 2003.

Investments

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 (deficit). 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 year ended December 31, 2004, 2003 and 2002. The Company’s available-for-sale investments are summarized as follows (in thousands):

December 31, 2004	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 79,342	$ --	$ --	$ 79,342
Corporate notes and bonds	28,646	--	(83)	28,563
Total	$ 107,988	$ --	$ (83)	$ 107,905
Reported as:				
Cash equivalents				$ 79,342
Short-term investments				24,421
Long-term investments				4,142
Total				$ 107,905

December 31, 2003	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 49,779	$ --	$ --	$ 49,779
Corporate notes and bonds	27,959	28	(2)	27,985
Total	$ 77,738	$ 28	$ (2)	$ 77,764
Reported as:				
Cash equivalents				$ 49,779
Short-term investments				13,456
Long-term investments				14,529
Total				$ 77,764

The following table summarizes the maturities of the Company's investments as of December 31, 2004 (in thousands):

Corporate notes and bonds:	
Maturities of one year or less	$ 24,421
Maturities between one and two years	4,142
Money market funds:	
Original maturities of three months or less	79,342
Total	$ 107,905

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 and sales returns and allowances 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 specific allowances are reevaluated and adjusted as additional information is received that impacts the amount reserved.

Inventories

Inventories are stated at the lower of cost (principally standard cost, which approximates actual cost on a first-in, first-out basis) or market value. Inventory costs include direct materials, direct labor, direct subcontract costs, and manufacturing overhead. Reserves for potentially excess and obsolete inventory are made based on management's analysis of inventory levels and future sales forecasts.

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 charged to the Statement of Operations as incurred.

Asset Retirement Obligation

The Company accounts for the retirement of tangible long-lived assets and the associated asset retirement costs in accordance with Statement of Financial Accounting Standards ("SFAS") No. 143, "Accounting for Asset Retirement Obligations". SFAS No. 143 requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. In accordance with SFAS No. 143, the fair value of the liability 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 obligation is associated with its commitment to return property subject to an operating lease in Brussels, Belgium to original condition upon lease termination. The Company estimated that as of December 31, 2004, gross expected future cash flows of approximately $404,000 would be required to fulfill these obligations.

The Company has recorded an asset retirement obligation of approximately $256,000 and a corresponding increase in leasehold improvements. This amount represents the present value of expected future cash flows associated with returning the leased property to original condition. This amount is subject to foreign exchange rate fluctuations and has been translated using the exchange rate at December 31, 2004. The leasehold improvements are being amortized to depreciation expense over the term of the lease. During the year ended December 31, 2004, approximately $39,000 of the leasehold improvements were amortized to expense.

Goodwill and Other Intangible Assets

SFAS No. 142, "Goodwill and Other Intangible Assets" requires goodwill to be tested for impairment on an annual basis and between annual tests in certain circumstances, and written down when impaired. Furthermore, SFAS No. 142 requires purchased intangible assets other than goodwill to be amortized over their useful lives unless these lives are determined to be indefinite.

The Company is amortizing its intangible assets on a straight line basis over a five year period. No amortization of goodwill has been recorded. Instead, the Company performs an impairment assessment by applying a fair-value based test in the first quarter of each year, or more frequently if changes in circumstances or the occurrence of events suggest the remaining value is not recoverable. The annual goodwill impairment analysis was completed in the first quarter of 2004, and it was determined that there was no impairment of goodwill at that time.

Impairment of Long-Lived Assets

Pursuant to SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," the Company periodically assesses whether long-lived assets have been impaired. An asset is deemed to be impaired if its estimated future undiscounted cash flows are less than the carrying value recorded on the Company's balance sheet. The Company's estimate of fair value is based on the net present value of expected future cash flows attributable to the asset. Predicting future cash flows attributable to a particular asset is difficult, and requires the use of significant judgment.

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 of America and in some major 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 of America and in Europe. The Company performs ongoing credit evaluations of its customers' financial condition and, generally, requires no collateral from its customers. As of December 31, 2004, 71% and 29%, respectively, of accounts receivable were from United States of America and Europe.
As of December 31, 2003, 73% and 27%, respectively, of accounts receivable were from United States of America

and Europe.

No customer accounted for more than 10% of total net sales for the year ended December 31, 2004, 2003 and 2002. No customer accounted for more than 10% of total accounts receivable at December 31, 2004, and 2003.

The Company's current line of products is limited to devices and bone filler biomaterials used in the repair of compression fractures of the spine caused primarily by osteoporosis and cancer. Some of the Company's products require clearance or approval from the United States Food and Drug Administration ("FDA") prior to the commencement of commercialized sales. In July 1998, the Company received initial FDA clearance for its *KyphX* Inflatable Bone Tamp. In February 2001, the Company received an additional 510(k) clearance that clarified that the *KyphX* Inflatable Bone Tamp is intended for use in the spine, hand, tibia, radius and calcaneus. In April 2004, the Company received 510(k) clearance from the FDA to market *KyphX HV-R* Bone Cement. Internationally, the Company received CE Mark approval to market its products from the European regulatory agency in April 2000. The Company cannot be assured that future products will receive the necessary approvals or clearances. If the Company is denied approval or clearance or if approval or clearance is delayed, this may have a material adverse impact on the Company.

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 $766,000 and $400,000 for the year ended December 31, 2004 and 2003, respectively. Prior to 2003, such amounts were insignificant and were classified as an offset to cost of goods sold. 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 $3,515,000, $3,552,000 and $1,873,000 for the year ended December 31, 2004, 2003 and 2002, respectively.

Income Taxes

The Company accounts for income taxes under the 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 expected to be realized.

Segments

The Company operates in one segment, using one measurement of profitability to manage its business. As of December 31, 2004 and 2003, 83% and 87%, respectively, of all long-lived assets were maintained in the United

States of America. For the year ended December 31, 2004, 2003 and 2002, 88%, 90% and 93%, respectively, of net sales were generated in the United States of America.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity (deficit) except those resulting from investments or contributions by stockholders. The Company's unrealized gains (losses) on available-for-sale investments and cumulative translation adjustments represent the components of comprehensive income (loss) that are excluded from the net income (loss).

The changes in components of comprehensive income (loss) for the periods presented are as follows (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Net income (loss)	$ 21,717	$ 27,323	$ (15,338)
Changes in unrealized gains (losses) on available-for-sale investments, net of taxes	(73)	(40)	66
Translation adjustments	1,366	1,934	252
Total comprehensive income (loss)	$ 23,010	$ 29,217	$ (15,020)

The components of comprehensive income (loss), net of taxes reflected in the consolidated statements of stockholders' equity (deficit) are as follows (in thousands):

	December 31,	
	2004	2003
Unrealized gains (losses) on available-for-sale investments, net of taxes	$ (47)	$ 26
Translation adjustments	3,536	2,170
	$ 3,489	$ 2,196

Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding for the period. Diluted net income (loss) per share is computed giving effect to all potential dilutive common stock, including options, warrants, common stock subject to repurchase, convertible promissory notes and redeemable convertible preferred stock. For the year ended December 31, 2004, 2003 and 2002, certain options, common stock subject to a right of repurchase and warrants were not included in the computation of diluted net income (loss) per share for the Company because the effect would be antidilutive.

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

	Year Ended December 31,		
	2004	2003	2002
Net income (loss)	$ 21,717	$ 27,323	$ (15,338)
Weighted-average shares outstanding	40,451	38,461	24,514
Less: weighted-average shares subject to repurchase	(2)	(28)	(109)
Basic weighted-average shares outstanding	40,449	38,433	24,405
Dilutive effect of:			
Options to purchase common stock	3,218	3,610	--
Warrants	3	47	--
Diluted weighted-average shares outstanding	43,670	42,090	24,405
Net income (loss) per share:			
Basic	$ 0.54	$ 0.71	$ (0.63)
Diluted	$ 0.50	$ 0.65	$ (0.63)

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

	December 31,		
	2004	2003	2002
Options to purchase common stock	509	146	6,826
Common stock subject to repurchase	--	13	34
Warrants	--	--	64

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, 2004 and 2003, 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 uses the intrinsic value method of Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees" ("APB No. 25"), in accounting for its employee stock options, and presents disclosure of pro forma information required under SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"), as amended by SFAS No. 148, "Accounting for Stock Based Compensation-Transition and Disclosure-an amendment of FASB Statement No. 123" ("SFAS No. 148").

The following table, assuming a 40% effective tax rate in 2004 and 2003, provides a reconciliation of net income (loss) and net income (loss) per share to pro forma net income (loss) and pro forma net income (loss) 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 consistent with the methodology prescribed by SFAS No. 123 (in thousands, except per share amounts):

	Year Ended December 31,		
	2004	2003	2002
Net income (loss), as reported	$ 21,717	$ 27,323	$ (15,338)
Add: Stock-based employee compensation expense included in reported net income (loss), net of taxes	1,754	2,447	5,183
Deduct: Total stock-based employee compensation expense, determined under fair value based method for all awards, net of taxes	(9,735)	(6,291)	(6,625)
Pro forma net income (loss)	$ 13,736	$ 23,479	$ (16,780)
Net income (loss) per share			
Basic:			
As reported	$ 0.54	$ 0.71	$ (0.63)
Pro forma	$ 0.34	$ 0.61	$ (0.69)
Diluted:			
As reported	$ 0.50	$ 0.65	$ (0.63)
Pro forma	$ 0.31	$ 0.56	$ (0.69)

The weighted-average assumptions used are as follows:

	Year Ended December 31,		
	Employee Stock Options		
	2004	2003	2002
Risk-free interest rate	3.04%	2.58%	3.59%
Expected volatility	62%	70%	76%
Expected life (in years)	4	4	4
Dividend yield	--	--	--

	Employee Stock Purchase Plan		
	2004	2003	2002
Risk-free interest rate	1.22%	1.15%	1.21%
Expected volatility	66%	66%	71%
Expected life (in years)	1.52	0.74	1.52
Dividend yield	--	--	--

The weighted-average grant date fair value per share of options granted during the year ended December 31, 2004, 2003 and 2002 was $12.61, $8.84 and $4.89, respectively. The weighted average fair value for shares purchased through the employee stock purchase plan during the years ended December 31, 2004 and 2003 were $6.80 and $3.96 per share, respectively. No shares were purchased under the employee stock purchase plan during the year ended December 31, 2002.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force Issue (“EITF”) No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," which require that these equity instruments are recorded 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.

Deferred and 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. In accordance with the requirements of APB No. 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock options 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.

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 were 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 as prescribed by SFAS No. 123 using the following weighted-average assumptions:

	Year Ended December 31,		
	2004	2003	2002
Risk-free interest rate	4.21%	3.92%	4.45%
Expected volatility	65%	74%	76%
Expected life (in years)	10	10	10
Dividend yield	--	--	--

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

	Year Ended December 31,		
	2004	2003	2002
Cost of goods sold	$ 317	$ 467	$ 587
Research and development	1,134	2,232	1,906
Sales and marketing	1,360	2,012	2,243
General and administrative	1,041	1,255	1,592
	$ 3,852	$ 5,966	$ 6,328

Reclassification

Certain amounts in the prior year consolidated financial statements have been reclassified to conform to the current year's presentation. The reclassification had no impact on the previously reported net income (loss).

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123(R), *Share-Based Payment* (revised 2004), ("SFAS No. 123(R)"). SFAS No. 123(R) will require companies to measure all stock-based compensation awards using a fair value method and record such expense in the consolidated 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) is effective for public companies for interim and annual periods beginning after June 15, 2005. The adoption of SFAS No. 123(R), which is effective as of July 1, 2005, will decrease the Company's earnings.

3. BALANCE SHEET COMPONENTS

Inventories (in thousands):

	December 31,	
	2004	2003
Raw materials	$ 5,715	$ 3,327
Work-in-process	1,042	647
Finished goods	4,700	2,265
	$ 11,457	$ 6,239

Property and Equipment (in thousands):

	December 31,	
	2004	2003
Furniture and fixtures	$ 2,752	$ 1,284
Computer software and hardware	4,929	3,455
Laboratory and manufacturing equipment	4,695	3,585
Leasehold improvements	5,943	965
	18,319	9,289
Less: Accumulated depreciation and amortization	(6,158)	(4,474)
Plus: Construction-in-progress	567	1,229
	$ 12,728	$ 6,044

Goodwill and Intangible Assets:

Changes in the carrying amount of goodwill and the intangible assets occurring during the year ended December 31, 2004 and 2003 are as follows (in thousands):

	2004	2003
Goodwill at beginning of the year	$ 4,584	$ --
Goodwill acquired during the year	--	4,072
Foreign currency translation	343	512
Total goodwill	4,927	4,584
Other intangibles at the beginning of the year	138	--
Other intangibles acquired during the year	--	--
Foreign currency translation	13	22
Amortization expense	(39)	(26)
Total other intangibles	112	(4)
Total goodwill and other intangible assets, net	$ 5,039	$ 4,722

Amortization expense for the Company's intangible assets was approximately $39,000 and $26,000 for the year ended December 31, 2004 and 2003, respectively. Based on the intangible assets held at December 31, 2004, and exchange rates in effect as of the balance sheet date, the Company expects to recognize amortization expense of approximately $35,000 in each of the years from 2005 to 2007, and approximately $7,000 in 2008.

Accrued Liabilities (in thousands):

	December 31,	
	2004	2003
Payroll and related expenses	$ 13,052	$ 7,366
Accrued income taxes	4,616	4,108
Legal, accounting and professional fees	1,620	1,122
Clinical studies	1,404	--
Professional training courses	666	227
Travel and entertainment	466	621
Other	2,225	1,255
	$ 24,049	$ 14,699

4. NOTES PAYABLE

In 1997 and 1998, the Company entered into two equipment financing lines totaling $650,000. Prior to the lines'

expirations, the Company had drawn down $541,800, which was collateralized by the related equipment. Both of these lines were repaid entirely in June 2002. The Company issued warrants to purchase an aggregate of 18,358 shares of convertible preferred stock to the lenders in connection with these lines at a weighted-average exercise price of $0.62 per share. To effect a cashless exercise of the warrants, 17,601 shares of common stock were issued subsequent to the Company's initial public offering. All warrants related to the equipment financing lines were exercised in 2002.

5. CONVERTIBLE PROMISSORY NOTES

Between July 2001 and February 2002, the Company raised $13,300,000 through the sale of convertible promissory notes with several affiliates pursuant to a loan agreement. The convertible promissory notes bore interest at 10% rate per annum. The outstanding principal and accrued interest were repaid upon the closing of the Company's initial public offering. In addition, in November 2001, the Company raised $700,000 through the sale of a convertible promissory note to one affiliate pursuant to the same loan agreement. The principal and accrued interest due on this note automatically converted into 49,090 shares of the Company's common stock at the initial public offering price of $15.00 per share. As required by the terms of the loan agreement, upon the closing date of the Company's initial public offering, the Company issued warrants exercisable for an aggregate of 99,334 shares of the Company's common stock at an exercise price of $0.01 per share to the holders of the convertible promissory notes. As of December 31, 2004, all warrants have been exercised.

The Company allocated the gross proceeds received from the convertible promissory notes and accrued interest to the convertible promissory notes and the warrants, based on their relative fair values. This allocation resulted in $13,300,000 of the proceeds being assigned to the convertible promissory note and $1,540,500 being assigned to the warrants. The warrants were valued at the May 22, 2002 issuance date using the Black-Scholes pricing model. The Company recognized the allocated fair value of the warrants of $1,540,500 as an immediate charge to interest expense. Based on the difference between the effective conversion price of the proceeds allocated to the convertible promissory notes and the fair market value of the common stock at the issuance date, the Company determined that the allocated value of the convertible promissory notes contained a beneficial conversion feature. The beneficial conversion feature, amounting to $1,540,500, represented additional interest yield on the convertible promissory notes and was also recognized as an immediate charge to interest expense.

6. ACQUISITION

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. In accordance with SFAS No. 141, "Business Combinations," this amount was included in the 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.

The following unaudited pro forma financial information is based on the respective historical financial statements of the Company and Sanatis. The unaudited pro forma financial information reflects the consolidated results of operations as if the acquisition of Sanatis occurred at the beginning of each of the periods presented and includes the amortization of the resulting other intangible assets. The unaudited pro forma financial data presented are not necessarily indicative of the Company's results of operations that might have occurred had the transaction been completed at the beginning of the periods presented, 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,	
	2003	2002
	(unaudited)	
Net sales	$ 131,028	$ 76,492
Net income (loss)	$ 27,286	$ (15,393)
Net income (loss) per share:		
Basic	$ 0.71	$ (0.63)
Diluted	$ 0.65	$ (0.63)
Weighted-average shares outstanding:		
Basic	38,433	24,405
Diluted	42,090	24,405

7. COMMITMENTS AND CONTINGENCIES

Operating leases

The Company has operations headquartered in an approximately 107,000 square foot facility in Sunnyvale, California. The facility is leased through August 2014. Under the terms of the lease agreement, the Company has an option to rent an adjacent existing facility as well as an option to have additional square footage built in the same surrounding campus.

The Company's European operations are headquartered in an approximately 22,000 square foot facility 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.

The Company records rent expense on a straight-line basis. In 2004, the Company also received cash incentives of $3.2 million from its landlord to be used for leasehold improvements. As of December 31, 2004 and 2003, deferred rent of approximately $3,923,000 and $24,000, respectively had been recorded. The Company recognized rent

expense of $2.7 million, $1.4 million and $1.2 million during 2004, 2003 and 2002, respectively.

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

Fiscal year ending December 31,	
2005	$ 2,260
2006	2,165
2007	2,127
2008	2,118
2009	2,210
Thereafter	9,548
Total	$ 20,428

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, 2004. 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. In accordance with the provision of SFAS No. 146 "Accounting for Costs Associated with Exit or Disposal Activities," 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.

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 maximum potential amount of future payments the Company could be required to make under these agreements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal.

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 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, which thereby terminated the ITC proceeding in the Company's favor. An enforcement proceeding against Disc-O-Tech in the ITC may later be initiated if it is determined that Disc-O-Tech is not complying fully with the ITC Order. In Delaware, the Company's complaint presently alleges, among other things, that by importing, manufacturing, distributing and promoting their SKy Bone Expander device and related tools for use in kyphoplasty procedures, Disc-O-Tech is willfully infringing five of the Company's U.S. patents, all of which generally concern the use of various medical devices to repair spinal compression fractures, and seeks enhanced damages and a permanent injunction for its willful infringement. Trial is set for June 2005. The Company is using the information discovered during the ITC proceeding about Disc-O-Tech's business activities to prosecute its case against Disc-O-Tech in Delaware and will continue to do so vigorously. 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.

8. INITIAL PUBLIC OFFERING

On May 17, 2002, the Company completed an initial public offering in which it sold 6,000,000 shares of common stock at $15.00 per share for net cash proceeds of approximately $82,400,000, net of underwriting discounts, commissions and other offering costs. Upon the closing of the offering, all the Company's outstanding shares of redeemable convertible preferred stock converted into 26,151,288 shares of common stock. On May 29, 2002, the underwriters exercised the over-allotment option to purchase an additional 900,000 shares, resulting in net cash proceeds of approximately $12,555,000.

9. REDEEMABLE CONVERTIBLE PREFERRED STOCK

In January 2002, 140,000 shares of the Company’s redeemable convertible preferred stock converted to common stock. Upon the closing of the Company’s initial public offering in May 2002, the remaining outstanding shares of redeemable convertible preferred stock converted into 26,151,288 shares of common stock.

10. STOCKHOLDERS' EQUITY (DEFICIT)

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, 2004.

The Company issued shares of its common stock to certain employees under stock purchase agreements, some of which contained repurchase provisions in the event of termination of employment. The shares are generally released from repurchase provisions ratably over four years. Included in common stock as of December 31, 2004 and December 31, 2003 are none and 12,501 shares subject to the Company's right of repurchase, respectively.

Employee Stock Purchase Plan

In April 2002, the Board of Directors adopted the 2002 Employee Stock Purchase Plan ("2002 ESPP"), under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. There were 750,000 shares of common stock originally reserved for issuance and that amount is increased on the first day of each fiscal year, commencing in 2003, by an amount equal to the lesser of (i) 1,500,000, (ii) 2.0% of the outstanding shares of common stock on such date or (iii) an amount as determined by the Board of Directors. The Company reserved an additional 747,000 shares of common stock for issuance in 2003. No additional shares were reserved for issuance in 2004. The 2002 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 initial offering period commenced on May 17, 2002, the effective date of the Company's initial public offering. At December 31, 2004, approximately 983,000 shares of common stock remained reserved for future issuance under the 2002 ESPP.

Director Option Plan

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. 200,000 shares of common stock were originally reserved for issuance and will be increased on the first day of each fiscal year, commencing in 2003, by an amount equal to the lesser of (i) the number of shares subject to options

granted under the 2002 Director Option Plan in the prior fiscal year or (ii) an amount as determined by the Board of Directors. There were no additional shares reserved and approximately 58,000 stock options were granted under the 2002 Director Option Plan in 2004. There were no stock options granted and no additional shares reserved under this plan in 2002 or 2003.

Stock 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. There were 2,500,000 shares of common stock originally reserved for issuance, and that amount is increased on the first day of each fiscal year, commencing in 2003, by an amount equal to the lesser of (i) 3,500,000, (ii) 5.0% of the outstanding shares of common stock on the last day of the preceding fiscal year or (iii) an amount as determined by the Board of Directors. There were 1,867,817 and 1,971,987 additional shares reserved for issuance in 2003 and 2004, respectively.

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.

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, 2002	965,350	6,377,384	$ 0.83	948,834	$ 0.87
Additional shares reserved	2,500,000	--	--	--	--
Shares repurchased	30,207	--	--	--	--
Options granted	(2,223,000)	2,151,500	9.17	71,500	2.77
Options exercised	--	(1,416,022)	0.71	(326,270)	0.77
Options cancelled	980,981	(980,981)	1.04	--	--
Balances, December 31, 2002	2,253,538	6,131,881	3.79	694,064	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	2,465,697	6,302,133	8.25	304,605	1.91
Additional shares reserved	1,971,987	--	--	--	--
Options granted	(3,044,300)	2,986,800	24.29	57,500	24.40
Options exercised	--	(1,441,228)	4.33	(100,316)	1.25
Options cancelled	475,897	(475,897)	18.43	--	--
Balances, December 31, 2004	1,869,281	7,371,808	$ 14.85	261,789	$ 7.10

The options outstanding and exercisable at December 31, 2004 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	3.81	$ 0.05	100,000	$ 0.05
$0.13	14,629	4.50	0.13	14,629	0.13
$0.31	45,850	5.10	0.31	45,850	0.31
$0.77	261,762	5.22	0.77	261,762	0.77
$1.00	1,290,089	6.21	1.00	1,093,577	1.00
$3.00	230,577	7.18	3.00	118,623	3.00
$6.95 - $7.00	192,008	7.76	6.96	62,981	6.96
$8.00 - $9.50	461,377	8.14	9.09	129,372	9.16
$9.98 - $12.67	1,062,006	7.71	12.25	506,568	12.24
$15.40 - $20.83	1,154,636	8.79	17.90	337,511	17.39
$20.96 - $26.13	2,351,663	9.44	24.29	230,086	24.36
$26.29 - $30.28	469,000	9.45	27.30	20,256	28.05
	7,633,597	8.11	$ 14.59	2,921,215	$ 7.37
Employees	7,371,808	8.15	$ 14.85	2,733,111	$ 7.72
Non-employees	261,789	7.15	7.10	188,104	2.25
	7,633,597	8.11	$ 14.59	2,921,215	$ 7.37

At December 31, 2003, there were 2,149,617 options outstanding granted to employees and 260,853 options outstanding granted to non-employees which were exercisable.

11. 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 20% 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 of $2,000 per calendar year. The Company's matching contributions totaled $620,000 and $372,000 in 2004 and 2003, respectively.

12. PURCHASED IN-PROCESS RESEARCH AND DEVELOPMENT

In August 2002, the Company entered into a patent sublicense agreement with Bonutti Research Inc. for the rights to a series of patents issued to Dr. Peter Bonutti. Under the terms of the agreement, the Company 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. The Company paid $12,250,000 in cash for the rights, all of which was immediately expensed to purchased in-process research and development in August 2002. The acquisition cost was immediately expensed to operations as at the time of purchase it was determined that the technology acquired would be used to develop products that have not been approved for sale by regulatory authorities, and the in-process projects to which the patents may apply had not yet reached technological feasibility and had no alternative future uses. In addition, the Company also entered into a two year consulting agreement with Dr. Peter Bonutti under which the Company paid $250,000. The prepayment was capitalized and recognized as research and development expense ratably throughout the two year consulting period.

13. 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 year ended December 31, 2004, 2003 and 2002 were $216,000, $216,000 and $217,000, respectively.

In October 2001, the Company entered into an agreement to loan $2,889,000 to its former President and Chief Executive Officer, Gary Grenter, for the purchase of a primary residence. The note was non-interest bearing and was collateralized by a deed of trust in the related primary residence. As of December 31, 2003, all outstanding balances were paid in full.

14. 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,		
	2004	2003	2002
U.S.	$ 35,153	$ 14,636	$ (15,316)
International	464	(1,313)	(22)
Total income (loss) before income taxes	$ 35,617	$ 13,323	$ (15,338)
Current			
Federal	$ 7,892	$ 4,152	$ --
State	1,285	907	--
Foreign	216	500	--
Total current	9,393	5,559	--
Deferred			
Federal	4,286	(15,803)	--
State	433	(3,336)	--
Foreign	(212)	(420)	--
Total deferred	4,507	(19,559)	--
Total provision (benefit) for income taxes	$ 13,900	$ (14,000)	$ --

The Company's income taxes payable for federal, state, and foreign purposes have been reduced by the tax benefits associated with dispositions of employee stock options. The Company received an income tax benefit of approximately $8,741,000 and $3,496,000 in 2004 and 2003, respectively, calculated as the difference between the fair market value and the option exercise price on the date of exercise.

At December 31, 2004, the Company had approximately $14,400,000 and $10,000,000 in federal and state net operating loss carryforwards, respectively, to reduce future taxable income. The federal and state carryforwards have expiration dates beginning in 2021 and 2007, respectively, if not utilized.

At December 31, 2004, the Company had research and development tax credit carryforwards of approximately $2,195,000 and $2,221,000 for federal and state income tax purposes, respectively. If not utilized, the federal research and development tax credit carryforwards will expire beginning in 2012. 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, as defined, occurred on August 8, 1996, December 14, 1999 and May 17, 2002. 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 gave rise to significant portions of deferred tax assets are as follows (in thousands):

	December 31,	
	2004	2003
Net operating loss carryforwards	$ 5,507	$ 13,850
Research and development credit carryforwards	3,638	2,051
Capitalized research and development costs	479	491
Purchased research and development	3,451	4,070
Other, accruals and reserves	4,471	1,163
Total deferred tax assets	$ 17,546	$ 21,625

Management periodically evaluates the recoverability of the deferred tax assets and recognizes the tax benefit only as reassessment demonstrates that they are realizable. At such time, if it is determined that it is more likely than not that the deferred tax assets are realizable, the valuation allowance will be adjusted. At December 31, 2004 and 2003, 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,		
	2004	2003	2002
Federal statutory rate	35.0 %	34.0 %	(34.0)%
State, net of federal benefit	4.7	5.8	(5.8)
Deferred stock-based compensation, net of tax benefit	--	(35.7)	--
Tax reserves	(0.2)	30.6	--
Other permanent difference	4.0	1.6	13.3
Change in valuation allowance	--	(142.0)	32.2
Utilization of net operating loss	--	--	(5.5)
Research and development tax credits	(4.5)	--	(0.2)
Total provision(benefit) for income taxes	39.0 %	(105.7)%	0.0 %

15. QUARTERLY FINANCIAL DATA (UNAUDITED)

The following tables contain selected unaudited Consolidated Statement of Operations data for each quarter of 2004 and 2003 (in thousands, except per share amounts):

	Year 2004 Quarter Ended			
	Mar. 31,	June 30,	Sept. 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

	Year 2003 Quarter Ended			
	Mar. 31,	June 30,	Sept. 30,	Dec. 31,
Net sales	$ 25,137	$ 31,081	$ 35,145	$ 39,665
Gross profit	21,787	27,131	30,554	34,762
Net income	$ 541 *	$ 2,820	$ 4,712	$ 19,250
Net income per share:				
Basic	$ 0.01	$ 0.07	$ 0.12	$ 0.49
Diluted	$ 0.01	$ 0.07	$ 0.11	$ 0.45
Weighted-average shares outstanding:				
Basic	37,566	38,069	38,767	39,298
Diluted	40,895	41,429	42,539	43,082

* Net income includes purchased in-process research and development expense of $636,000.

** Net income includes lease termination cost of $1,200,000 and income tax benefit of $14,500,000.

KYPHON INC.
SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS
FOR THE YEARS ENDED DECEMBER 31, 2002, 2003 AND 2004
(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 2002	$ 100	3	3	$ 100
Fiscal year ended 2003	100	404	4	500
Fiscal year ended 2004	$ 500	737	183	$ 1,054
Allowance for inventories valuation:				
Fiscal year ended 2002	$ 191	470	54	$ 607
Fiscal year ended 2003	607	550	532	625
Fiscal year ended 2004	$ 625	158	254	$ 529
Valuation allowance for deferred tax assets:				
Fiscal year ended 2002	$ 15,249	5,149	--	$ 20,398
Fiscal year ended 2003	20,398	--	20,398	--
Fiscal year ended 2004	$ --	--	--	$ --

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

An evaluation of the effectiveness of our disclosure controls and procedures "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15(d)-15(e) of the Securities and Exchange Act of 1934, as amended) as of the end of the period covered by this report was carried out under the supervision and with the participation of our management, including our chief executive officer and chief financial officer. Based on that evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities and Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission's rules and forms.

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Management's Report on Internal Control over Financial Reporting is incorporated by reference to Item 8 of this Annual Report on Form 10-K.

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 2005 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2004 fiscal year (the "2005 Proxy Statement").

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the 2005 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 2005 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item is incorporated by reference to the 2005 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the 2005 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 (1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.4 (1)	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.
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.

* 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, 2005.

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, 2005
/s/ ARTHUR T. TAYLOR **Arthur T. Taylor**	Vice President, Chief Financial Officer and Treasurer (Principal Accounting and Financial Officer)	March 2, 2005
/s/ JAMES T. TREACE **James T. Treace**	Chairman of the Board	March 2, 2005
/s/ STEPHEN M. CAMPE **Stephen Campe**	Director	March 2, 2005
/s/ DOUGLAS W. KOHRS **Douglas W. Kohrs**	Director	March 2, 2005
/s/ JACK W. LASERSOHN **Jack W. Lasersohn**	Director	March 2, 2005
/s/ KAREN D. TALMADGE, PH.D. **Karen D. Talmadge, Ph.D.**	Executive Vice President, Co-Founder, Chief Science Officer and Director	March 2, 2005
/s/ LOUIS J. LAVIGNE, JR. **Louis J. Lavigne, Jr.**	Director	March 2, 2005
/s/ ELIZABETH H. WEATHERMAN **Elizabeth H. Weatherman**	Director	March 2, 2005