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 September 30, 2004 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 October 29, 2004
Common Stock, $0.001 par value	41,049,273

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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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net sales	$ 55,811	$ 35,145	$ 150,989	$ 91,363
Cost of goods sold	6,247	4,591	17,164	11,891
Gross profit	49,564	30,554	133,825	79,472
Operating expenses:				
Research and development	5,548	4,186	15,077	11,232
Sales and marketing	26,342	17,259	73,443	48,269
General and administrative	7,785	4,174	19,960	11,534
Purchased in-process research and development	--	--	--	636
Total operating expenses	39,675	25,619	108,480	71,671
Income from operations	9,889	4,935	25,345	7,801
Interest income and other, net	343	277	803	771
Net income before income taxes	10,232	5,212	26,148	8,572
Provision for income taxes	4,100	500	10,500	500
Net income	$ 6,132	$ 4,712	$ 15,648	$ 8,072
Net income per share:				
Basic	$ 0.15	$ 0.12	$ 0.39	$ 0.21
Diluted	$ 0.14	$ 0.11	$ 0.36	$ 0.19
Weighted-average shares outstanding:				
Basic	40,733	38,767	40,216	38,140
Diluted	43,734	42,539	43,503	41,604

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

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

	September 30, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 83,779	$ 57,494
Investments	26,389	13,456
Accounts receivable, net	35,342	24,632
Inventories	9,891	6,239
Prepaid expenses and other current assets	3,564	3,810
Deferred tax assets	2,222	1,163
Total current assets	161,187	106,794
Investments	1,451	14,529
Property and equipment, net	9,179	6,044
Goodwill and other intangible assets, net	4,630	4,722
Deferred tax assets	19,120	20,462
Other assets	3,112	1,929
Total assets	$ 198,679	$ 154,480
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,226	$ 5,531
Accrued liabilities	22,417	14,699
Total current liabilities	28,643	20,230
Deferred rent	937	--
Total liabilities	29,580	20,230
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, $0.001 par value per share	41	39
Additional paid-in capital	187,328	171,359
Treasury stock, at cost	(201)	(201)
Deferred stock-based compensation, net	(3,011)	(6,435)
Accumulated other comprehensive income	2,002	2,196
Accumulated deficit	(17,060)	(32,708)
Total stockholders' equity	169,099	134,250
Total liabilities and stockholders' equity	$ 198,679	$ 154,480

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

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

	Nine Months Ended September 30,	
	2004	**2003**
Cash flows from operating activities:		
Net income	$ 15,648	$ 8,072
Adjustments to reconcile net income to net cash provided by operating activities:		
Provision for doubtful accounts receivable	310	304
Provision for excess and obsolete inventories	158	489
Depreciation and amortization	2,343	1,559
Deferred taxes including tax benefits from stock options	8,551	--
Loss on disposal of property and equipment	--	45
Amortization of deferred stock-based compensation	3,255	4,612
Purchased in-process research and development	--	636
Changes in operating assets and liabilities, net of effects of acquisition:		
Accounts receivable	(11,020)	(6,698)
Inventories	(3,810)	(2,603)
Prepaid expenses and other current assets	854	312
Other assets	(997)	(147)
Accounts payable	695	1,139
Accrued liabilities	7,718	147
Deferred rent	937	--
Net cash provided by operating activities	24,642	7,867
Cash flows from investing activities:		
Acquisition of property and equipment	(5,454)	(2,320)
Maturities and sales of investments	11,945	18,273
Purchase of investments	(12,687)	(20,821)
Payment for acquisition	--	(4,693)
Net cash used in investing activities	(6,196)	(9,561)
Cash flows from financing activities:		
Proceeds from issuance of common stock	3,421	1,416
Proceeds from exercise of stock options	4,478	1,922
Proceeds from payment of related party note receivable	--	1,882
Net cash provided by financing activities	7,899	5,220
Effect of foreign exchange rate changes on cash and cash equivalents	(60)	130
Net increase in cash and cash equivalents	26,285	3,656
Cash and cash equivalents at beginning of period	57,494	49,867
Cash and cash equivalents at end of period	$ 83,779	$ 53,523

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 spine 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.

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 nine month period ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004, 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, 2003.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the Company's Form 10-K for the year ended December 31, 2003 and have not changed materially as of September 30, 2004.

NOTE 2--Accounting for Stock-Based Compensation:

The Company uses the intrinsic value method of Accounting Principles Board Opinion No. 25 ("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 No. 123, ("SFAS No. 123"), "Accounting for Stock-Based Compensation" as amended by SFAS No. 148, ("SFAS No. 148"), "Accounting for Stock Based Compensation-Transition and Disclosure-an amendment of FASB Statement No. 123".

The following table 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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income, as reported	$ 6,132	$ 4,712	$ 15,648	$ 8,072
Add: Stock-based employee compensation expense included in reported net income, net of tax	416	963	1,417	3,127
Deduct: Total stock-based employee compensation expense, determined under fair value based method for all awards, net of tax	(2,913)	(2,928)	(7,297)	(6,979)
Pro forma net income	$ 3,635	$ 2,747	$ 9,768	$ 4,220
Basic income per share				
As reported	$ 0.15	$ 0.12	$ 0.39	$ 0.21
Pro forma	$ 0.09	$ 0.07	$ 0.24	$ 0.11
Diluted income per share				
As reported	$ 0.14	$ 0.11	$ 0.36	$ 0.19
Pro forma	$ 0.08	$ 0.06	$ 0.22	$ 0.10

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.

Stock-based compensation expense is being recognized on a straight-line basis over the vesting periods of the related options, generally four years. The Company recognized stock-based compensation expense as follows (in thousands):

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 potential dilutive common stock, including options, warrants and common stock subject to repurchase. The following table sets forth the computation of basic and diluted net income per share (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income	$ 6,132	$ 4,712	$ 15,648	$ 8,072
Weighted-average shares outstanding	40,733	38,790	40,219	38,172
Less: weighted-average shares subject to repurchase	--	(23)	(3)	(32)
Basic weighted-average shares outstanding	40,733	38,767	40,216	38,140
Dilutive effect of:				
Options to purchase common stock	2,997	3,716	3,282	3,403
Warrants	4	56	5	61
Diluted weighted-average shares outstanding	43,734	42,539	43,503	41,604
Basic income per share	$ 0.15	$ 0.12	$ 0.39	$ 0.21
Diluted income per share	$ 0.14	$ 0.11	$ 0.36	$ 0.19
Anti-dilutive weighted options to purchase common stock excluded from calculation	695	25	393	229

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income	$ 6,132	$ 4,712	$ 15,648	$ 8,072
Unrealized gains (losses) on available-for-sale investments, net of tax	23	(6)	(66)	(19)
Cumulative translation adjustment	290	92	(128)	858
Comprehensive income	$ 6,445	$ 4,798	$ 15,454	$ 8,911

The components of other comprehensive income reflected in the consolidated statements of stockholders' equity are as follows (in thousands):

	September 30, 2004	December 31, 2003
Unrealized gains (losses) on available-for-sale investments, net of tax	$ (40)	$ 26
Cumulative translation adjustments	2,042	2,170
	$ 2,002	$ 2,196

NOTE 5--Inventories:

Inventories consisted of the following (in thousands):

	September 30, 2004	December 31, 2003
Raw materials	$ 4,994	$ 3,327
Work-in-process	1,057	647
Finished goods	3,840	2,265
	$ 9,891	$ 6,239

NOTE 6--Goodwill and Intangible Assets:

Goodwill and intangible assets consisted of the following (in thousands):

	September 30, 2004	December 31, 2003
Goodwill	$ 4,519	$ 4,584
Intangible assets:		
Patents	162	164
Accumulated amortization	(51)	(26)
	111	138
Total	$ 4,630	$ 4,722

Intangible assets consist of patents acquired from Sanatis GmbH ("Sanatis") in February 2003. Intangible assets amortization expense for the three months ended September 30, 2004 and 2003 was approximately $8,000 and $7,000, respectively. Amortization expense for the nine months ended September 30, 2004 and 2003 was approximately $24,000 and $17,000, respectively. Based on the intangible assets held at September 30, 2004, the Company expects to recognize amortization expense of approximately $8,000 for the remaining three months of fiscal 2004, $32,400 in each of the years from 2005 to 2007, and approximately $5,400 in 2008. The amortization period for intangible assets is five years.

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. An enforcement proceeding against Disc-O-Tech in the ITC may later be initiated if it is determined that Disc-O-Tech is not complying fully with the ITC Order. In Delaware, the Company's complaint 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 six of the Company's U.S. patents, all of which generally concern the use of various medical devices to repair spinal compression fractures, and seeks enhanced damages and a permanent injunction for its willful infringement. Trial is set for June 2005. The Company is using the information discovered during the ITC proceeding about Disc-O-Tech's business activities to prosecute its case against Disc-O-Tech in Delaware and will continue to do so vigorously. A motion for a preliminary injunction against Disc-O-Tech on a single claim of one of the six patents-in-suit is now pending and will be heard during the fourth quarter. No provision for any liability that may result upon the resolution of this matter has been made in the accompanying financial statements.

NOTE 8--Recent Accounting Pronouncements:

In March 2004, the EITF reached a consensus on EITF No. 03-06, "Participating Securities and Two-Class Method under FASB Statement No. 128, Earnings per Share". EITF No. 03-06 addresses a number of questions regarding the computation of earnings per share (EPS) by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares

dividends on its common stock. EITF No. 03-06 also provides further guidance in applying the two-class method of calculating EPS. EITF No. 03-06 clarifies what constitutes a participating security and how to apply the two-class method of computing EPS once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. The consensus reached on EITF No. 03-06 was effective for fiscal periods beginning after March 31, 2004 and requires restatement of prior period earnings per share amounts to ensure comparability year over year. The adoption of EITF No. 03-06 did not have any impact on the Company's results of operations or financial condition.

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

Introduction

Management's discussion and analysis of financial condition and results of operations, or MD&A, is provided as a supplement to the accompanying condensed consolidated financial statements and footnotes contained in Item 1 of this report to provide an understanding of our results of operations, financial condition, and changes in financial condition. This discussion contains forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's results, levels of activity, performance or achievement to be materially different from any future results, levels of activity, performance or achievements expressed or implied in or contemplated by the forward-looking statements. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of selected factors, including those set forth in this section. 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, 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 statements.

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

- *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 September 30, 2004.

- *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 to treat and restore spinal anatomy using minimally invasive technology. Our devices are presently used primarily by spine specialists including orthopedic surgeons and neurosurgeons, interventional radiologists, and interventional neuroradiologists who repair compression fractures of the spine caused by osteoporosis, cancer or benign lesions. Our first commercial products, comprising our *KyphX* instruments, utilize our proprietary balloon technology. Surgeons use these instruments to help repair fractures during minimally invasive spine surgeries, known as kyphoplasty procedures. Most alternative spine fracture treatments are either highly invasive or are pain management therapies.

Our corporate headquarters and U.S. operations are located in Sunnyvale, California, where we conduct our manufacturing, warehousing, research, regulatory and administrative activities. Outside the U.S., we operate sales, clinical and administrative facilities in Brussels, Belgium, research and biomaterial manufacturing facilities in

Rosbach, Germany, a clinical 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 230 individuals who market our products to physicians, surgeons and hospitals and distributors and sales agents in a few other countries in which we do not have a direct sales force.

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

Effective August 11, 2004, Mr. Arthur T. Taylor assumed the role as our Vice President, Chief Financial Officer and Treasurer. Mr. Taylor most recently was Chief Financial Officer for Terayon Communication Systems, Inc. of Santa Clara, California. As previously announced, Mr. Jeffrey L. Kaiser, who had been our Vice President, Finance & Administration & Chief Financial Officer since March 2000, had transitioned into a part-time role of Vice President, Finance, primarily as a result of health issues related to chronic hip and back ailments.

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

Products and Significant Business Trends. Our net sales include sales of our *KyphX* instruments including our *KyphX* Inflatable Bone Tamps, *KyphX* Inflation Syringe, *KyphX* Bone Access Systems, *KyphX* Bone Filler Device, *Kyphon* Mixer and *KyphX* Bone Biopsy Device, as well as our recently cleared *KyphX HV-R* Bone Cement.

During the first nine months of 2004, our business experienced significant growth. Net sales in the first nine months of 2004 increased to $151.0 million, compared to $91.4 million in the first nine months of 2003, representing growth of 65%. We trained approximately 1,230 physicians to use our products during the first nine months of 2004 in the United States and Europe. In the U.S., we added approximately 270 new hospitals to our customer base during that same period. We continued a program whereby additional spine education specialists were hired with a primary role of educating referring primary care physicians about surgical options to treating patients with vertebral compression fractures with our products.

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

Recently, we concluded an extensive review of the published clinical literature describing the results for 897 patients treated with kyphoplasty and 2,408 patients treated with vertebroplasty. The data in the published literature demonstrate that kyphoplasty is associated with a statistically significantly lower procedure-related complication rate, and a statistically significantly lower procedure-related bone cement complication rate, as compared to vertebroplasty. As a result, we have now introduced the corresponding comparative claims into our educational and marketing materials.

In April 2004, we filed two patent infringement suits against Disc-O-Tech Medical Technologies Ltd., an Israel-based company doing business in the United States as Disc Orthopaedic Technologies Inc. ("Disc-O-Tech"). We filed suit in the United States District Court in Delaware and in the International Trade Commission ("ITC") in Washington, D.C. In 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 our favor. An enforcement proceeding against Disc-O-Tech in the ITC may later be initiated if it is determined that Disc-O-Tech is not complying fully with the ITC Order. In Delaware, our complaint 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 six of our U.S. patents, all of which generally concern the use of various medical devices to repair spinal compression fractures, and seeks enhanced damages and a permanent injunction for its willful infringement. Trial is set for June 2005. We are using the information discovered during the ITC proceeding about Disc-O-Tech's business activities to prosecute our case against Disc-O-Tech in Delaware and

will continue to do so vigorously. A motion for a preliminary injunction against Disc-O-Tech on a single claim of one of the six patents-in-suit is now pending and will be heard during the fourth quarter. 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 such products are deemed to infringe our patents, we will consider both how best to protect our market space as well as whether to take action against any potentially infringing competitor activities. As a result, we may decide that litigation or other legal activity to seek to protect and enforce our rights, in addition to our ongoing actions against Disc-O-Tech, would be appropriate. Regardless of if we do so, however, we likely will have to compete with these competitive products for some period of time. We may not have the ability to prevent those products from remaining on the market in at least some geographic locations, and we may lose market share or have our growth impeded as a result.

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

There was also progress in surgeon reimbursement during the year. On a national level, the Healthcare Common Procedure Coding System (HCPCS) National Editorial Panel established two new HCPCS "S" codes for kyphoplasty effective January 1, 2004. These S codes are intended for use by private payors, such as the Blue Cross Blue Shield Association and the Health Insurance Association of America, although no payment level is associated with these codes. In addition, policy and/or bulletin coverage is now established in 40 states, with the remaining states providing coverage on a case-by-case basis. The private payor community has also shown significant interest in establishing reimbursement policies for kyphoplasty. Specifically, Blue Cross Blue Shield has now adopted policy coverage for kyphoplasty in 30 states, and a number of private payors nationwide have also adopted policy coverage. However, there are some private payors that may continue to perceive the procedure which uses our products as experimental and thus not subject to reimbursement. Another challenge we face is to achieve consistent and/or increased payment levels among the different insurers. We continue to focus on addressing these issues.

Presently, no national current procedural terminology (CPT) code exists for spine specialist reimbursement under Medicare for performing kyphoplasty, and a CPT code may not exist for some time. Physicians presently must report procedures using our instruments under an unlisted CPT code. Multiple applications for a national CPT code for spine specialist reimbursement for kyphoplasty are now pending before the American Medical Association (AMA) CPT Editorial Panel for consideration during the fourth quarter of 2004, which is the initial step in the lengthy CPT process. The AMA CPT panel will consider these applications, hear from their proponents, and decide whether to issue any one of several possible CPT codes or whether to defer consideration until a later date. Since there are many possible outcomes, we do not know what action the AMA will take, or how its decision may affect our marketplace or our business, or whether any CPT code would ultimately 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 potentially to our revenues. The process for consideration, adoption and implementation of a CPT code could occur very quickly or take as long as several years.

In Europe, kyphoplasty was assigned a code in the newly implemented German DRG 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 a favorable outcome for the company.

We frequently evaluate potential opportunities for growth in our business by evaluating external products or technologies. While our ultimate 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. These efforts may require us to seek

additional funding and may be dilutive to our earnings.

Significant Industry Factors. Our industry is impacted by numerous competitive, regulatory and other significant factors. The growth of our business relies on our ability to continue to develop new products and innovative technologies, obtain regulatory clearance and compliance for our products, protect the proprietary technology of our products and our manufacturing processes, manufacture our products cost-effectively, and successfully market and distribute our products in a profitable manner. We, and the entire industry, are subject to extensive government regulation, primarily by the FDA. Failure to comply with regulatory requirements could have a material adverse effect on our business. Additionally, our industry is highly competitive and our success depends on our ability to compete successfully against our competitors. We devote significant resources to assessing and analyzing competitive, regulatory and economic risks and opportunities. A detailed discussion of these and other factors is provided in the "Factors Affecting Future Operating Results" section of our MD&A.

Results of Operations

Three Months Ended September 30, 2004 and September 30, 2003

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

	Three Months Ended September 30,			
	2004		2003	
	Amount	% of Net sales	Amount	% of Net sales
U.S. sales	$ 49,645	89%	$ 32,179	92%
International sales	6,166	11%	2,966	8%
Net sales	55,811	100%	35,145	100%
Cost of goods sold	6,247	11%	4,591	13%
Gross profit	49,564	89%	30,554	87%
Operating expenses:				
Research and development	5,548	10%	4,186	12%
Sales and marketing	26,342	47%	17,259	49%
General and administrative	7,785	14%	4,174	12%
Total operating expenses	39,675	71%	25,619	73%
Income from operations	9,889	18%	4,935	14%
Other and interest income, net	343	--	277	1%
Net income before income taxes	10,232	18%	5,212	15%
Provision for income taxes	4,100	7%	500	2%
Net income	$ 6,132	11%	$ 4,712	13%

***Net Sales*.** Net sales increased $20.7 million, or 59%, for the three months ended September 30, 2004 as compared to the same period in 2003. The increase in net sales resulted from an increase in the number of trained physicians as well as an increase in the number of procedures performed by the trained physicians. The increase in international sales also reflected the favorable currency impact of $483,000 in the three months ended September 30, 2004 as the Euro exchange rate strengthened against the U.S. dollar. No customer accounted for more than 10% of total net sales for the three months ended September 30, 2004 and 2003. As of September 30, 2004, we had trained approximately 3,600 surgeons in the U.S. and approximately 1,600 surgeons in Europe. We believe the total number of potential physicians who can be trained for the use of our products is approximately 6,000 to 7,000 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 believe we will continue to have an active spine specialist training program for the foreseeable future.

Cost of Goods Sold. Cost of goods sold consists of material, labor, subcontract, and overhead costs. Cost of goods sold increased $1.7 million, or 36%, for the three months ended September 30, 2004 as compared to the same period in 2003. However, cost of goods sold as a percentage of net sales continue to decrease primarily as a result of fixed

overhead costs being spread over increased production volume. The absolute increase in cost of goods sold resulted primarily from increased material, labor, subcontract, and overhead costs in relation to the increased sales volume of our products. Our cost of goods sold and corresponding gross profit percentages can be expected to fluctuate in future periods depending upon changes in our product sales mix and prices, distribution channels and geographies, manufacturing yields, period expenses and levels of production volume.

Research and Development. Research and development expenses consist of costs of product research, product development, regulatory and clinical functions and personnel. Research and development expenses increased $1.4 million, or 33%, for the three months ended September 30, 2004 as compared to the same period in 2003. The increase was primarily attributable to increased personnel costs of $895,000, increased consulting fees of $349,000, and increased clinical expense of $290,000, offset partially by decreased stock-based compensation expense of $441,000. We expect to continue to make substantial investments in research and development and anticipate that research and development expenses for the rest of 2004 will increase in absolute dollars. As a percentage of net sales, we anticipate our research and development expenses to be in the range of 10% to 11% for 2004.

Sales and Marketing. Sales and marketing expenses consist of costs for personnel, physician training programs and marketing activities. Sales and marketing expenses increased $9.1 million, or 53%, for the three months ended September 30, 2004 as compared to the same period in 2003. The increase resulted primarily to increased costs of hiring, training and compensating additional direct selling representatives of $6.8 million, increased sales travel expenses of $880,000, and increased surgeon training expense of $680,000. As we continue to commercialize our *KyphX* instruments during 2004, we expect to significantly increase our sales and marketing efforts and expenditures in absolute dollars while maintaining our sales and marketing expenses as a percentage of net sales to between 48% to 49% for the year.

***General and Administrative*.** General and administrative expenses consist of personnel costs, professional service fees, expenses related to intellectual property rights and general corporate expenses. General and administrative expenses increased $3.6 million, or 87%, for the three months ended September 30, 2004 as compared to the same period in 2003. The increase resulted primarily from increased personnel costs of $1.3 million, increased litigation fees of $817,000, and increased legal and consulting fees of $686,000. 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, we anticipate total legal expenses of $2.8 to $3.3 million related to our litigation with Disc-O-Tech during 2004. 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 13% and 14% during 2004.

Interest Income and other, Net. Interest income and other, net, increased $66,000 for the three months ended September 30, 2004 as compared to the same period in 2003. The increase resulted primarily from increased interest income from higher cash, cash equivalent and investment balances.

Provision for Income Taxes. Provision for income taxes was $4.1 million for the three months ended September 30, 2004 as compared to $500,000 in the same period in 2003. We recorded a $300,000 tax liability, net, for the three months ended September 30, 2004. We believe that in 2004 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. We incurred a $500,000 tax liability for the three months ended September 30, 2003 which includes $230,000 for federal alternative minimum taxes, $170,000 for foreign taxes, and $100,000 for state income taxes.

Nine Months Ended September 30, 2004 and September 30, 2003

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

	Nine Months Ended September 30,			
	2004		2003	
	Amount	% of Net sales	Amount	% of Net sales
U.S. sales	$ 135,314	90%	$ 82,731	91%
International sales	15,675	10%	8,632	9%
Net sales	150,989	100%	91,363	100%
Cost of goods sold	17,164	11%	11,891	13%
Gross profit	133,825	89%	79,472	87%
Operating expenses:				
Research and development	15,077	10%	11,232	12%
Sales and marketing	73,443	49%	48,269	53%
General and administrative	19,960	13%	11,534	13%
Purchased in-process research and development	--	--	636	1%
Total operating expenses	108,480	72%	71,671	79%
Income from operations	25,345	17%	7,801	8%
Other and interest income, net	803	--	771	1%
Net income before income taxes	26,148	17%	8,572	9%
Provision for income taxes	10,500	7%	500	--
Net income	$ 15,648	10%	$ 8,072	9%

Net Sales. Net sales increased $59.6 million, or 65%, for the nine months ended September 30, 2004 as compared to the same period in 2003. The increase in international sales also reflected the favorable currency impact of $1.3 million in the nine months ended September 30, 2004 as the Euro exchange rate strengthened against the U.S. dollar. The increase in net sales resulted from an increase in the number of trained physicians as well as an increase in the number of procedures performed by trained physicians. No customer accounted for more than 10% of total net sales for the nine months ended September 30, 2004 and 2003.

Cost of Goods Sold. Cost of goods sold increased $5.3 million, or 44%, for the nine months ended September 30, 2004 as compared to the same period in 2003. The absolute increase in the cost of goods sold resulted primarily from increased material, labor, and overhead costs associated with increased sales volume of our products. However, cost of goods sold as a percentage of net sales continue to decrease primarily as a result of fixed overhead costs being spread over increased production volume.

Research and Development. Research and development expenses increased $3.8 million, or 34%, for the nine months ended September 30, 2004 as compared to the same period in 2003. The increase primarily resulted from increased personnel costs of $2.5 million, increased clinical expense of $647,000, increased consulting fees of $624,000 and increased travel expense of $507,000, offset partially by decreased stock-based compensation expense of $952,000.

Sales and Marketing. Sales and marketing expenses increased $25.2 million, or 52%, for the nine months ended September 30, 2004 as compared to the same period in 2003. The increase resulted primarily from increased costs of hiring, training and compensating additional direct selling representatives of $18.4 million, increased travel expense of $2.9 million, increased surgeon training expense of $1.2 million, and increased consulting fee of $1.0 million.

General and Administrative. General and administrative expenses increased $8.4 million, or 73%, for the nine months ended September 30, 2004 as compared to the same period in 2003. The increase resulted primarily from increased personnel costs of $3.1 million, increased litigation fees of $1.8 million, and increased legal and consulting fees of $1.3 million.

Purchased In-Process Research and Development. In February 2003, we acquired Sanatis, a privately-held developer and manufacturer of orthopedic biomaterials based in Rosbach, Germany. An independent appraisal was performed to determine the fair value of identified intangible assets and the allocation of the purchase price. The total cost of the acquisition was $4.7 million including assumed liabilities and acquisition costs, $636,000 of which was immediately expensed to purchased in-process research and development in February 2003. It was immediately

expensed to operations as the technology acquired was not considered to have reached technological feasibility and it has no alternative future use.

Interest Income and Other, Net. Interest income and other, net, increased $32,000 for the nine months ended September 30, 2004 as compared to the same period in 2003. The increase resulted primarily from increased interest income.

Provision for Income Taxes. Provision for income taxes was $10.5 million for the nine months ended September 30, 2004 as compared to $500,000 in the same period in 2003. We recorded a $500,000 tax liability, net, for the nine months ended September 30, 2004. Our income taxes currently payable for federal and state purposes have been reduced primarily by the tax benefits from employee stock option transactions. We incurred a $500,000 tax liability for the nine months ended September 30, 2003 which includes $230,000 for federal alternative minimum taxes, $170,000 for foreign taxes, and $100,000 for state income taxes.

Deferred Stock-Based Compensation

We recorded deferred stock-based compensation for financial reporting purposes as the difference between the exercise price of options granted to employees and the deemed fair value of our common stock at the time of grant. Deferred stock-based compensation is amortized to cost of goods sold, research and development expense, sales and marketing expense and general and administrative expense. Deferred stock-based compensation recorded through September 30, 2004 was $18.5 million, with accumulated amortization of $15.8 million. The remaining $2.7 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 a straight-line method. We expect to record amortization expense for deferred stock-based compensation as follows:

Year	Amount
2004	$0.6 million (October to December)
2005	$2.0 million
2006	$0.1 million

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. The stock-based compensation expense will fluctuate as the fair market value of our common stock fluctuates. In connection with the grant of stock options to non-employees, we recorded deferred stock-based compensation of $6.6 million through September 30, 2004, of which $6.3 million has been amortized to expense as of September 30, 2004.

Liquidity and Capital Resources

In May 2002, we received net proceeds of $94.9 million from our initial public offering of common stock. From inception through June 2001, we raised $38.0 million through private sales of redeemable convertible preferred stock. As of September 30, 2004, we had $83.8 million of cash and cash equivalents, $27.8 million of investments (short and long-term), and working capital of $132.5 million.

Cash Provided by Operations. Our operating cash flow in the first nine months of 2004 was primarily the result of our operational profitability. Specifically, net cash provided by operations was $24.6 million for the nine months ended September 30, 2004 attributable primarily to net income of $15.6 million, adjustments for non-cash charges related to deferred taxes including tax benefit from stock options of $8.6 million, amortization of deferred stock-based compensation of $3.3 million, and an increase in accrued liabilities of $7.7 million, offset partially by the increase in accounts receivable of $11.0 million and inventories of $3.8 million. Our accrued liabilities, accounts receivables and inventories have increased as we increased our sales and our operating expenses during 2004. Our net cash flow from operations in the first nine months of 2003 was also primarily the result of our operational profitability. Specifically, net cash provided by operations was $7.9 million for the nine months ended September 30, 2003 attributable primarily to net income of $8.1 million, adjustments for non-cash charges related to amortization of deferred stock-based compensation of $4.6 million, depreciation and amortization expenses of $1.6 million, and increases in accounts payable of $1.1 million as we increased our operating expenses, offset partially by the increases in accounts receivable of $6.7 million and inventories of $2.6 million as we increased our sales.

Cash Used in Investing Activities. Net cash used in investing activities was $6.2 million for the nine months ended September 30, 2004 and primarily reflected purchases of property and equipment of $5.5 million due to the outfitting

of our new Sunnyvale facility. Net cash used in investing activities was $9.6 million for the nine months ended September 30, 2003 and primarily reflected the payment of $4.7 million in connection with the Sanatis acquisition, $2.5 million in net purchases of investments, and $2.3 million in purchases for property and equipment.

Cash Provided by Financing Activities. Net cash provided by financing activities was $7.9 million during the nine months ended September 30, 2004 and was attributable to proceeds from the exercise of stock options of $4.5 million and issuance of common stock under the employee stock purchase plan of $3.4 million. Net cash provided by financing activities was $5.2 million during the nine months ended September 30, 2003 and was attributable to proceeds from the exercise of stock options of $1.9 million, repayment of related party note receivable of $1.9 million, and issuance of common stock under the employee stock purchase plan of $1.4 million.

Contractual Cash Obligations. At September 30, 2004 we had contractual cash obligations as follows (in thousands):

	Payment Due by Periods						
	Total	**2004**	**2005**	**2006**	**2007**	**2008**	**After 2008**
Operating leases	$ 20,626	$ 559	$ 2,190	$ 2,106	$ 2,076	$ 2,071	$ 11,624

The amounts reflected in the table above for operating leases represent aggregate future minimum lease payments under non-cancelable 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 September 30, 2004. These future payments are subject to foreign currency exchange rate risk.

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

Off-Balance-Sheet Arrangements. As of September 30, 2004, we did not have any significant off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Stock Repurchase. The 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 from time to time by management and the Board. The purchases will be funded from available working capital. As of September 30, 2004, we had repurchased 30,000 shares pursuant to this repurchase program.

Summary. We believe our current cash, cash equivalents, investments, and cash generated from operations will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. If existing cash, cash equivalents, and cash generated from operations are insufficient to satisfy our liquidity requirements, or for other reasons related to our business, we may seek to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock, and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and marketing efforts.

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

Recent Accounting Pronouncements

In March 2004, the Emerging Issues Task Force (EITF) reached a consensus on EITF No. 03-06, "Participating Securities and Two-Class Method under FASB Statement No. 128, Earnings per Share". EITF No. 03-06 addresses a number of questions regarding the computation of earnings per share (EPS) by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF No. 03-06 also provides further guidance in applying the two-class method of calculating EPS. EITF No. 03-06 clarifies what constitutes a participating security and how to apply the two-class method of computing EPS once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. The consensus reached on EITF No. 03-06 was effective for fiscal periods beginning after March 31, 2004 and requires restatement of prior period earnings per share amounts to ensure comparability year over year. The adoption of EITF No. 03-06 did not have any impact on our results of operations or financial condition.

Factors Affecting Future Operating Results

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

The market for medical devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. While the direct competition we have faced to date has been limited, we are aware that several companies are developing and already introducing products to directly compete with ours in similar procedures, both in the United States and abroad. Some of these competitors' products may be successful in our market as a result of greater efficacy, less expensive alternatives to our products, or some other advantage that makes their products more attractive than ours, which could significantly impact our reimbursement levels, anticipated revenues and future growth. Our industry also includes large pharmaceutical companies that are developing drug products that may reduce the incidence of osteoporosis and cancer and, therefore, the market for our instruments. Our ability to compete successfully depends in part on our ability to respond quickly to medical and technological changes and user preferences through the development and introduction of new products that are of high quality and that address patient and surgeon requirements. We compete with many larger companies that enjoy several competitive advantages, including:

- longer-standing distribution networks, and relationships with health care providers and payors;
- additional lines of products, and the ability to bundle products to offer higher discounts or other incentives to gain a competitive advantage; and
- greater resources for product development, sales and marketing and patent litigation.

At any time, other companies may develop additional competitive products. If we are unable to compete effectively against existing or future competitors, sales of our instruments will decline.

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

We believe that the proprietary technology embodied in our instruments and methods gives us a competitive advantage. Maintaining this competitive advantage is important to our future success. We rely on patent protection in the U.S. and abroad, as well as on a combination of copyright, trade secret and trademark laws, to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our patents may be challenged, invalidated or circumvented by third parties. Our two earliest patents, which we believe provide broad protection to our technology but which are 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 without effective recourse. If our intellectual property rights are not adequately protected, we may be unable to keep other companies from competing directly with us, which could result in a decrease in our market share. To protect our rights, we may in the future initiate other claims or litigation against third parties for infringement of our proprietary rights, in order to protect our rights or further determine the scope and validity of our intellectual property protection. We may also begin one or more patent proceedings in various administrative agencies, such as the world's various Patent Offices, to protect our

patent rights and prevent them from being undermined by our competitors' patent filings. If we decide to enforce our intellectual property rights to prevent or inhibit appropriation of our technology by competitors, that process will be expensive and time consuming to litigate or otherwise dispose of, will divert management's attention from our core business, and may harm our business if we do not prevail.

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

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

Adverse changes in reimbursement procedures by domestic and international payors may impact our ability to market and sell our instruments.

Even if the use of our instruments is reimbursed by private payors and Medicare, adverse changes in payors' policies toward reimbursement for procedures using our products would harm our ability to market and sell our instruments. We are unable to predict what changes will be made in the reimbursement methods used by payors. We cannot be certain that under prospective payment systems, such as those utilized by Medicare, and in many managed care systems used by private health care payors, the cost of our instruments will be justified and incorporated into the overall cost of the procedure.

Even if we fulfill domestic and international regulatory requirements to market our instruments, our success will be partly dependent upon the availability of reimbursement within prevailing health care payment systems in those jurisdictions in which we operate. 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. Although we intend to seek international reimbursement approvals, we may not obtain approvals in a timely manner, if at all, or any approvals may not be adequate to justify use of our products or may be modified or withdrawn even if they are initially granted. Future regulatory action by a U.S. or foreign government agency, including the adoption of a national CPT code, or negative clinical results may diminish reimbursement coverage for both the physician and hospital.

If reimbursement for the procedures using our instruments becomes difficult to obtain or is not available in sufficient amounts, our instruments may not be widely used.

In a small number of cases, physicians performing a procedure using our instruments have not been reimbursed, either adequately or at all. In addition, although physicians have obtained reimbursement from Medicare for the use of our products in all 50 states and in the District of Columbia, some physicians in some states believe that the level of reimbursement they receive is too low. Reimbursement for competing procedures, such as vertebroplasty, may also continue to be perceived in some cases as more favorable for the doctor or hospital and thus may reduce the frequency with which procedures using our products are performed. Continued adoption of our 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. Presently, no national CPT code exists for spine specialist reimbursement for performing kyphoplasty, and a CPT code may not exist for some time. Although the AMA CPT Editorial panel presently has under consideration applications for a national CPT code for spine specialist reimbursement for kyphoplasty, we do not know what action the AMA will take since there are many possible outcomes. Were a national CPT code to issue for spine specialist reimbursement for performing kyphoplasty, our business and revenues could be harmed by how the category of code issued is perceived by the reimbursement and investment community, or if the levels of reimbursement presently available are decreased or eliminated as a result. We presently do not know, and can provide you no assurances concerning, how the AMA's decision may affect our marketplace or our business, or whether any CPT code would ultimately increase or decrease any of the spine specialist reimbursement already available. We believe that any type of CPT code has at least the potential to be

detrimental to spine specialist reimbursement and thus potentially to our revenues. Any amount of reimbursement assigned to any CPT code may not be sufficient for many spine specialists to justify continuing to perform procedures with our products. The process for consideration, adoption and implementation of a CPT code could occur very quickly or take as long as several years. Until a specific national CPT code is granted, physician reimbursement from Medicare may be harder to obtain in some states, and some states may not reimburse for a procedure using our products in an adequate amount.

On August 11, 2004, CMS published a new ICD–9-CM in-patient procedure code effective October 1, 2004 for the kyphoplasty procedure and assigned it to five DRG codes for facility reimbursement. At this time, it is not clear how each of the five codes will be applied. With the exception of Germany, specific reimbursement codes for these instruments and procedures either have not been established internationally, or are in the early stages of development. If physicians or hospitals are unable to obtain adequate reimbursement for procedures in which our *KyphX* instruments are used, we may be unable to sell our instruments and our business could suffer.

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

Our *KyphX* instruments are considered medical devices and are subject to extensive regulation in the United States and in foreign countries where we currently conduct, or intend to do business. Unless an exemption applies, each medical device that we wish to market in the United States must first receive either 510(k) clearance or premarket approval from the FDA. The FDA's 510(k) clearance process usually takes from three to 12 months, but may take longer. The premarket approval process generally takes from one to three years from the time the application is filed with the FDA, but it can take longer and be significantly more expensive than the 510(k) clearance process. So far, we have obtained 510(k) clearance for the *KyphX* Inflatable Bone Tamps for fracture reduction or void creation in specific sites including the spine (including for use during balloon kyphoplasty using our bone cement), hand, tibia, radius and calcaneus, and clearance for our *KyphX HV-R* Bone Cement for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions during kyphoplasty procedures. These clearances allow us to promote numerous short- and long-term clinical benefits associated with kyphoplasty procedures. Nevertheless, our 510(k) clearances can be revoked if safety or effectiveness problems develop. We also will be required to obtain 510(k) clearance or premarket approval to market additional products, such as biomaterials for use in trauma-related fractures, and will be required to obtain additional clearances/approvals for new indications for some of our *KyphX* devices, such as treatment of fractures caused by trauma. If the clinical data gathered are not supportive, then applications will not be filed. If we choose to seek additional clearances or approvals by filing one or more applications, we cannot be certain that we would obtain any further 510(k) clearances or premarket approvals in a timely manner or at all, and delays in obtaining clearances or approvals may adversely affect our revenue growth and future profitability.

If regulatory authorities do not modify or retract their prior pronouncements concerning the use of bone cement in the spine, our ability to promote and sell our instruments 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, balloon kyphoplasty and pedicle screw augmentation procedures." The UK 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 used 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 recent 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. An increase in reports of deaths or serious injuries could lead the FDA or foreign regulatory agencies to issue safety alerts, health advisories, or mandated labeling changes restricting use of our instruments, including new warnings regarding their use or contraindicating their use with bone cement. In addition, use of our products in the spine causes a surgeon to use a bone void filler of choice, typically bone cement, in the spine to fill the voids created by our products. Although we now are able to promote our *KyphX HV-R* bone cement for use in kyphoplasty procedures, increased reporting of adverse events in connection with 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. Product liability insurance is expensive and may not be available to us in the future on acceptable terms, if at all.

Modifications to our marketed devices may require new 510(k) clearances or premarket approvals or 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 instrument, 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.

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

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

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

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 involves significant risk of serious complications, including cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, and death. Use of bone filler material by surgeons to fill the void created using our *KyphX* Inflatable Bone Tamp may also lead to these complications, as a result of leakage of the bone filler material into the spinal canal or surrounding tissue or for other reasons. Consequently, companies that produce instruments for use in

the spine are subject to a significant risk of product liability litigation. If any of our instruments is 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 instruments increase. Product liability insurance is expensive and may not be available to us in the future on acceptable terms, if at all.

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

Sales outside of the United States account for a significant percentage of our revenues and we intend to continue to expand our presence in international markets. Non-U.S. sales are subject to a number of special risks. For example:

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

Any of these events could harm our foreign operations.

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

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

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

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

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

Our world-wide direct sales organization has increased from approximately 30 employees in October 2000 to over 230 employees in September 2004, which we believe represents very significant growth over a relatively short period of time. We intend to continue to grow rapidly. The growth that we have experienced, and in the future likely will experience, provides challenges to our organization, requiring us to rapidly expand our personnel and manufacturing operations. We may not be able to hire sufficient personnel to meet our growth goals or may have difficulty managing such rapid growth. As a result, our failure to recruit additional sales 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.

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

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. 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.

If we fail to comply with Quality System regulations, our manufacturing operations could be delayed, and our product sales and profitability could suffer.

Our manufacturing processes and those of our suppliers are required to comply with the FDA's Quality System Regulations, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our instruments. The FDA enforces its Quality System Regulations through periodic announced or unannounced inspections. If we fail a Quality System inspection, our operations could be disrupted and our manufacturing delayed. Failure to take adequate corrective action in response to an adverse Quality System inspection could force a shut-down of our manufacturing operations, recall of our instruments, and civil penalties and criminal prosecution, which would cause our instrument sales and business to suffer.

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

We may acquire companies, products or technologies that we believe to be complementary to our present or future direction of our business. If we do so, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees and increase our expenses, which could harm our business.

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

Our officers, directors and principal stockholders together control approximately 44% of our outstanding common stock as of October 29, 2004. 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 the Company's 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 a "poison pill" and other anti-takeover provisions that 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 shareholders. Those provisions might discourage, delay or prevent a change in the control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

Recently enacted and proposed changes in securities and corporate governance laws and regulations are likely to increase our costs.

The Sarbanes-Oxley Act of 2002 that became law in July 2002, as well as new rules and regulations subsequently implemented by the Securities and Exchange Commission and the NASDAQ exchange on which we are listed, have required changes to some of our corporate governance practices. The Act also requires the Securities and Exchange Commission to promulgate additional new rules on a variety of subjects. We expect all of these new rules and regulations to increase our legal and financial compliance costs, to make some activities more difficult, time consuming and/or costly, and to make it more difficult and more expensive for us to obtain director and officer

liability insurance, all of which may affect our financial performance. These new rules and regulations may also make it more difficult for us to attract or retain qualified executive officers and members of our board of directors, particularly to serve on our audit committee.

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

Section 404 of the Sarbanes-Oxley Act of 2002 (the "Act") will require us to include an internal control report from management in our Annual Report on Form 10-K for the year ended December 31, 2004 and in subsequent Annual Reports. 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 December 31, 2004, including a statement as to whether or not internal control over financial reporting is effective; and
- That our independent auditors have issued an attestation report on management's assessment of internal control over financial reporting.

While we are expending significant resources in developing the necessary documentation and testing procedures required by Section 404, given the risks inherent in the design and operation of internal controls over financial reporting, we can provide no assurance as to our, or our independent auditor's, conclusions at December 31, 2004 with respect to the effectiveness of our internal controls over financial reporting. If we are unable to comply with all of the requirements imposed by Section 404 by December 31, 2004, or if we do not effectively complete our assessment, 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 ability to run our business as we otherwise would like to.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest rate risk at September 30, 2004 is related primarily to our investment portfolio. Our investment portfolio includes fixed rate debt instruments of the U.S. government and its agencies and high quality corporate issuers. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk, investments are generally held to maturity and the weighted average duration of our investments is 12 months or less. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

We have operated mainly in the United States, 90%, and 91% our sales were made in U.S. dollars for the nine months ended September 30, 2004 and 2003, respectively. To date, we have not had any material exposure to foreign currency rate fluctuations. The majority of our European sales is derived from European Union countries and is denominated in the Euro. Monthly income and expense from our European operations are translated using average rates and balance sheets are translated using month end rates. Differences are recorded within stockholders' equity as a component of accumulated other comprehensive income (loss).

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our management, including our President and Chief Executive Officer and Chief Financial Officer conducted an evaluation as of September 30, 2004 of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e)). Based on that evaluation, the President and Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures were effective in ensuring that all material information required to be disclosed in the reports we file and

submits under the Securities and Exchange Act of 1934 has been made known to them on a timely basis and that such information has been properly recorded, processed, summarized and reported, as required.

Changes in Internal Control over Financial Reporting. There have been no significant changes in our internal control over financial reporting during the most recent fiscal quarter that materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

Sarbanes-Oxley Section 404 Compliance. Section 404 of the Sarbanes-Oxley Act of 2002 (the "Act") will require us to include an internal control report from management in our Annual Report on Form 10-K for the year ended December 31, 2004 and in subsequent Annual Reports thereafter. The internal control report must include the following: (1) a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting, (2) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (3) management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004, including a statement as to whether or not internal control over financial reporting is effective, and (4) a statement that our independent auditors have issued an attestation report on management's assessment of internal control over financial reporting.

Management acknowledges its responsibility for establishing and maintaining internal controls over financial reporting and seeks to continually improve those controls. In addition, in order to achieve compliance with Section 404 of the Act within the required timeframe, we have been conducting a process to document and evaluate our internal controls over financial reporting since 2003. In this regard, we have dedicated internal resources, engaged outside consultants and adopted a detailed work plan to: (i) assess and document the adequacy of internal control over financial reporting; (ii) take steps to improve control processes where required; (iii) validate through testing that controls are functioning as documented; and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. We believe our process for documenting, evaluating and monitoring our internal control over financial reporting is consistent with the objectives of Section 404 of the Act.

We are continuing our evaluation of our internal controls versus the standards adopted by the Public Company Accounting Oversight Board (PCAOB). Given the risks inherent in the design and operation of internal control over financial reporting, we can provide no assurance as to our or our independent auditor's conclusions at December 31, 2004 with respect to the effectiveness of our internal control over financial reporting.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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. An enforcement proceeding against Disc-O-Tech in the ITC may later be initiated if it is determined that Disc-O-Tech is not complying fully with the ITC Order. In Delaware, the Company's complaint 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 six of the Company's U.S. patents, all of which generally concern the use of various medical devices to repair spinal compression fractures, and seeks enhanced damages and a permanent injunction for its willful infringement. Trial is set for June 2005. The Company is using the information discovered during the ITC proceeding about Disc-O-Tech's business activities to prosecute its case against Disc-O-Tech in Delaware and will continue to do so vigorously. A motion for a preliminary injunction against Disc-O-Tech on a single claim of one of the six patents-in-suit is now pending and will be heard during the fourth quarter.

The Company is presently party to no other material litigation.

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) tax matter consultations concerning foreign, U.S. federal and state taxes; (2) the preparation of federal and state income tax returns; and (3) services related to the assessment of internal accounting and risk management controls.

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.
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 Form 10-Q filed on November 13, 2002.
(3) Incorporated by reference from our Form 8-K filed on March 7, 2003.
(4) Incorporated by reference from our Form 10-Q filed on November 14, 2003.
* 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: November 5, 2004

By: /s/ Richard W. Mott

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

Date: November 5, 2004

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)) 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) 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

c) 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: November 5, 2004

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)) 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) 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

c) 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: November 5, 2004

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 September 30, 2004 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: November 5, 2004

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 September 30, 2004 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: November 5, 2004

By: /s/ Arthur T. Taylor

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