# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

# FORM 10-Q

(Mark One)
[ X ] Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended March 31, 2005 or
[ ] Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____ .

**Commission File Number 000-49804**

## Kyphon Inc.
(Exact name of registrant as specified in its charter)

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

**77-0366069**
(I.R.S. Employer Identification No.)

**1221 Crossman Avenue, Sunnyvale, California, 94089**
(Address of principal executive offices, including zip code)

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

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 whether the registrant is an accelerated filer (as defined by rule 12b-2 of the Exchange Act).
YES [ X ] NO [ ]

| Class | Shares Outstanding at April 20, 2005 |
|---|---|
| Common Stock, $0.001 par value | 42,375,247 |

**KYPHON INC.**
**FORM 10-Q**
**TABLE OF CONTENTS**

**PART I: FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2005** | **2004** |
| Net sales | $ 66,234 | $ 44,433 |
| Cost of goods sold | 7,925 | 4,917 |
| Gross profit | 58,309 | 39,516 |
| Operating expenses: | | |
| Research and development | 5,460 | 4,557 |
| Sales and marketing | 34,985 | 22,341 |
| General and administrative | 7,698 | 4,840 |
| Total operating expenses | 48,143 | 31,738 |
| Income from operations | 10,166 | 7,778 |
| Interest income and other, net | 525 | 235 |
| Net income before income taxes | 10,691 | 8,013 |
| Provision for income taxes | 4,270 | 3,200 |
| Net income | $ 6,421 | $ 4,813 |
| Net income per share: | | |
| Basic | $ 0.15 | $ 0.12 |
| Diluted | $ 0.15 | $ 0.11 |
| Weighted-average shares outstanding: | | |
| Basic | 41,843 | 39,761 |
| Diluted | 44,231 | 43,332 |

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

**KYPHON INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(unaudited, in thousands)**

| | March 31, 2005 | December 31, 2004 (1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 102,659 | $ 87,236 |
| Investments | 25,611 | 24,421 |
| Accounts receivable, net | 43,335 | 42,347 |
| Inventories | 10,988 | 11,457 |
| Prepaid expenses and other current assets | 3,503 | 4,521 |
| Deferred tax assets | 13,547 | 13,537 |
| Total current assets | 199,643 | 183,519 |
| Investments | 2,041 | 4,142 |
| Property and equipment, net | 14,659 | 12,728 |
| Goodwill and other intangible assets, net | 4,819 | 5,039 |
| Deferred tax assets | 4,009 | 4,009 |
| Other assets | 4,197 | 3,952 |
| Total assets | $ 229,368 | $ 213,389 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,797 | $ 5,544 |
| Accrued liabilities | 22,492 | 24,049 |
| Total current liabilities | 30,289 | 29,593 |
| Deferred rent and other | 4,113 | 4,161 |
| Total liabilities | 34,402 | 33,754 |
| Commitments and contingencies (Note 7) | | |
| Stockholders' equity: | | |
| Common stock, $0.001 par value per share | 42 | 41 |
| Additional paid-in capital | 198,642 | 189,410 |
| Treasury stock, at cost | (201) | (201) |
| Deferred stock-based compensation, net | (1,461) | (2,113) |
| Accumulated other comprehensive income | 2,514 | 3,489 |
| Accumulated deficit | (4,570) | (10,991) |
| Total stockholders' equity | 194,966 | 179,635 |
| Total liabilities and stockholders' equity | $ 229,368 | $ 213,389 |

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

(1) The balance sheet at December 31, 2004 was derived from audited consolidated financial statements, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements.

**KYPHON INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(unaudited, in thousands)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2005** | **2004** |
| **Cash flows from operating activities:** | | |
| Net income | $ 6,421 | $ 4,813 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Provision for accounts receivable allowances | 83 | 53 |
| Provision for excess and obsolete inventories | 54 | 73 |
| Depreciation and amortization | 1,031 | 709 |
| Deferred taxes including tax benefits from stock options | 4,327 | 3,105 |
| Loss on disposal of property and equipment | 37 | -- |
| Amortization of deferred stock-based compensation | 721 | 1,245 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,604) | (3,254) |
| Inventories | 277 | (653) |
| Prepaid expenses and other current assets | 1,162 | 1,676 |
| Other assets | (274) | 459 |
| Accounts payable | 2,291 | (1,354) |
| Accrued liabilities | (1,558) | 1,524 |
| Deferred rent and other | 223 | -- |
| Net cash provided by operating activities | 13,191 | 8,396 |
| **Cash flows from investing activities:** | | |
| Acquisition of property and equipment | (3,082) | (3,146) |
| Maturities and sales of investments | 8,750 | 4,835 |
| Purchase of investments | (8,041) | (4,874) |
| Net cash used in investing activities | (2,373) | (3,185) |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of common stock | 2,456 | 1,433 |
| Proceeds from exercise of stock options | 2,381 | 928 |
| Net cash provided by financing activities | 4,837 | 2,361 |
| Effect of foreign exchange rate changes on cash | (232) | (222) |
| Net increase in cash and cash equivalents | 15,423 | 7,350 |
| Cash and cash equivalents at beginning of period | 87,236 | 57,494 |
| Cash and cash equivalents at end of period | $ 102,659 | $ 64,844 |

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

**KYPHON INC.**
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**(unaudited)**

**NOTE 1--Organization, Basis of Presentation, and Significant Accounting Policies:**

**Organization**

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

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. The results for the three month period ended March 31, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005, or for any future period. These condensed consolidated financial statements and notes should be read in conjunction with the consolidated financial statements included in the Company's Form 10-K for the fiscal year ended December 31, 2004.

**Significant Accounting Policies**

The Company's significant accounting policies are disclosed in the Company's Form 10-K for the year ended December 31, 2004 and have not changed materially as of March 31, 2005.

**Reclassification**

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

**NOTE 2--Accounting for Stock-Based Compensation:**

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

The following table, assuming a 40% effective tax rate, provides a reconciliation of net income and net income per share to pro forma net income and pro forma net income per share had compensation cost for the Company's stock option grants to employees been determined based on the fair value of each option on the date of grant, consistent with the methodology prescribed by SFAS No. 123 (in thousands, except per share amounts):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2005 | 2004 |
| Net income, as reported | $ 6,421 | $ 4,813 |
| Add: Stock-based employee compensation expense included in reported net income, net of taxes | 349 | 543 |
| Deduct: Total stock-based employee compensation expense, determined under fair value based method for all awards, net of taxes | (3,104) | (2,074) |
| Pro forma net income | $ 3,666 | $ 3,282 |
| Net income per share | | |
| Basic: | | |
| As reported | $ 0.15 | $ 0.12 |
| Pro forma | $ 0.09 | $ 0.08 |
| Diluted: | | |
| As reported | $ 0.15 | $ 0.11 |
| Pro forma | $ 0.08 | $ 0.08 |

The fair values of option grants and the employee stock purchase plan ("ESPP") were estimated as of the grant date or purchase date using the Black-Scholes option pricing model. The Black-Scholes model was originally developed for use in estimating the fair value of traded options and requires the input of highly subjective assumptions including expected stock price volatility. The Company's stock options and ESPP have characteristics significantly different from those of traded options and changes in the subjective input assumptions can materially affect the fair value estimates.

In December 2004, the FASB originally issued SFAS No. 123(R), "Share-Based Payment (revised 2004)". SFAS No. 123(R) will require companies to measure all stock-based compensation awards using a fair value-based method and record such expense in their financial statements, including grants of employee stock options. SFAS No. 123(R) as amended, will be effective for public companies for the first annual period beginning after June 15, 2005 (See Note 8).

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 be 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**

Prior to the Company's initial public offering, the Company issued options under the 1996 Stock Option Plan (the "1996 Plan") and shares of common stock under stock purchase agreements to certain employees, some of which contained repurchase provisions. These options and shares of common stock had 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 was remeasured at each vesting date. The Company believes that the fair value of the stock options is more reliably

measurable than the fair value of the services received.

Stock-based compensation expense for both employee and non-employee options was recognized as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2005 | 2004 |
| Cost of goods sold | $ 39 | $ 109 |
| Research and development | 239 | 327 |
| Sales and marketing | 377 | 428 |
| General and administrative | 66 | 381 |
| | $ 721 | $ 1,245 |

**NOTE 3--Net Income Per Share:**

Basic net income per share is computed by dividing net income by the weighted-average number of common shares outstanding for the period less the weighted average shares subject to repurchase. Diluted net income per share is computed by giving effect to all potentially-dilutive common stock, including options, warrants and common stock subject to repurchase. For the three months ended March 31, 2005 and 2004, respectively, 804,000 and 137,000 options outstanding were not included in the computation of diluted net income per share for the Company because the effect would be antidilutive.

The following table sets forth the computation of basic and diluted net income per share (in thousands, except per share amounts):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2005 | 2004 |
| Net income | $ 6,421 | $ 4,813 |
| Weighted-average shares outstanding | 41,843 | 39,769 |
| Less: weighted-average shares subject to repurchase | -- | (8) |
| Basic weighted-average shares outstanding | 41,843 | 39,761 |
| Dilutive effect of: | | |
| Options to purchase common stock | 2,388 | 3,566 |
| Warrants | -- | 5 |
| Diluted weighted-average shares outstanding | 44,231 | 43,332 |
| Net income per share: | $ 0.15 | $ 0.12 |
| Basic: | | |
| Diluted: | $ 0.15 | $ 0.11 |

**NOTE 4--Comprehensive Income:**

Comprehensive income generally represents all changes in stockholders' equity 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 other comprehensive income that are excluded from net income.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2005 | 2004 |
| Net income | $ 6,421 | $ 4,813 |
| Changes in unrealized gains (losses) on available-for-sale investments, net of taxes | (17) | 11 |
| Translation adjustments | (958) | (337) |
| Total comprehensive income | $ 5,446 | $ 4,487 |

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

| | March 31, 2005 | December 31, 2004 |
|---|---|---|
| Unrealized losses on available-for-sale investments, net of taxes | $ (64) | $ (47) |
| Translation adjustments | 2,578 | 3,536 |
| | $ 2,514 | $ 3,489 |

**NOTE 5--Inventories:**

Inventories consisted of the following (in thousands):

| | March 31, 2005 | December 31, 2004 |
|---|---|---|
| Raw materials | $ 5,486 | $ 5,715 |
| Work-in-process | 1,331 | 1,042 |
| Finished goods | 4,171 | 4,700 |
| | $ 10,988 | $ 11,457 |

**NOTE 6--Goodwill and Intangible Assets:**

Changes in the carrying amount of goodwill during the three months ended March 31, 2005 and 2004 resulted from changes in foreign currency rates.

Amortization expense related to the Company's other intangible assets was approximately $8,000 and $9,000 for the three months ended March 31, 2005 and 2004, respectively. Based on the intangible assets balance at March 31, 2005, the Company expects to recognize amortization expense of approximately $25,000 for the remaining nine months of fiscal 2005, $34,000 in 2006 and 2007, and approximately $6,000 in 2008.

**NOTE 7--Commitments and Contingencies:**

In April 2004, the Company filed two patent infringement suits against Disc-O-Tech Medical Technologies Ltd., an Israel-based company doing business in the United States as Disc Orthopaedic Technologies Inc. ("Disc-O-Tech"). The Company filed suit in the United States District Court in Delaware and in the International Trade Commission ("ITC") in Washington, D.C. In the ITC proceeding in September 2004, the ITC entered an Order barring Disc-O-Tech from all further importation of its SKy Bone Expander device into the United States and from engaging in any further sales activities and uses of such imported products, which thereby terminated the ITC proceeding in the Company's favor. In Delaware, the Company's complaint 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 at least 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 presently set for June 2005. No provision for any liability that may result upon the resolution of this matter has been made in the accompanying condensed consolidated 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 that the final disposition of any such litigation matters will have a material adverse affect on the Company.

In March 2005, the Company signed a lease for an additional facility in Sunnyvale, California which expires in March 2008. The total commitment is approximately $433,000 to be paid over the term of the lease.

**NOTE 8--Recent Accounting Pronouncements:**

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

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

**NOTE 9--Subsequent Event:**

Effective April 1, 2005, the Company entered into an agreement to exclusively license, in the field of orthopaedics including all spinal applications, Dr. J. Lee Berger's portfolio of patents concerning medical devices and methods for creating voids in, or moving, tissue or bone, including balloon platform cannulae. Under the agreement, Dr. Berger retained all of his rights in the field of diagnosis and treatment of carpel tunnel syndrome. The Company made an up-front payment of $1,000,000 in April 2005 and has agreed to provide a lifetime-capped royalty stream on any products developed that practice the licensed patent rights. The cost of this agreement will be immediately charged to in-process research and development as the in-process projects to which the patents apply have not yet reached technological feasibility and have no alternative future use. The Company also entered into a multi-year consulting agreement with Dr. Berger pursuant to which he will advise the Company on the development of future related products.

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

**Introduction**

This Quarterly Report on Form 10-Q 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, projections 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 competitive position; the protection of our technology and intellectual property rights; the effects of regulation on our business; 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," "target" or "anticipate" or the negative of these terms or other comparable terminology. These statements are subject to risks, uncertainties and assumptions that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. The risks, uncertainties and assumptions referred to above include: our ability to develop and successfully introduce new products, product extensions and improvements, the availability of adequate physician and hospital reimbursement for kyphoplasty procedures, continued referrals by primary care physician to trained clinicians that use our products, competition in our markets, assumed continuation of current litigation, any failure to maintain or obtain additional regulatory clearances or approvals, our ability to expand our manufacturing capacity and reliance on suppliers, our dependence on distributors and the impact of any acquisitions or divestitures that we may complete in the future. The reader is cautioned not to place undue reliance on these forward looking statements and projections, which reflect management's analysis only as of the date of this Quarterly Report on Form 10-Q. We undertake no obligation to update forward-looking statements and projections to reflect events or circumstances occurring after the date of this Form 10-Q. Management's discussion and analysis of financial condition and results of operations ("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 income statement.

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

- *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 March 31, 2005.

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

- *Factors affecting future operating results.* This section discusses the most significant factors that could affect our future financial results. The factors discussed in this section are in addition to factors that may be described in the 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 orthopaedic surgeons and neurosurgeons, interventional radiologists and interventional neuroradiologists who repair compression fractures of the spine caused by osteoporosis, trauma, cancer or benign lesions through minimally invasive spine surgeries known as 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 a sales, clinical, regulatory and administrative facility in Brussels, Belgium, a research and biomaterials manufacturing facility in Rosbach, Germany, a clinical, regulatory and administrative facility in Japan, and we have direct selling operations in 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 and Canada and distributors and sales agents in other countries in which we do not have a direct sales force. In Japan, we are presently focused primarily on procuring the appropriate governmental regulatory clearances and approvals necessary to market and sell our *KyphX* products.

***Products and Significant Business Trends.*** Our net sales consist of the sales of our *KyphX* instruments including our *KyphX* Inflatable Bone Tamps, *KyphX* Inflation Syringe, *KyphX* Bone Access Systems, *KyphX* Bone Filler Device, *KyphX* Curettes, *KyphX* Bone Biopsy Device, *KyphX HV-R* Bone Cement, *KyphX* Mixer and our CE-Marked *KyphOs* calcium phosphate from our acquisition of Sanatis GmbH.

During the first quarter of 2005, our business experienced significant growth. Net sales in the first quarter of 2005 increased to $66.2 million, compared to $44.4 million in the first quarter of 2004, representing growth of 49%. We trained over 500 physicians during the first quarter of 2005 in the United States and Europe. In the U.S., we added approximately 80 new hospitals to our customer base. 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. We expect to expand our spine education specialist sales force to approximately 85 positions by the end of 2005.

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. 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 presently set for June 2005. 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 to protect and enforce our rights through litigation or other appropriate means. We likely will have to compete with these competitive products for some period of time and ultimately may not succeed in protecting or enforcing our rights. We also 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 in those geographic markets as a result.

Effective April 1, 2005, we entered into an agreement to exclusively license, in the field of orthopaedics including all spinal applications, Dr. J. Lee Berger's portfolio of patents concerning medical devices and methods for creating voids in or moving tissue or bone, including balloon platform cannulae. Under the agreement, Dr. Berger retained all of his rights in the field of diagnosis and the treatment of carpel tunnel syndrome. We made an up-front payment of $1.0 million in April 2005 and have agreed to provide a lifetime-capped royalty stream on any products developed that practice the licensed patent rights. The cost of this agreement will be immediately charged to in-process research and development as the in-process projects to which the patents apply have not yet reached technological feasibility and have no alternative future use. We also entered into a multi-year consulting agreement with Dr. Berger pursuant to which we will work together on the development of future related products.

There have been several recent developments related to reimbursement for our products. First, in May 2004, the Centers for Medicare & 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 that went 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 is being applied, especially 442, 443 and 486. The distribution to each of these DRGs is dependent on the ICD-9-CM diagnosis code.

Second, in November 2004, CMS published the Final Rule on the Medical Hospital Outpatient Prospective System and created new and distinct hospital outpatient procedure codes for kyphoplasty, C9718 and C9719. These new C-codes are assigned to APC 51 and became effective January 1, 2005. Site of service is determined by the physician

based on medical necessity. Although our customers and potential customers may believe that the present level of reimbursement in effect for kyphoplasty procedures performed on an outpatient basis is not sufficient, the level of reimbursement may not be increased.

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 has been 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 34 states, and a number of private payors nationwide have also adopted policy coverage. However, there are some private payors that may continue to perceive kyphoplasty 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 recent progress in national reimbursement for physicians. Presently, no national Current Procedural Terminology ("CPT") code exists for spine specialist reimbursement under Medicare for performing kyphoplasty. Physicians presently must report procedures using our instruments under an unlisted CPT code. In the fourth quarter of 2004, the American Medical Association ("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 since 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 is now underway. We understand that upon conclusion of the survey process and determination of the appropriate reimbursement level by CMS, 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.

CMS has also announced its intention to conduct a meeting of the Medicare Coverage Advisory Committee on May 24, 2005 to "review the scientific evidence on the effectiveness of surgical management of vertebral compression fractures, particularly vertebroplasty and kyphoplasty." We view this as an opportunity to provide further input to CMS on the clinical effectiveness of kyphoplasty.

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 of our products in those markets. We do not know whether these efforts will continue or will 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 disease states 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.

In the first quarter of 2005 and through the date of this filing, we continued to adjust the responsibilities of some of our executive team to better serve our needs. Rick S. Kline, with over 25 years of manufacturing and operations experience in relevant industries, joined Kyphon as Vice President, Operations and Quality effective April 11, 2005.

Elizabeth A. Rothwell, our Vice President of Operations since February 2003 and our Vice President of Quality since November 2002, became our Vice President, Research and Development to lead our ongoing new product initiatives. Julie D. Tracy, our Vice President, Marketing since January 2003, assumed additional responsibility for our Investor Relations in April 2005, and now serves as our Vice President, Investor Relations and Corporate Marketing. We may continue to make further adjustments to the responsibilities and reporting structure of our executive team as we continue to grow.

***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 United States Food and Drug Administration ("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. 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**

**Three Months Ended March 31, 2005 and March 31, 2004**

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

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2005 | | 2004 | |
| | Amount | % of Net sales | Amount | % of Net sales |
| U.S. net sales | $ 57,866 | 87% | $ 40,624 | 91% |
| International net sales | 8,368 | 13% | 3,809 | 9% |
| Net sales | 66,234 | 100% | 44,433 | 100% |
| Cost of goods sold | 7,925 | 12% | 4,917 | 11% |
| Gross profit | 58,309 | 88% | 39,516 | 89% |
| Operating expenses: | | | | |
| Research and development | 5,460 | 8% | 4,557 | 10% |
| Sales and marketing | 34,985 | 53% | 22,341 | 50% |
| General and administrative | 7,698 | 12% | 4,840 | 11% |
| Total operating expenses | 48,143 | 73% | 31,738 | 71% |
| Income from operations | 10,166 | 15% | 7,778 | 18% |
| Interest income and other, net | 525 | 1% | 235 | -- |
| Net income before income taxes | 10,691 | 16% | 8,013 | 18% |
| Provision for income taxes | 4,270 | 6% | 3,200 | 7% |
| Net income | $ 6,421 | 10% | $ 4,813 | 11% |

***Net Sales*.** Net sales increased $21.8 million, or 49%, for the three months ended March 31, 2005 as compared to the same period in 2004. The increase in net sales resulted primarily from an increase in the number of physicians trained in the use of our *KyphX* instruments and thus an increase in the number of kyphoplasty procedures performed by these trained physicians. We trained over 500 physicians during the first quarter of 2005 in the United States, and other parts of the world, primarily Europe. The increase in international sales also reflected the favorable currency impact of $383,000 in the three months ended March 31, 2005. No customer accounted for more than 10% of total net sales for the three months ended March 31, 2005 and 2004. As of March 31, 2005, we had trained approximately 4,200 spine specialists in the U.S. and approximately 2,000 spine specialists in Europe. We believe the total number of potential physicians who may perform kyphoplasty procedures using our products is approximately 10,000 in the U.S.

The number of trainable physicians in Europe is less well-defined at this time, but we believe it to be more than 3,000. We have targeted a range of $280 million to $295 million in net sales of our *KyphX* products for 2005.

***Cost of Goods Sold***. Cost of goods sold consists of material, labor, subcontract, and overhead costs. Cost of goods sold increased $3.0 million, or 61%, for the three months ended March 31, 2005 as compared to the same period in 2004. The increase in cost of goods sold in absolute dollars resulted primarily from increased material, labor, subcontract, and overhead costs in relation to the increased sales volume of our products. As a percentage of net sales, cost of goods sold increased as a result of changes in product mix and prices and increased period expenses. In addition, the gross margin in the first quarter of 2004 benefited from favorable manufacturing absorption variances from the advance build-up of inventory in preparation of our move to new facilities in the second quarter of 2004. Our cost of goods sold and corresponding gross profit percentages can be expected to fluctuate in future periods depending upon changes in our product sales mix and prices, distribution channels and geographies, manufacturing yields, period expenses and levels of production volume. As a percentage of net sales, we expect cost of goods sold to be in the range of 11% to 12% for the year.

***Research and Development.*** Research and development expenses consist for costs of product research, product development, regulatory and clinical functions and personnel. Research and development expenses increased $903,000, or 20%, for the three months ended March 31, 2005 as compared to the same period in 2004. The increase was primarily attributable to increased personnel costs of $454,000, and increased clinical expenses of $451,000. We expect to continue to make substantial investments in research and development and anticipate that research and development expenses for the rest of 2005 will increase in absolute dollars compared to research and development expenses for the year ended December 31, 2004. As a percentage of net sales, we anticipate our research and development expenses for the continued development of our current product research efforts, products in development, regulatory and clinical efforts 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 $12.6 million, or 57%, for the three months ended March 31, 2005 as compared to the same period in 2004. The increase resulted primarily from increased costs of hiring, training and compensating additional direct selling representatives of $8.1 million and increased sales travel expenses of $1.5 million. As we continue to commercialize our *KyphX* instruments on a global basis during 2005, we expect to increase our sales and marketing efforts and expenditures in absolute dollars. As a percentage of net sales, we expect that our sales and marketing expenses for sales of our *KyphX* instruments will range between 49% to 50% for the year.

***General and Administrative*.** General and administrative expenses consist of personnel costs, professional service fees, expenses related to intellectual property rights and general corporate expenses. General and administrative expenses increased $2.9 million, or 59%, for the three months ended March 31, 2005 as compared to the same period in 2004. The increase resulted primarily from increased litigation fees of $1.4 million, increased personnel costs of $738,000, and increased legal and consulting fees of $596,000. We expect general and administrative expenses to increase in the future as we add personnel, continue to expand our patent portfolio, incur litigation fees, and incur public reporting, governmental compliance and investor-related expenses as a public company. In addition, assuming the continuation of our litigation with Disc-O-Tech at the present rate and the commencement of trial in June 2005 as presently scheduled, we estimate total legal expenses of $4.0 million to $6.0 million related to litigation during 2005. We expect that our general and administrative expenses will increase in absolute dollars as we expand our infrastructure and incur litigation costs. As a percentage of net sales, we expect that our general and administrative expenses will range between 11% and 12% during 2005, including costs related to the assumed continuation of our litigation with Disc-O-Tech.

***Interest Income and other.*** Interest income and other, net, increased $290,000 for the three months ended March 31, 2005 as compared to the same period in 2004. The increase resulted primarily from increased interest income from increased cash, cash equivalents and investment balances of $130.3 million as of March 31, 2005 compared to $85.5 million as of March 31, 2004, as well as higher interest rates.

***Provision for Income Taxes.*** Provision for income taxes was $4.3 million for the three months ended March 31, 2005 as compared to $3.2 million for the same period in 2004. We recorded a $430,000 and $200,000 tax liability, net, for the three months ended March 31, 2005 and 2004, respectively. We believe that in 2005, our effective tax rate will be approximately 40%, even though the actual amount of taxes paid may be reduced by net operating loss and research and development tax credit carry-forwards as well as deductions due to stock option activities. Our income taxes

currently payable for federal and state purposes have been reduced primarily by the tax benefits from employee stock option transactions.

**Deferred and Stock-Based Compensation**

We recorded deferred stock-based compensation on options issued prior to our initial public offering as the difference between the exercise price of options granted to employees and the deemed fair value of our common stock at the time of grant. Deferred stock-based compensation is amortized to cost of goods sold, research and development expense, sales and marketing expense and general and administrative expense as the options vest. Deferred stock-based compensation for employee stock options recorded through March 31, 2005 was $18.4 million, with accumulated amortization of $16.9 million. The remaining $1.5 million will be amortized over the vesting periods of the options, generally four years from the date of grant. All option amounts are being amortized using the straight-line method. We expect to record amortization expense for deferred stock-based compensation as follows:

| Year | Amount |
|---|---|
| 2005 (April – December) | $1.4 million |
| 2006 | $0.1 million |

Stock-based compensation expense for stock options granted to non-employees is recognized as the stock options are earned. The stock-based compensation expense will fluctuate as the fair market value of our common stock fluctuates. In connection with the grant of stock options to non-employees, we recorded stock-based compensation expense of approximately $138,000 and $341,000 for the three months ended March 31, 2005 and 2004, respectively.

**Liquidity and Capital Resources**

As of March 31, 2005, we had $102.7 million of cash and cash equivalents, $27.7 million of investments (short and long-term), and working capital of $169.4 million. Our cash and cash equivalents increased during the three months ended March 31, 2005 by $15.4 million over the corresponding amount of cash and cash equivalents as of December 31, 2004.

***Cash Provided by Operations.*** Net cash provided by operations was $13.2 million for the three months ended March 31, 2005 attributable primarily to net income of $6.4 million, adjustments for non-cash charges related to deferred taxes including a tax benefit from stock options of $4.3 million, an increase in accounts payable of $2.3 million, and decreases in prepaid expenses and other current assets of $1.2 million, offset partially by an increase in accounts receivable of $1.6 million and decreases in accrued liabilities of $1.6 million. Net cash provided by operations was approximately $8.4 million for the three months ended March 31, 2004 attributable primarily to net income of $4.8 million and adjustments for non-cash charges related to deferred taxes including a tax benefit from stock options of $3.1 million, amortization of deferred stock-based compensation of $1.2 million, increases in accrued liabilities of $1.5 million and decreases in prepaid expenses and other current assets of $1.7 million, offset partially by the increase in accounts receivable of $3.3 million as we increased our net sales, and a decrease in accounts payable of $1.4 million.

***Cash Used in Investing Activities.*** Net cash used in investing activities was $2.4 million for the three months ended March 31, 2005 and resulted primarily from the purchase of information systems to improve our infrastructure and operating efficiencies. Net cash used in investing activities was $3.2 million for the three months ended March 31, 2004 and primarily reflected purchases of property and equipment due to the outfitting of our Sunnyvale facility.

***Cash Provided by Financing Activities.*** Net cash provided by financing activities was $4.8 million during the three months ended March 31, 2005 and was attributable to issuance of common stock under the employee stock purchase plan of $2.4 million and proceeds from the exercise of stock options of $2.4 million. Net cash provided by financing activities was $2.4 million during the three months ended March 31, 2004 and was attributable to proceeds from the issuance of common stock under the employee stock purchase plan of $1.4 million and exercise of stock options of $928,000.

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

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

| | Payment Due by Periods | | | | | | |
|---|---|---|---|---|---|---|---|
| | Total | Remainder of 2005 | 2006 | 2007 | 2008 | 2009 | After 2009 |
| Operating leases | $ 19,933 | $ 1,751 | $ 2,243 | $ 2,209 | $ 2,094 | $ 2,151 | $ 9,485 |
| Asset retirement obligation | 246 | -- | -- | -- | -- | -- | 246 |
| Total commitments | $ 20,179 | $ 1,751 | $ 2,243 | $ 2,209 | $ 2,094 | $ 2,151 | $ 9,731 |

The amounts reflected in the table above for operating leases represent aggregate future minimum lease payments and asset retirement obligations under non-cancellable 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 March 31, 2005. 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 have not repurchased any of our common stock after 2002.

***Summary***. We believe our current cash, cash equivalents, investments, and cash generated from operations will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. If existing cash, cash equivalents, and cash generated from operations are insufficient to satisfy our liquidity requirements, whether as a result of increased capital expenditures, expansion of product lines or investment in new markets or businesses, or for other reasons related to our business, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or 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.

**Recent Accounting Pronouncements**

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

In December 2004, the FASB originally issued SFAS No. 123(R), “Share-Based Payment (revised 2004)”. SFAS No. 123(R) will require companies to measure all stock-based compensation awards using a fair value-based method and record such expense in their financial statements, including grants of employee stock options. In addition, the adoption of SFAS No. 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R) is effective for our quarterly report for the period ending March 31, 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin (“SAB”) No. 107, “TOPIC 14: Share-based payment”. SAB No. 107

addresses the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides views regarding the valuation of share-based payment arrangements for public companies. SAB No. 107 was effective immediately. The adoption of SFAS No. 123(R) and SAB No. 107 will decrease our earnings.

**Factors Affecting Future Operating Results**

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

Our current products offer orthopaedic surgeons and neurosurgeons, interventional radiologists and interventional neuroradiologists the ability to treat and restore spinal anatomy during kyphoplasty. We cannot assure you that the market for the treatment of spine fractures will continue to generate significant or consistent demand for our *KyphX* instruments. Demand for our products could be significantly diminished by alternative treatment methods, and by new technologies or products that replace and render our products obsolete or too expensive. Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory approval for, manufacture, sell and achieve market acceptance of new products, product extensions and improvements to our existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables. These variables include price, safety, efficacy, reliability, marketing and sales efforts, the availability of third-party reimbursement for 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 improvements to our existing products may also be subject to government regulation, including clearance/approval by the FDA and foreign government agencies. Any failure in our ability to successfully develop, obtain regulatory approval for, manufacture, sell and achieve market acceptance of our new products, product extensions or improvements to our existing products could have a material adverse effect on our operating results and our business.

**Our success is dependent upon the availability of adequate physician and hospital reimbursement for kyphoplasty procedures using our *KyphX* instruments.**

Physicians and hospitals are currently eligible for reimbursement by Medicare at varying payment levels in all 50 states and in the District of Columbia when kyphoplasty is performed using our *KyphX* instruments. In some cases, physicians performing a procedure using our instruments have not been reimbursed, either adequately or at all. In addition, some physicians and hospitals 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.

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 is now underway. We understand that upon conclusion of the survey process and determination of the appropriate reimbursement level by CMS, 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.

**If domestic and international payors adversely change reimbursement policies for kyphoplasty procedures, our ability to market and sell our *KyphX* instruments would be adversely impacted, which would harm our business, revenues and operating results.**

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.

**If primary care physicians are unwilling or unable to refer 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 program whereby selected sales representatives call on primary care physicians to educate them about our products and the clinical outcome of the kyphoplasty procedure. We believe that primary care physicians and spine specialists may not widely adopt our products unless they determine, based on experience, clinical data and published, peer-reviewed journal articles, that our products provide benefits or an attractive alternative to conventional treatments of 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.

**Because we may face significant competition from other companies with greater resources or superior technology than we have, we may be unable to maintain our competitive position and sales of our *KyphX* instruments may decline.**

The market for medical devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. While the direct competition we have faced to date has been limited, we are aware that several companies, some with more resources than ours, are developing and may already be introducing products to directly compete with ours in similar procedures, both in the United States and abroad. 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 *KyphX* instruments. Our ability to compete successfully depends in part on our ability to respond quickly to medical and technological changes and user preferences through the development and introduction of new products that are of high quality and that address patient and surgeon requirements. We compete with many larger companies that enjoy 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;
- greater experience completing preclinical testing and clinical trials and obtaining FDA and other regulatory approvals; and
- greater resources for product development, manufacturing, sales and marketing and patent litigation.

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

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

We believe that the proprietary technology embodied in our instruments and methods gives us a competitive advantage. Maintaining this competitive advantage is important to our future success. We rely on patent protection in the U.S. and abroad, as well as on a combination of copyright, trade secret and trademark laws, to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our patents may be challenged, invalidated or circumvented by third parties. Our two earliest patents, which we believe provide broad protection to our technology 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. In addition, in many foreign jurisdictions, we have either acquired patent protection that is narrower in scope than our corresponding protection in the U.S. or chosen, for various business reasons, not to pursue any patent protection at all. 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 and patent offices to protect our patent rights and prevent them from being undermined by our competitors' patent filings. If we decide to enforce our intellectual property rights to prevent or inhibit appropriation of our technology by competitors, that process will be expensive and time consuming to litigate or otherwise dispose of, will divert management's attention from our core business, and may harm our business if we do not prevail.

**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 a patent infringement suit against Disc-O-Tech in the United States District Court in Delaware, which is still in litigation. 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. While we believe our allegations have merit, we cannot assure you that we will prevail in our suit against Disc-O-Tech if the merits of our allegations are reached. Regardless of whether we prevail, this suit will be costly to us, dilutive to our earnings 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, rulings on various motions, and/or the public's perception of the litigation's progress or outcome.

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

The medical device industry has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights. Whether a medical device infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that our instruments and methods infringe their patents. From time to time, we receive correspondence from various third parties accusing us of infringing their patents or inviting us to license their patents. In addition, they may claim that their patents have priority over ours because they invented first or their patents were filed or issued first. Because patent applications can take many years to issue, there may be applications now pending of which we may be aware or unaware, which may later result in issued patents that our instruments or methods may infringe. There could also be existing patents that one or more of our instruments or methods may inadvertently be infringing. As the number of competitors in the market for minimally invasive spine disorder treatments grow, the possibility of a patent infringement claim against us increases.

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

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

Our *KyphX* instruments and bone cement and our *KyphOs* calcium phosphate are considered medical devices and are subject to extensive regulation in the United States and in foreign countries where we currently conduct, or intend to conduct, our business. Unless an exemption applies, each medical device that we wish to market in the United States must first receive either 510(k) clearance or premarket approval from the FDA. The FDA's 510(k) clearance process usually takes from three to 12 months, but may take longer. The premarket approval process generally takes from one to three years from the time the application is filed with the FDA, but it can take longer 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. We have also procured CE marking for promoting our products in Europe and the appropriate governmental regulatory clearances to conduct business in Canada and several other foreign countries. Nevertheless, our 510(k) and foreign regulatory clearances can be revoked if safety or effectiveness problems develop. We also will be required to obtain 510(k) clearance or premarket approval and foreign regulatory clearances to market additional products, such as new biomaterials for use in kyphoplasty, which will likely require clinical data, and to market our existing products for new indications, such as treatment of fractures caused by trauma, or in new geographic jurisdictions for us, such as Japan. If the clinical data gathered are not supportive, then applications will not be filed. If we choose to seek additional clearances or approvals by filing one or more applications, we cannot be certain that we would obtain any further regulatory clearances or premarket approvals in a timely manner or at all, and delays in obtaining clearances or approvals may adversely affect our revenue growth, future profitability and ability to penetrate what otherwise might be lucrative markets for our products.

**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. The use of bone filler material by surgeons to fill the void created using our *KyphX* Inflatable Bone Tamp may also lead to these complications, as a result of leakage of the bone filler material into the spinal canal or surrounding tissue or for other reasons. We are aware that some of these complications have occurred during procedures performed with our products, including our *KyphX HV-R* bone cement and *KyphOs* calcium phosphate, and we have had to publicly report that information through filing a Medical Device Report to the FDA or Vigilance Reports in Europe. Increased reporting of adverse events in connection with the use of our or other bone void filler materials during kyphoplasty could expose us to increased risk of product liability litigation, and our current insurance coverage limits may not be adequate and we may not be able to obtain continued product liability coverage on commercially reasonable terms, if at all. Companies, including ours, which produce devices for use in the spine, are subject to a significant risk of product liability litigation. If any of our devices are found to have caused or contributed to any injury, we could be held liable for substantial damages, and our current product liability coverage limits may not be adequate to protect us from any liabilities we might incur. In addition, we may require increased product liability coverage if sales of our devices increase. Product liability insurance is expensive and may not be available to us in the future on acceptable terms, if at all.

**We derive a significant portion of our operating results from non-U.S. sales, which are subject to additional risks arising from international operations and sales.**

Sales outside of the United States account for a significant percentage of our revenues and we intend to continue to expand our presence in international markets. International net sales accounted for $8.4 million, or approximately 13% of total net sales, for the three months ended March 31, 2005. Our international operations and sales are subject to a number of further risks in addition to those faced for our business, generally including:

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

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

**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 the 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.

**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 several foreign jurisdictions and are in the process of establishing, or have already established, new relationships in those and other geographic regions. We may also terminate or modify other distribution relationships in further geographic locations in the future. If we lose a distributor or a distributor fails to perform, our revenues will be harmed in those geographies, and the market for our products may also be harmed in those geographies as a result of the distributor's or agent's actions.

**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 March 2005, which we believe represents significant growth over a relatively short period of time. Our world-wide organization as a whole has increased from approximately 131 employees in October 2000 to over

750 employees in March 2005. We intend to continue growing rapidly. The growth that we have experienced, and in the future likely will experience, provides challenges to our organization, requiring us to rapidly expand our personnel and manufacturing operations. We may not be able to hire sufficient personnel to meet our growth goals or may have difficulty managing such rapid growth. As a result, our failure to recruit additional sales and other personnel may result in our inability to meet our projections. Future growth may strain our infrastructure, operations, product development and other managerial and operating resources. If our business resources become strained, we may not be able to deliver instruments in a timely manner.

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

Our continued success depends in part upon the continued availability and contributions of our senior management team and key personnel. We have entered into an employment agreement with Richard W. Mott, but this agreement does not guarantee his service for any specified period of time. We have not entered into employment agreements with any of our other senior management or key personnel. The loss of members of our senior management or key personnel, or our inability to attract and retain other qualified personnel or advisors could have a material adverse effect on our financial condition and results of operations.

**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 relating to compliance with future environmental laws. In addition, we could be held responsible for costs and damages arising from any contamination at our present facilities or third-party waste disposal sites. Such costs could be material. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur material liability as a result of any contamination or injury.

**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 the 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, harm our liquidity, disrupt our ongoing business, distract our management and employees, increase our expenses and expose us to new risks and liabilities, any or all of 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 38% of our outstanding common stock as of April 20, 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.

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

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

**We can provide no assurance regarding our, or our independent auditor's, conclusions after December 31, 2004 with respect to the effectiveness of our internal control over financial reporting.**

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to include an internal control report from management in our Annual Report on Form 10-K for the years ending on and after December 31, 2004. The internal control report must include a statement:

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

While we expended significant resources in developing the necessary documentation and testing procedures required by Section 404, given the risks inherent in the operation of internal controls over financial reporting, we can provide no assurance as to our, or our independent auditor's, conclusions after December 31, 2004 with respect to the effectiveness of our internal control over financial reporting. Although we received unqualified opinions as of December 31, 2004, if we are unable to maintain compliance with all of the requirements imposed by Section 404, or if we are unable to complete any assessment of our internal controls, or if our internal controls are not designed or operating effectively, 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 FASB 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-based 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 annual periods beginning after June 15, 2005. Currently, we disclose such expenses on a pro forma basis in the notes to our consolidated financial statements, but we do not record a charge for employee stock option expense in the financial statements. Once we begin to comply with SFAS No. 123(R) as of the beginning of fiscal year 2006, our reported earnings will decrease, which may affect our stock price.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest-rate risk as of March 31, 2005 is related primarily to our investment portfolio. Our investment portfolio includes fixed rate debt instruments of the U.S. government and its agencies and high quality corporate issuers. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk, investments are generally held to maturity and the weighted average duration of our investments is 12 months or less. Due to the short-term nature of these investments, we believe we have no material exposure to interest-rate risk arising from our investments.

We have operated mainly in the United States, and 87%, and 91% our sales were made in U.S. dollars for the three months ended March 31, 2005 and 2004, respectively. The majority of our international sales are derived from European Union countries and are denominated in the Euro. Monthly income and expense from our European operations are translated using average rates for the month and balance sheets are translated using rates in effect on the balance sheet date. Differences are recorded within stockholders' equity as a component of accumulated other comprehensive income or to the income statement, as applicable.

## ITEM 4. CONTROLS AND PROCEDURES

An evaluation of the effectiveness of our “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.

# PART II: OTHER INFORMATION

## ITEM 1. LEGAL PROCEEDINGS

In April 2004, the Company filed two patent infringement suits against Disc-O-Tech. The Company 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 the Company’s favor. 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 presently set for June 2005. No provision for any liability that may result upon the resolution of this matter has been made in the accompanying financial statements.

## ITEM 5. OTHER INFORMATION

In accordance with Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002 (the “Act”), we are required to disclose the non-audit services approved by our Audit Committee to be performed by PricewaterhouseCoopers LLP, our external accountants. Non-audit services are defined in the Act as services other than those provided in connection with an audit or a review of the financial statements of a company. The Audit Committee has approved the engagement of PricewaterhouseCoopers LLP for

the following non-audit services: (1) various tax matter consultations concerning foreign, U.S. federal and state taxes; and (2) the preparation of federal and state income tax returns.

**ITEM 6. 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. |
| 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 7, 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 the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Kyphon Inc.

Date: April 29, 2005

By: /s/ Richard W. Mott

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

Date: April 29, 2005

By: /s/ Arthur T. Taylor

Arthur T. Taylor
Vice President, Chief Financial Officer and
Treasurer
(Principal Accounting and Financial Officer)

Exhibit 31.1

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

I, Richard W. Mott certify that:

1. I have reviewed this quarterly report on Form 10-Q of Kyphon Inc;

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

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

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

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

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

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

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

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

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

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

Date: April 29, 2005 By: /s/ Richard W. Mott

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

Exhibit 31.2

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

I, Arthur T. Taylor certify that:

1. I have reviewed this quarterly report on Form 10-Q of Kyphon Inc;

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

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

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

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

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

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

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

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

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

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

Date: April 29, 2005

By: /s/ Arthur T. Taylor

Arthur T. Taylor
Vice President, Chief Financial Officer and Treasurer
(Principal Accounting and Financial Officer)

Exhibit 32.1

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

I, Richard W. Mott, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Kyphon Inc. on Form 10-Q for the fiscal quarter ended March 31, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Kyphon Inc.

Date: April 29, 2005 By: /s/ Richard W. Mott

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

I, Arthur T. Taylor, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Kyphon Inc. on Form 10-Q for the fiscal quarter ended March 31, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Kyphon Inc.

Date: April 29, 2005 By: /s/ Arthur T. Taylor

Arthur T. Taylor
Vice President, Chief Financial Officer and Treasurer
(Principal Accounting and Financial Officer)