

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

FORM 10-Q

(Mark One)

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended September 30, 2005 or

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____ .

Commission File Number **000-49804**



(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 NO

Indicate by check mark whether the registrant is an accelerated filer (as defined by rule 12b-2 of the Exchange Act).

YES NO

Indicate by check mark whether the registrant is a shell company (as defined in rule 12b-2 of the Exchange Act).

YES NO

Class
Common Stock, \$0.001 par value

Shares Outstanding at October 26, 2005
43,485,539

**KYPHON INC.
FORM 10-Q
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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		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Net sales	\$ 79,014	\$ 55,811	\$ 220,274	\$ 150,989
Cost of goods sold	9,456	6,247	25,875	17,164
Gross profit	<u>69,558</u>	<u>49,564</u>	<u>194,399</u>	<u>133,825</u>
Operating expenses:				
Research and development	6,415	5,604	18,513	15,214
Sales and marketing	36,151	26,855	107,310	74,708
General and administrative	8,280	7,216	26,321	18,558
Purchased in-process research and development	--	--	1,000	--
Total operating expenses	<u>50,846</u>	<u>39,675</u>	<u>153,144</u>	<u>108,480</u>
Income from operations	18,712	9,889	41,255	25,345
Interest income and other, net	1,212	343	2,556	803
Income before income taxes	19,924	10,232	43,811	26,148
Provision for income taxes	8,170	4,100	17,700	10,500
Net income	<u>\$ 11,754</u>	<u>\$ 6,132</u>	<u>\$ 26,111</u>	<u>\$ 15,648</u>
Net income per share:				
Basic	<u>\$ 0.27</u>	<u>\$ 0.15</u>	<u>\$ 0.61</u>	<u>\$ 0.39</u>
Diluted	<u>\$ 0.26</u>	<u>\$ 0.14</u>	<u>\$ 0.58</u>	<u>\$ 0.36</u>
Weighted-average shares outstanding:				
Basic	<u>43,195</u>	<u>40,733</u>	<u>42,522</u>	<u>40,216</u>
Diluted	<u>45,898</u>	<u>43,734</u>	<u>45,035</u>	<u>43,503</u>

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

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

	<u>September 30,</u> <u>2005</u>	<u>December 31,</u> <u>2004</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 131,700	\$ 87,236
Investments	34,966	24,421
Accounts receivable, net	48,180	42,347
Inventories	9,689	11,457
Prepaid expenses and other current assets	7,408	4,521
Deferred tax assets	<u>13,135</u>	<u>13,537</u>
Total current assets	245,078	183,519
Investments	4,501	4,142
Property and equipment, net	14,850	12,728
Goodwill and other intangible assets, net	4,465	5,039
Deferred tax assets	4,009	4,009
Other assets	<u>2,677</u>	<u>3,952</u>
Total assets	<u>\$ 275,580</u>	<u>\$ 213,389</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,595	\$ 5,544
Accrued liabilities	<u>30,586</u>	<u>24,049</u>
Total current liabilities	36,181	29,593
Deferred rent and other	<u>3,828</u>	<u>4,161</u>
Total liabilities	<u>40,009</u>	<u>33,754</u>
Commitments and contingencies (Notes 7 and 8)		
Stockholders' equity:		
Common stock, \$0.001 par value per share	43	41
Additional paid-in capital	220,269	189,410
Treasury stock, at cost	(201)	(201)
Deferred stock-based compensation, net	(423)	(2,113)
Accumulated other comprehensive income	763	3,489
Retained earnings (accumulated deficit)	<u>15,120</u>	<u>(10,991)</u>
Total stockholders' equity	<u>235,571</u>	<u>179,635</u>
Total liabilities and stockholders' equity	<u>\$ 275,580</u>	<u>\$ 213,389</u>

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

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

	Nine Months Ended	
	September 30,	
	2005	2004
Cash flows from operating activities:		
Net income	\$ 26,111	\$ 15,648
Adjustments to reconcile net income to net cash provided by operating activities:		
Provision for accounts receivable allowances	704	310
Provision for excess and obsolete inventories	652	158
Depreciation and amortization	3,082	2,343
Provision for deferred taxes including tax benefits from stock options	13,124	8,551
Loss on disposal of property and equipment	130	--
Amortization of deferred stock-based compensation	2,403	3,255
Write-off of in-process research and development	1,000	--
Changes in operating assets and liabilities:		
Accounts receivable	(8,013)	(11,020)
Inventories	366	(3,810)
Prepaid expenses and other current assets	(2,675)	854
Other assets	1,201	(997)
Accounts payable	159	695
Accrued liabilities	7,036	7,718
Deferred rent and other	(44)	937
Net cash provided by operating activities	45,236	24,642
Cash flows from investing activities:		
Acquisition of property and equipment	(5,593)	(5,454)
Maturities and sales of investments	26,150	11,945
Purchase of investments	(37,408)	(12,687)
Payment for technology license	(1,000)	--
Net cash used in investing activities	(17,851)	(6,196)
Cash flows from financing activities:		
Proceeds from issuance of common stock	4,697	3,421
Proceeds from exercise of stock options	12,710	4,478
Net cash provided by financing activities	17,407	7,899
Effect of foreign exchange rate changes on cash and cash equivalents	(328)	(60)
Net increase in cash and cash equivalents	44,464	26,285
Cash and cash equivalents at beginning of period	87,236	57,494
Cash and cash equivalents at end of period	\$ 131,700	\$ 83,779

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

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

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

Organization

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

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 ("SEC"). 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, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005, or for any future period. These condensed consolidated financial statements and notes should be read in conjunction with the consolidated financial statements included in the Company's Form 10-K for the fiscal year ended December 31, 2004.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the Company's Form 10-K for the year ended December 31, 2004 and have not changed significantly as of September 30, 2005.

Reclassification

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

NOTE 2--Accounting for Stock-Based Compensation:

The Company uses the intrinsic value method and presents disclosure of pro forma information for its employee stock options. The following table, assuming a 40% effective tax rate, provides a reconciliation of net income and net income per share to pro forma net income and pro forma net income per share had compensation cost for the Company's stock option grants to employees been determined based on the fair value of each option on the date of grant, consistent with the methodology prescribed by Statement of Financial Accounting Standards Board ("SFAS") No. 123 (in thousands, except per share amounts):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Net income, as reported	\$ 11,754	\$ 6,132	\$ 26,111	\$ 15,648
Add: Stock-based employee compensation expense included in reported net income, net of related taxes	260	416	919	1,417
Deduct: Total stock-based employee compensation expense, determined under fair value based method for all awards, net of related taxes	<u>(4,665)</u>	<u>(2,913)</u>	<u>(11,118)</u>	<u>(7,297)</u>
Pro forma net income	<u>\$ 7,349</u>	<u>\$ 3,635</u>	<u>\$ 15,912</u>	<u>\$ 9,768</u>
Net income per share				
Basic:				
As reported	<u>\$ 0.27</u>	<u>\$ 0.15</u>	<u>\$ 0.61</u>	<u>\$ 0.39</u>
Pro forma	<u>\$ 0.17</u>	<u>\$ 0.09</u>	<u>\$ 0.37</u>	<u>\$ 0.24</u>
Diluted:				
As reported	<u>\$ 0.26</u>	<u>\$ 0.14</u>	<u>\$ 0.58</u>	<u>\$ 0.36</u>
Pro forma	<u>\$ 0.16</u>	<u>\$ 0.08</u>	<u>\$ 0.35</u>	<u>\$ 0.22</u>

In December 2004, the Financial Accounting Standards Board (“FASB”) originally issued SFAS No. 123(R), “Share-Based Payment (revised 2004).” SFAS No. 123(R) requires companies to measure all stock-based compensation awards using a fair value-based method and record the related expense in their financial statements, including grants of employee stock options. SFAS No. 123(R), as amended, is effective for public companies for the first annual period beginning after June 15, 2005 (See Note 9).

Deferred and Stock-Based Compensation

Prior to the Company’s initial public offering, the Company issued options under the 1996 Stock Option Plan and shares of common stock under stock purchase agreements to certain employees, some of which contained repurchase provisions. These options and shares of common stock had exercise prices below the deemed fair market value of the Company’s common stock at the date of grant. The Company’s right to repurchase shares of restricted common stock lapsed as these shares became vested to the employee. In accordance with the requirements of Accounting Principles Board (“APB”) No. 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock options or restricted common stock and the deemed fair market value of the Company’s stock at the date of grant. This deferred stock-based compensation is amortized to expense on a straight line basis, over the period during which the Company’s right to repurchase the restricted common stock lapses or the options become exercisable, generally four years.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force (“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 related to stock options granted to non-employees is recognized as the stock options are earned. The options generally vest ratably over four years. The values attributable to these options have been amortized over the service period on a graded vesting method, and the vested portion of these options is remeasured at each vesting date. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Cost of goods sold	\$ 33	\$ 78	\$ 106	\$ 277
Research and development	240	269	717	899
Sales and marketing	388	319	1,157	1,086
General and administrative	214	232	423	993
	<u>\$ 875</u>	<u>\$ 898</u>	<u>\$ 2,403</u>	<u>\$ 3,255</u>

NOTE 3--Net Income Per Share:

Basic net income per share is computed by dividing net income by the weighted-average number of common shares outstanding for the period less the weighted-average shares subject to repurchase. Diluted net income per share is computed by giving effect to all potentially dilutive common stock, including options, warrants and common stock subject to repurchase. For the three months ended September 30, 2005 and 2004, 56,000 and 695,000, respectively, options outstanding were not included in the computation of diluted net income per share for the Company because the effect would be antidilutive. For the nine months ended September 30, 2005 and 2004, 331,000 and 393,000, respectively, options outstanding were not included in the computation of diluted net income per share for the Company because the effect would be antidilutive.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Net income	\$ <u>11,754</u>	\$ <u>6,132</u>	\$ <u>26,111</u>	\$ <u>15,648</u>
Weighted-average shares outstanding	43,195	40,733	42,522	40,219
Less: weighted-average shares subject to repurchase	--	--	--	(3)
Basic weighted-average shares outstanding	43,195	40,733	42,522	40,216
Dilutive effect of:				
Options to purchase common stock	2,703	2,997	2,513	3,282
Warrants	--	4	--	5
Diluted weighted-average shares outstanding	<u>45,898</u>	<u>43,734</u>	<u>45,035</u>	<u>43,503</u>
Net income per share:	\$ <u>0.27</u>	\$ <u>0.15</u>	\$ <u>0.61</u>	\$ <u>0.39</u>
Basic				
Diluted	\$ <u>0.26</u>	\$ <u>0.14</u>	\$ <u>0.58</u>	\$ <u>0.36</u>

NOTE 4--Comprehensive Income:

The Company's unrealized gains (losses) on available-for-sale investments and cumulative translation adjustments represent the components of other comprehensive income that are excluded from net income.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Net income	\$ 11,754	\$ 6,132	\$ 26,111	\$ 15,648
Changes in unrealized gains (losses) on available-for-sale investments, net of taxes	16	23	25	(66)
Translation adjustments	(203)	290	(2,751)	(128)
Total comprehensive income	<u>\$ 11,567</u>	<u>\$ 6,445</u>	<u>\$ 23,385</u>	<u>\$ 15,454</u>

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

	September 30,	December 31,
	2005	2004
Unrealized losses on available-for-sale investments, net of taxes	\$ (22)	\$ (47)
Translation adjustments	785	3,536
	<u>\$ 763</u>	<u>\$ 3,489</u>

NOTE 5--Inventories:

Inventories consisted of the following (in thousands):

	September 30,	December 31,
	2005	2004
Raw materials	\$ 4,352	\$ 5,715
Work-in-process	1,511	1,042
Finished goods	3,826	4,700
	<u>\$ 9,689</u>	<u>\$ 11,457</u>

NOTE 6--Goodwill and Intangible Assets:

Changes in the carrying amount of goodwill during the nine months ended September 30, 2005 are as follows (in thousands):

Goodwill at December 31, 2004	\$ 4,927
Foreign currency translation	(538)
Total goodwill at September 30, 2005	<u>\$ 4,389</u>

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

	September 30,	December 31,
	2005	2004
Other intangibles	\$ 142	\$ 142
Foreign currency translation	16	35
Accumulated amortization	(82)	(65)
Total other intangibles	<u>\$ 76</u>	<u>\$ 112</u>

Amortization expense related to the Company's other intangible assets was approximately \$8,000 for both the three months ended September 30, 2005 and 2004. Amortization expense for the nine months ended September 30, 2005 and 2004 was approximately \$25,000 and \$24,000, respectively. Based on the intangible assets balance at September

30, 2005, the Company expects to recognize amortization expense of approximately \$8,000 for the remaining three months of fiscal 2005, \$32,000 in 2006 and 2007, and approximately \$4,000 in 2008.

NOTE 7--In-Process Research and Development:

In April 2005, the Company entered into an agreement to exclusively license, in the field of orthopaedics including all spinal applications, Dr. J. Lee Berger's portfolio of patents concerning medical devices and methods for creating voids in, or moving, tissue or bone, including platform cannulae for expandable bodies. The Company made an up-front payment of \$1,000,000 in April 2005 and has agreed to provide a lifetime-capped royalty stream on any products that may be developed that practice the licensed patent rights. The \$1,000,000 payment was immediately expensed as purchased in-process research and development, as the technology acquired may be used to develop products that have not been approved for sale by regulatory authorities and have not yet reached technological feasibility. In conjunction with the license agreement, the Company entered into a consulting agreement with Dr. J. Lee Berger for services pertaining to research and development in the area of spinal surgery. Dr. J. Lee Berger will be paid \$100,000 per year for a period of three years in exchange for these services.

NOTE 8--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, thereby terminating the ITC proceeding in the Company's favor. In June 2005, the Delaware District court entered a Consent Judgment permanently enjoining Disc-O-Tech from further infringing the Company's patent rights with its SKy Bone Expander device or products not colorably different from the SKy Bone Expander, which took effect on July 22, 2005. This Consent Judgement bars further importation or selling of Disc-O-Tech's SKy Bone Expander device or colorable variations of that device for performing kyphoplasty in the US market. This concluded the litigation in the Company's favor without the possibility of further trial or appeal.

In October 2005, the Company filed suit for patent infringement against a Korean-based company in the Seoul Central District Court in Seoul, Korea, to protect the Company's Korean patent rights and ability to continue to provide products to the Korean market without inappropriate interference. No provision for any liability that may result upon the resolution of this matter has been made in the accompanying financial statements.

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

From March through October 2005, the Company entered into several facility lease agreements with terms which expire through August 2014. The total commitment under these lease agreements is approximately \$5,908,000 to be paid over the terms of the lease. Under the terms of one of the facility leases, the Company is obliged to increase the amount of its irrevocable standby letter of credit previously provided to the landlord pursuant to the lease agreement by \$105,000 to \$1,105,000.

NOTE 9--Recent Accounting Pronouncements:

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

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

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

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

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

Introduction

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning our intentions, beliefs and expectations regarding our future growth, projections of expenses and operating results; expected reimbursement by Medicare, Medicaid and third party payors of our products; the timing and success of our clinical trials and regulatory submissions; our belief that our cash and cash equivalents will be sufficient to satisfy our anticipated cash requirements; our expectations regarding our revenues and customers; our competitive position; the protection of our technology and intellectual property rights; the effects of regulation on our business; our distributors and territorial expansion efforts and our plans to pursue research, development and commercialization of additional spine products developed internally or arising from acquisitions. In some cases, forward-looking statements can be identified by the use of forward-looking terminology such as “believe,” “may,” “can,” “if,” “will,” “could,” “would,” “might,” “intend,” “plan,” “expect,” “likely,” “potential,” “possibility,” “target” or “anticipate” or the negative of these terms or other comparable terminology. These statements are subject to risks, uncertainties and assumptions that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. The risks, uncertainties and assumptions referred to above include: our ability to develop and successfully introduce new products, product extensions and improvements, the availability of adequate physician and hospital reimbursement for kyphoplasty procedures, continued referrals by primary care physicians to trained clinicians that use our products, competition in our markets and our ability, if any, to address it, any failure to maintain or obtain additional regulatory clearances or approvals, our ability to expand our manufacturing capacity and reliance on suppliers, our dependence on distributors and the impact of any acquisitions or divestitures that we may complete in the future. The reader is cautioned not to place undue reliance on these forward looking statements and projections, which reflect management’s analysis only as of the date of this Quarterly Report on Form 10-Q. We undertake no obligation to update forward-looking statements and projections to reflect events or circumstances occurring after the

date of this Form 10-Q. Management's discussion and analysis of financial condition and results of operations is organized as follows:

- *Executive summary.* This section provides a general description and history of our business, a brief discussion of our product lines and the opportunities, trends, challenges and risks we focus on in the operation of our business.
- *Results of operations.* This section provides our analysis and outlook for the significant line items on our condensed consolidated income statement.
- *Deferred and stock-based compensation.* This section describes the accounting method and financial reporting of our stock options granted to employees and non-employees.
- *Liquidity and capital resources.* This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of September 30, 2005.
- *Recent accounting pronouncements.* This section describes the issuance and effects of recently issued accounting pronouncements.
- *Factors affecting future operating results.* This section discusses the most significant factors that could affect our future financial results. The factors discussed in this section are in addition to factors that may be described in the captions discussed above and elsewhere in this report.

Executive Summary

Company Description. We are a global medical device company specializing in the design, manufacture and marketing of medical devices used to treat and restore spinal anatomy using minimally invasive technology. Our devices are presently used primarily by spine specialists, including orthopaedic surgeons and neurosurgeons, interventional radiologists and interventional neuroradiologists, who repair compression fractures of the spine caused by osteoporosis, trauma, cancer or benign lesions through minimally invasive spine surgeries known as kyphoplasty procedures. Our commercial products consist of our *KyphX* instruments, which are used to treat spine fractures during kyphoplasty, including our proprietary *KyphX* balloon technology, and our proprietary brands of bone filler materials. Most alternative treatments for these types of spine fractures are either highly invasive or are only pain management therapies.

Our corporate headquarters and United States operations are located in Sunnyvale, California, where we conduct our manufacturing, warehousing, research, regulatory and administrative activities. Outside the United States, we operate a sales, clinical, regulatory and administrative facility in Brussels, Belgium, a research and biomaterials manufacturing facility in Rosbach, Germany, a clinical, regulatory and administrative facility in Japan and we have direct selling operations in many of the major countries in Europe and in Canada. Our global distribution network consists of a direct sales organization in excess of 400 individuals who market our products in the U.S., many of the major countries in Europe and in Canada and distributors and sales agents in other countries in which we do not have a direct sales force. In Japan, we are presently focused primarily on procuring the appropriate governmental regulatory clearances and approvals necessary to market and sell our *KyphX* products, and we recently enrolled our first patient in our Japanese clinical trial.

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

During the first nine months of 2005, our business experienced significant growth. Net sales in the first nine months of 2005 increased to \$220.3 million, compared to \$151.0 million in the first nine months of 2004, representing growth of 46%. We trained over 1,700 physicians during the first nine months of 2005, primarily in the United States and in Europe. In the U.S., we added approximately 216 new hospitals to our customer base during the first nine months of 2005.

In April 2004, we filed two patent infringement suits against Disc-O-Tech Medical Technologies Ltd. , an Israel-based company doing business in the United States. This was the first time we enforced our patent rights against any entity.

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

In 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, including, in a few instances, making copies of some of our products that are apparently intended for distribution in one or more Asian markets. To the extent any competing products infringe our patents or utilize our trade secrets, we will consider how best to protect our market space as well as whether to take action against any potentially infringing activities. As a result, we may decide to protect and enforce our rights through litigation or other appropriate means and also may choose to take steps to address any patent rights associated with any competitive products. Regardless of any steps we take, however, we likely will have to compete with these competitive products for some period of time and ultimately may not succeed in protecting or enforcing our rights. We also may not have the ability to prevent those products from remaining on the market in at least some geographic locations, and we may lose market share or have our growth impeded in those geographic markets as a result. To protect our Korean patent rights and our ability to continue to effectively provide our products to the Korean market, we recently instituted patent infringement litigation against one Korean company distributing balloon catheters for kyphoplasty, and we may add additional defendants as the litigation progresses or file other lawsuits.

There have been several recent developments related to reimbursement for our products. In November 2004, the Centers for Medicare & Medicaid Services (“CMS”) published the Final Rule on the Medical Hospital Outpatient Prospective System and created new and distinct hospital outpatient procedure codes for kyphoplasty, C9718 and C9719. These new C-codes are assigned to APC 51 and became effective January 1, 2005. Although our customers and potential customers may believe that the present level of facility reimbursement in effect for kyphoplasty procedures performed on an outpatient basis is not sufficient, the level of reimbursement may not be increased. We continue to work with our hospital customers to collect charge data for presentation to, and consideration by, CMS so that the level of reimbursement may potentially be increased to be more in-line with the charges associated with kyphoplasty when performed on an outpatient basis. We understand that CMS is presently reviewing the current level of reimbursement for kyphoplasty and if it recommends any changes to the level of reimbursement for kyphoplasty performed on an outpatient basis, the recommendations will be published in the Final Rule during the fourth quarter of 2005.

There was also recent progress in national reimbursement for physicians. In October, 2005, following the American Medical Association (“AMA”) CPT Editorial Panel’s recommendation in late 2004 for adoption of a Category 1 national Current Procedure Terminology (“CPT”) code for spine specialist reimbursement for kyphoplasty, CMS published three new CPT codes in the final 2006 Physician Fee Schedule, numbers 22523, 22524 and 22525, to take effect on January 1, 2006. Each of these codes concerns performance of percutaneous vertebral augmentation, including cavity creation (fracture reduction including biopsy when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g. kyphoplasty), and also concerns, respectively, thoracic, lumbar, and each additional vertebral body. In addition, CMS also modified two existing radiologic codes, 76012 and 76013, concerning, respectively, fluoroscopic and CT guidance, to include vertebral augmentation including cavity creation per vertebral body. We understand that the proposed relative value units associated with each of these five CPT codes should be published for comment in the Federal Register during the fourth quarter of 2005. Despite these developments, we cannot be certain what level of physician reimbursement will be associated with procedures performed with our products as a result of this process. While we perceive this development to be significant progress in improving the reimbursement process for physicians performing kyphoplasty and helping to assist kyphoplasty to become a standard of care for treating vertebral compression fractures, we cannot be certain how any action taken by CMS may affect our marketplace or our business, or whether any CPT code relative value unit ultimately would increase or decrease any of the spine specialist reimbursement already available. Any CPT code and associated value have at least the potential to be detrimental to spine specialist reimbursement, and thus to our revenues.

The present environment for seeking reimbursement for procedures performed with our products is not yet optimal for ensuring that our customers always appropriately code for kyphoplasty. For example, the level of facility reimbursement available for performing kyphoplasty on an outpatient basis presently remains significantly less than the level of facility reimbursement available for kyphoplasty performed on an in-patient basis, with an overnight stay. While a treating physician typically decides to perform kyphoplasty on either an in-patient or an out-patient basis based on the standard of “medical necessity,” the difference in reimbursement available could influence, and in some cases likely has influenced, the treatment decision of how and under what circumstances to perform kyphoplasty. In addition, since no specific billing code presently exists in any state for physician reimbursement for kyphoplasty, some physicians may seek reimbursement for performing kyphoplasty using one or more codes that may not be deemed appropriate. We believe these influences will tend to diminish or disappear if and when the level of facility reimbursement available for kyphoplasty performed on an outpatient basis increases and as national CPT codes for physician reimbursement for kyphoplasty are adopted by the local reimbursement authorities. Nevertheless, while we educate and train our employees on how to interact appropriately with healthcare providers on these issues, and have placed particular emphasis on how properly to seek reimbursement in the presently existing reimbursement environment, we believe that a small number of clinicians has chosen to use inappropriate reimbursement codes for kyphoplasty. Such inappropriate treatment or coding decisions by clinicians may subject us to an increased risk of investigation under relevant federal regulations.

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

In Europe, kyphoplasty has been assigned a code in the recently implemented German OPS system. In other European countries, we continue to focus efforts on obtaining reimbursement coverage for the procedure, although no assurances can be provided that such efforts will result in favorable outcomes for us. We are aware that one or more competitors has attempted to adversely affect our ability to acquire timely and appropriate levels of reimbursement in several foreign countries by seeking much lower levels of reimbursement for their own competitive products that may not support the pricing or anticipated pricing of our products in those markets. We do not know whether these efforts will continue or will be effective or broad in application. We are also aware that some foreign governments, including Germany, are continuing to evaluate reimbursement coverage for kyphoplasty, which ultimately may increase or decrease the reimbursement available for procedures performed with our products. Our business could be harmed in countries where the level of reimbursement available is ultimately decreased. Notwithstanding all of these activities, we will continue to seek appropriate levels of reimbursement in those markets using appropriate measures.

We frequently evaluate potential opportunities for growth in our business by evaluating external products and technologies. While our primary focus will remain on our core business and the opportunities the osteoporosis, cancer and trauma vertebral fracture markets present, we may choose to pursue one or more business development opportunities which we believe are appropriate initiatives for our business, even if such opportunities are outside of the field for the treatment of spinal fractures or disease, or outside of the spine itself. Some of the opportunities we are presently investigating include technologies and products that address degenerative disc disease and various cancers associated with our core market. These efforts may require us to seek additional funding and may be dilutive to our earnings. And until such time, if ever, that Kyphon succeeds in diversifying its business through internal development or external business development activities, Kyphon will remain dependent on the single opportunity of treating vertebral compression fractures with kyphoplasty with its products and bear the traditional risks to its business of being a company whose revenues are principally derived from one procedure.

Significant Industry Factors. Our industry is impacted by numerous competitive, regulatory and other significant factors. The growth of our business relies on our ability to continue to develop new products and innovative technologies, obtain regulatory clearances and compliance for our products, protect the proprietary technology of our

products and our manufacturing processes, manufacture our products cost-effectively, and successfully market and distribute our products in a profitable manner. We, and the entire industry, are subject to extensive government regulation, including the United States Food and Drug Administration (“FDA”). Failure to comply with regulatory requirements could have a material adverse effect on our business. Additionally, our industry is highly competitive and our success depends on our ability to compete successfully. A detailed discussion of these and other factors is provided in the “Factors Affecting Future Operating Results” section below.

Results of Operations

Three Months Ended September 30, 2005 and September 30, 2004

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

	Three Months Ended September 30,			
	2005		2004	
	Amount	% of Net sales	Amount	% of Net sales
U.S. net sales	\$ 66,863	85%	\$ 49,645	89%
International net sales	12,151	15%	6,166	11%
Net sales	79,014	100%	55,811	100%
Cost of goods sold	9,456	12%	6,247	11%
Gross profit	69,558	88%	49,564	89%
Operating expenses:				
Research and development	6,415	8%	5,604	10%
Sales and marketing	36,151	46%	26,855	48%
General and administrative	8,280	10%	7,216	13%
Total operating expenses	50,846	64%	39,675	71%
Income from operations	18,712	24%	9,889	18%
Interest income and other, net	1,212	2%	343	--
Income before income taxes	19,924	25%	10,232	18%
Provision for income taxes	8,170	10%	4,100	7%
Net income	\$ 11,754	15%	\$ 6,132	11%

Net Sales. Net sales increased \$23.2 million, or 42%, for the three months ended September 30, 2005 as compared to the same period in 2004. The increase in net sales resulted primarily from an increase in the number of physicians trained worldwide in the use of our *KyphX* instruments as well as an increase in the number of kyphoplasty procedures performed by trained physicians. International sales reflected the unfavorable currency impact of \$37,000 for the three months ended September 30, 2005 and the favorable currency impact \$483,000 for the three months ended September 30, 2004. No customer accounted for more than 10% of total net sales for the three months ended September 30, 2005 and 2004. As of September 30, 2005, we have trained approximately 7,400 physicians worldwide, with approximately 4,750 spine specialists in the U.S. and approximately 2,650 spine specialists internationally. We believe the total number of potential physicians who may perform kyphoplasty procedures using our products is approximately 11,000 in the U.S. Internationally, the number of physicians who may perform kyphoplasty is not as well-defined, but we believe it to be more than 10,000. We have targeted a range of \$304 million to \$307 million in net sales of our *KyphX* products for 2005.

Cost of Goods Sold. Cost of goods sold consists of material, labor, subcontract, and overhead costs. Cost of goods sold increased \$3.2 million, or 51%, for the three months ended September 30, 2005 as compared to the same period in 2004. The increase in cost of goods sold in absolute dollars resulted primarily from increased material, labor, subcontract, and overhead costs in relation to the increased sales volume of our products. As a percentage of net sales, cost of goods sold increased primarily as a result of changes in our product mix and due to an increase in our provision for excess and obsolete inventories due to product transition and expiration. Our cost of goods sold and corresponding gross profit percentages can be expected to fluctuate in future periods depending upon changes in our

product sales mix and prices, distribution channels and geographies, manufacturing yields, period expenses and levels of production volume. As a percentage of net sales, we expect cost of goods sold to be in the range of 11% to 12% for the year.

Research and Development. Research and development expenses consist of costs for product research, product development, clinical functions and outside costs related to clinical trials and personnel. Research and development expenses increased \$811,000, or 14%, for the three months ended September 30, 2005 as compared to the same period in 2004. The increase was primarily attributable to increased clinical expenses of \$523,000, increased personnel costs of \$464,000, and increased facilities cost of \$199,000, offset partially by decreased consulting fees of \$354,000. We expect to continue to make substantial investments in research and development and clinical expenses, and anticipate that research and development expenses for the rest of 2005 will increase in absolute dollars compared to research and development expenses for the year ended December 31, 2004. As a percentage of net sales, we anticipate our research and development expenses for our product research efforts and clinical efforts to be in the range of 8% to 9% for 2005.

Sales and Marketing. Sales and marketing expenses consist of costs for personnel, physician training programs and marketing activities. Sales and marketing expenses increased \$9.3 million, or 35%, for the three months ended September 30, 2005 as compared to the same period in 2004. The increase resulted primarily from increased costs of hiring, training and compensating additional direct selling representatives of \$6.4 million, increased educational, advertising and trade shows expenses of \$982,000, increased sales travel expenses of \$803,000, and increased facilities expenses of \$428,000. As we continue to commercialize our *KyphX* instruments on a global basis during 2005, we expect to increase our sales and marketing efforts and expenditures in absolute dollars. As a percentage of net sales, we expect that our sales and marketing expenses will range between 47% and 49% for 2005.

General and Administrative. General and administrative expenses consist of personnel costs, professional service fees, expenses related to enforcement of our intellectual property rights through litigation and general corporate expenses. General and administrative expenses increased \$1.1 million, or 15%, for the three months ended September 30, 2005 as compared to the same period in 2004. The increase resulted primarily from increased personnel costs of \$786,000 and increased consulting fees of \$732,000, offset partially by decreased litigation fees of \$498,000. We expect general and administrative expenses to increase in the future as we add personnel, continue to expand our patent portfolio, engage in offensive and defensive litigation, and incur public reporting, governmental compliance and investor-related expenses. We also expect that our general and administrative expenses will increase in absolute dollars as we expand our infrastructure and the number of countries where we operate. As a percentage of net sales, we expect that our general and administrative expenses will range between 11% and 12% for 2005.

Interest Income and Other, Net. Interest income and other, net, increased \$869,000 for the three months ended September 30, 2005 as compared to the same period in 2004. \$684,000 of the increase resulted primarily from increased interest income from increased cash, cash equivalents and investment balances of \$171.2 million as of September 30, 2005 compared to \$111.6 million as of September 30, 2004, as well as increasing interest rates. In addition, \$183,000 of the increase is attributable to foreign currency exchange rate fluctuation.

Provision for Income Taxes. Provision for income taxes was \$8.2 million for the three months ended September 30, 2005 as compared to \$4.1 million for the same period in 2004. We recorded \$771,000 and \$300,000 of tax liabilities, net, for the three months ended September 30, 2005 and 2004, respectively. We believe that in 2005, our effective tax rate will be approximately 40%, even though the actual amount of taxes paid may be reduced by net operating losses 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.

Net Income and Earnings Per Share. Net income for the three months ended September 30, 2005 was \$11.8 million as compared to \$6.1 million for the same period in 2004. Earnings per diluted share were \$0.26 for the three months ended September 30, 2005 as compared to \$0.14 for the same period in 2004. We expect the full-year 2005 earnings per diluted share range to be \$0.84 to \$0.86.

Nine Months Ended September 30, 2005 and September 30, 2004

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

	Nine Months Ended September 30,			
	2005		2004	
	Amount	% of Net sales	Amount	% of Net sales
U.S. net sales	\$ 188,426	86%	\$ 135,314	90%
International net sales	31,848	14%	15,675	10%
Net sales	220,274	100%	150,989	100%
Cost of goods sold	25,875	12%	17,164	11%
Gross profit	194,399	88%	133,825	89%
Operating expenses:				
Research and development	18,513	8%	15,214	10%
Sales and marketing	107,310	49%	74,708	49%
General and administrative	26,321	12%	18,558	12%
Purchased in-process research and development	1,000	--	--	--
Total operating expenses	153,144	69%	108,480	72%
Income from operations	41,255	19%	25,345	17%
Interest income and other, net	2,556	1%	803	1%
Income before income taxes	43,811	20%	26,148	17%
Provision for income taxes	17,700	8%	10,500	7%
Net income	\$ 26,111	12%	\$ 15,648	10%

Net Sales. Net sales increased \$69.3 million, or 46%, for the nine months ended September 30, 2005 as compared to the same period in 2004. The increase in net sales resulted from an increase in the number of physicians trained worldwide in the use of our *KyphX* instruments, as well as an increase in the number of kyphoplasty procedures performed by trained physicians. International sales reflected the favorable currency impact of \$934,000 and \$1.3 million for the nine months ended September 30, 2005 and 2004, respectively. No customer accounted for more than 10% of total net sales for the nine months ended September 30, 2005 and 2004.

Cost of Goods Sold. Cost of goods sold increased \$8.7 million, or 51%, for the nine months ended September 30, 2005 as compared to the same period in 2004. The increase in the cost of goods sold resulted primarily from increased material, labor, and overhead costs associated with increased sales volume of our products. As a percentage of net sales, cost of goods sold increased primarily as a result of changes in our product mix and due to an increase in our provision for excess and obsolete inventories due to product transition and expiration. In addition, the gross margin in the first quarter of 2004 benefited from favorable manufacturing absorption variances from the advance build-up of inventory in preparation for our move to new facilities in the second quarter of 2004.

Research and Development. Research and development expenses increased \$3.3 million, or 22%, for the nine months ended September 30, 2005 as compared to the same period in 2004. The increase primarily resulted from increased clinical expenses of \$2.0 million, increased personnel costs of \$1.7 million, increased facilities expenses of \$496,000, increased engineering and lab expenses of \$373,000, and increased travel expenses of \$318,000, offset partially by decreased consulting fees of \$913,000 and decreased education grants expenses of \$712,000.

Sales and Marketing. Sales and marketing expenses increased \$32.6 million, or 44%, for the nine months ended September 30, 2005 as compared to the same period in 2004. The increase resulted primarily from increased costs of hiring, training and compensating additional direct selling representatives of \$22.1 million, increased travel expenses of \$2.9 million, increased advertising expenses of \$1.9 million, increased expenses of \$1.4 million mainly attributable to educational, trade shows and promotional materials activities, increased facilities expenses of \$1.2 million, and increased surgical training expenses of \$1.1 million.

General and Administrative. General and administrative expenses increased \$7.8 million, or 42%, for the nine months ended September 30, 2005 as compared to the same period in 2004. The increase resulted primarily from increased consulting fees of \$3.5 million, increased personnel costs of \$2.3 million, and increased litigation fees of \$1.8 million.

Purchased In-Process Research and Development. In April 2005, we entered into an agreement to exclusively license, in the field of orthopaedics including all spinal applications, Dr. J. Lee Berger's portfolio of patents concerning medical devices and methods for creating voids in or moving tissue or bone, including platform cannulae for expandable bodies. We made an up-front payment of \$1.0 million which was immediately expensed to purchased in-process research and development, as the technology acquired will be used to develop products that have not been approved for sale by regulatory authorities and have not yet reached technological feasibility.

Interest Income and Other, Net. Interest income and other, net, increased \$1.8 million for the nine months ended September 30, 2005 as compared to the same period in 2004. The increase resulted primarily from increased interest income of \$1.7 million from increased cash, cash equivalents and investment balances, as well as increasing interest rates.

Provision for Income Taxes. Provision for income taxes was \$17.7 million for the nine months ended September 30, 2005 as compared to \$10.5 million in the same period in 2004. We recorded \$1.5 million and \$500,000 tax liabilities, net, for the nine months ended September 30, 2005 and 2004, respectively.

Net Income and Earnings Per Share. Net income for the nine months ended September 30, 2005 was \$26.1 million as compared to \$15.6 million for the same period in 2004. Earnings per diluted share were \$0.58 for the nine months ended September 30, 2005 as compared to \$0.36 for the same period in 2004.

Deferred and Stock-Based Compensation

We recorded deferred stock-based compensation on options issued prior to our initial public offering as the difference between the exercise price of options granted to employees and the deemed fair value of our common stock at the time of grant. Deferred stock-based compensation is amortized to cost of goods sold, research and development expense, sales and marketing expense and general and administrative expense as the options vest. Deferred stock-based compensation for employee stock options recorded through September 30, 2005 was \$18.3 million, with accumulated amortization of \$17.9 million. The remaining \$423,000 will be amortized over the remaining vesting periods of the options. All option amounts are being amortized using the straight-line method. We expect to record amortization expense for deferred stock-based compensation as follows:

<u>Year</u>	<u>Amount</u>
2005 (October – December)	\$302,000
2006	\$121,000

Stock-based compensation expense for stock options granted to non-employees is recognized as the stock options are earned. The stock-based compensation expense will fluctuate as the fair market value of our common stock fluctuates. In connection with the grant of stock options to non-employees, we recorded stock-based compensation expense of approximately \$440,000 and \$204,000 for the three months ended September 30, 2005 and 2004, respectively. We recorded stock-based compensation expense of approximately \$870,000 and \$893,000 for the nine months ended September 30, 2005 and 2004, respectively.

Liquidity and Capital Resources

As of September 30, 2005, we had \$131.7 million of cash and cash equivalents, \$39.5 million of investments (short and long-term), and working capital of \$208.9 million. Our cash and cash equivalents increased during the nine months ended September 30, 2005 by \$44.5 million over the corresponding amount of cash and cash equivalents as of December 31, 2004.

Cash Provided by Operations. Net cash provided by operations was \$45.2 million for the nine months ended September 30, 2005, attributable primarily to net income of \$26.1 million, adjusted for non-cash charges, primarily deferred taxes including a tax benefit from stock options of \$13.1 million, and increases in accrued liabilities of \$7.0 million primarily from accruals for payroll and related expenses and income taxes due to increases in headcount, offset partially by an increase in accounts receivable of \$8.0 million as we increased our sales. Net cash provided by operations was approximately \$24.6 million for the nine months ended September 30, 2004, attributable primarily to net income of \$15.6 million, adjusted for non-cash charges, primarily deferred taxes including a tax benefit from stock options of \$8.6 million, and amortization of deferred stock-based compensation of \$3.3 million, increases in accrued

liabilities of \$7.7 million primarily from accruals for payroll and related expenses, offset partially by the increase in accounts receivable of \$11.0 million and increase in inventories of \$3.8 million as we increased our net sales.

Cash Used in Investing Activities. Net cash used in investing activities was \$17.9 million for the nine months ended September 30, 2005, and resulted primarily from net investment activities of \$11.3 million and purchase of property and equipment of \$5.6 million. 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 due to the outfitting of our Sunnyvale facility.

Cash Provided by Financing Activities. Net cash provided by financing activities was \$17.4 million during the nine months ended September 30, 2005 and \$7.9 million for the nine months ended September 2004 and was attributable to proceeds from the exercise of stock options and issuance of common stock under the employee stock purchase plan.

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

Contractual Cash Obligations. At September 30, 2005 we had contractual cash obligations as follows (in thousands):

	Payment Due by Periods						
	Total	Remainder of 2005	2006	2007	2008	2009	After 2009
Operating leases	\$ 23,942	\$ 586	\$ 2,702	\$ 2,811	\$ 2,716	\$ 2,790	\$ 12,337
Consulting agreement	250	25	100	100	25	--	--
Asset retirement obligation	228	--	--	--	--	--	228
Total commitments	<u>\$ 24,420</u>	<u>\$ 611</u>	<u>\$ 2,802</u>	<u>\$ 2,911</u>	<u>\$ 2,741</u>	<u>\$ 2,790</u>	<u>\$ 12,565</u>

The amounts reflected in the table above for operating leases represent aggregate future minimum lease payments and asset retirement obligations under non-cancellable facility leases. Portions of these payments are denominated in foreign currencies and were translated in the tables above based on their respective U.S. dollar exchange rates at September 30, 2005. These future payments are subject to foreign currency exchange rate risk.

On September 28, 2005, we entered into an amendment to our lease agreement dated September 2003 to lease an additional 43,434 square feet of space in the building located at 441 Moffett Park Drive, which is located within the Sunnyvale Corporate Campus, which also includes our principal executive offices at 1221 Crossman Avenue and our leased facilities at 480 Java Drive, all in the City of Sunnyvale, California. The lease of the additional 43,434 square feet of space is effective as of the later of January 1, 2006 and three months following the date on which the landlord delivers possession of the additional space to us. Under the terms of the amendment, we increased the amount of the irrevocable standby letter of credit previously provided to the landlord pursuant to the lease agreement from \$1.0 million to \$1.1 million. The lease term for the additional space extends until August 2014.

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

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

Summary. We believe our current cash, cash equivalents, investments, and cash generated from operations will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. We anticipate conducting significant additional clinical trial activity both in the United States and abroad to collect further data that may support the use and clinical efficacy of our products. The costs of these trials will be significant. If existing cash, cash equivalents, and cash generated from operations are insufficient to satisfy our liquidity requirements, whether as a result of investment in new markets or businesses through both internal or external business development, expansion of product lines, additional clinical trials, possible increased capital expenditures, or, or for other reasons related to our business, we may seek to sell additional equity securities or obtain a credit facility. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock, and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or eliminate certain of our business expansion activities.

Recent Accounting Pronouncements

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

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

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

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

Factors Affecting Future Operating Results

Our future success depends on our ability to develop and successfully introduce new products, product

extensions and improvements to existing products to address unmet patient and market needs.

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

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

Physicians and hospitals are currently eligible for reimbursement by Medicare at varying payment levels in all 50 states and in the District of Columbia when kyphoplasty is performed using our *KyphX* instruments. In some cases, physicians performing a procedure using our instruments have not been reimbursed, either adequately or at all. In addition, some physicians and hospitals in some states believe that the level of reimbursement they receive is too low to justify performing kyphoplasty when properly coded. Reimbursement for competing procedures, such as vertebroplasty, may also continue to be perceived in some cases as more favorable for the physician or hospital than that available for using our products and thus may reduce the frequency with which kyphoplasty procedures using our products are performed.

Currently, Medicare reimburses physicians who use our *KyphX* instruments on a state-by-state basis. This form of reimbursement is not uniform across all states because there is presently no national CPT code or associated national payment rate relating to kyphoplasty procedures using our instruments. In October, 2005, following the American Medical Association (“AMA”) CPT Editorial Panel’s recommendation in late 2004 for adoption of a Category 1 national Current Procedure Terminology (“CPT”) code for spine specialist reimbursement for kyphoplasty, CMS published three new CPT codes in the final 2006 Physician Fee Schedule, numbers 22523, 22524 and 22525, to take effect on January 1, 2006. Each of these codes concerns performance of percutaneous vertebral augmentation, including cavity creation (fracture reduction including biopsy when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g. kyphoplasty), and also concerns, respectively, thoracic, lumbar, and each additional vertebral body. In addition, CMS also modified two existing radiologic codes, 76012 and 76013, concerning, respectively, fluoroscopic and CT guidance, to include vertebral augmentation including cavity creation per vertebral body. We understand that the proposed relative value units associated with each of these five CPT codes should be published for comment in the Federal Register during the fourth quarter of 2005. Despite these developments, we cannot assure you that establishment of these national CPT codes will not adversely affect our business since any reimbursement levels ultimately associated with these codes could be less than what physicians in some or all states are presently receiving, and thus could make surgery with our products less attractive, which would harm our revenues. Continued adoption of our *KyphX* instruments by the medical community may be adversely impacted if physicians perceive that they do not receive sufficient reimbursement from payors for their services in performing the procedures using our instruments. If physicians or hospitals are unable to obtain adequate reimbursement for procedures in which our *KyphX* instruments are used, we may be unable to sell our instruments and our business could suffer.

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

Medicare, as well as private health maintenance organizations and insurance plans, may institute adverse changes in payors' policies toward reimbursement of kyphoplasty procedures. Medicare and private insurance payors are developing increasingly sophisticated methods of controlling health care costs through limitation on reimbursable procedures and the exploration of more cost-effective methods of delivering health care. New limits on coverage and reimbursement of hospitals and other health care providers may significantly impact the willingness of hospitals, clinics and doctors to purchase and use our *KyphX* instruments. Reimbursement and health care payment systems in international markets vary significantly by country and include both government-sponsored health care and private insurance. In addition, health care cost containment efforts similar to those we face in the United States are prevalent in many of the other countries in which we intend to sell our instruments, and these efforts are expected to continue in both the United States and abroad. Given that the vast majority of our revenues indirectly rely on government-funded healthcare systems that reimburse our customers for their use of our products to treat patients, any adverse change in reimbursement coverage and reimbursement policies, including as a result of reaction to rapidly escalating budget pressures, would adversely impact our ability to market and sell our *KyphX* instruments, harm our business and reduce our revenues.

Differences in the amount of reimbursement presently available for kyphoplasty procedures using our *KyphX* instruments based on site-of-service, and the present lack of specific kyphoplasty codes for physician reimbursement, may increase our exposure under regulations governing reimbursement claims made to Medicare and Medicaid, which may harm our business and cause our stock price to decline.

Presently, the amount of facility reimbursement available for kyphoplasty performed on an out-patient basis is significantly less than reimbursement available for kyphoplasty performed on an in-patient basis, with an overnight stay. While a treating physician typically decides to perform kyphoplasty on either an in-patient or an out-patient basis based on the standard of "medical necessity," the difference in reimbursement available could influence, and in some cases likely has influenced, the treatment decision. In addition, since no specific billing code presently exists in any state for physician reimbursement for kyphoplasty, some physicians may seek reimbursement for performing kyphoplasty using one or more codes that may not be deemed appropriate. While we educate and train our employees on how to interact appropriately with healthcare providers on these issues, and have placed particular emphasis on how properly to seek reimbursement in the present environment, we believe that a small number of clinicians has chosen to use inappropriate reimbursement codes for kyphoplasty. Such inappropriate treatment or coding decisions by clinicians may subject us to an increased risk of investigation under relevant federal regulations. We cannot assure you that we will not be subject to any future investigation based on the actions of our employees or our customers, which could significantly affect our business and cause our stock price to decline.

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

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

Medical device manufacturers have recently been the subject of investigations and enforcement activities by the United States government in connection with the industry's interactions with healthcare professionals. If we were to become subject to any government investigation or enforcement action, our business could be adversely affected which could cause our stock price to decline.

Federal regulators recently issued subpoenas to at least five companies in the orthopaedics industry. Several other subpoenas recently issued to cardiac rhythm management medical device companies. We believe these subpoenas

were aimed at investigating the interactions of these various medical device companies with healthcare professionals as related to the federal anti-kickback laws. While we educate and train our employees on how to interact appropriately with healthcare providers under those and related laws, we cannot assure you that we will not be subject to any future investigation or enforcement activity based on the actions of our employees, which could significantly affect our business and cause our stock price to decline.

If primary care physicians are unwilling or unable to refer patients to trained clinicians that use our *KyphX* products to perform kyphoplasty, our revenues will suffer and our business may not expand or may decline.

A key element of our business strategy is to educate primary care physicians and spine specialists on the use of our *KyphX* instruments as an alternative to conventional spine fracture treatment and conservative pain management therapies. We believe primary care is an important source of patient referral, and, therefore, it is important to educate them about our products and the clinical outcome of the kyphoplasty procedure. We believe that primary care physicians and spine specialists may not widely adopt our products unless they determine, based on experience, clinical data and published, peer-reviewed journal articles, that our products provide benefits or an attractive alternative to conventional treatments of spine fractures. In addition, we believe that recommendations and support of our products by influential practitioners are essential for market acceptance and adoption of our products. If we are unable to have continued referrals from primary care physicians, then our future growth will be harmed and our business may decline.

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

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

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

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

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

We believe that the proprietary technology embodied in our instruments and methods gives us a competitive advantage. Maintaining this competitive advantage is important to our future success. We rely on patent protection in the U.S. and abroad, as well as on a combination of copyright, trade secret and trademark laws, to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our patents may be challenged, invalidated or circumvented by third parties. Our two earliest patents, which we believe provide broad protection to our technology, expire no later than February 2009. Our patent applications may not issue as patents at all or in a

form that will be advantageous to us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees and current employees, despite the existence of nondisclosure and confidentiality agreements and other contractual restrictions. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States and may permit others to copy our products abroad without effective recourse. We have recently detected what we believe are the first attempts to copy some of our products for distribution in one or more foreign countries. In addition, in many foreign jurisdictions, we have either acquired patent protection that is narrower in scope than our corresponding protection in the U.S. or chosen, for various business reasons, not to pursue any patent protection at all. We also may not have the ability to prevent infringing products from remaining on the market in at least some geographic locations, and we may lose market share or have our growth impeded in those geographic markets as a result. To protect our rights, we may in the future initiate other claims or litigation against third parties for infringement of our proprietary rights, including, for example, our recently instituted patent infringement litigation against a Korean company distributing balloon catheters for kyphoplasty. We may also begin one or more patent proceedings in various administrative agencies and patent offices to protect our patent rights and prevent them from being undermined by our competitors' patent filings. If we decide to enforce our intellectual property rights to prevent or inhibit appropriation of our technology by competitors, that process will be expensive and time consuming to litigate or otherwise dispose of, will divert management's attention from our core business, and may harm our business if we do not prevail.

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

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

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

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

Our *KyphX* instruments and bone cement and our *KyphOs* calcium phosphate are considered medical devices and are subject to extensive regulation in the United States and in foreign countries where we currently conduct, or intend to conduct, our business. Unless an exemption applies, each medical device that we wish to market in the United States must first receive either 510(k) clearance or premarket approval from the FDA. The FDA's 510(k) clearance process usually takes from three to 12 months, but may take longer. The premarket approval process generally takes from one to three years from the time the application is filed with the FDA, but it can take longer and be significantly more expensive than the 510(k) clearance process. So far, we have obtained 510(k) clearance for the *KyphX* Inflatable Bone Tamps for fracture reduction or void creation in specific sites including the spine (including for use during

kyphoplasty using our bone cement), hand, tibia, radius and calcaneus, and clearance for our *KyphX HV-R* Bone Cement for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions during kyphoplasty procedures. These clearances allow us to promote numerous short- and long-term clinical benefits associated with kyphoplasty procedures. We have also procured CE marking for promoting our products in Europe and the appropriate governmental regulatory clearances to conduct business in Canada and several other foreign countries. Nevertheless, our 510(k) and foreign regulatory clearances can be revoked if safety or effectiveness problems develop. We also will be required to obtain 510(k) clearance or premarket approval and foreign regulatory clearances to market additional products, such as new biomaterials for use in kyphoplasty, which will likely require clinical data, and to market our existing products for new indications, such as treatment of fractures caused by trauma, or in new geographic jurisdictions for us, such as Japan. If the clinical data gathered are not supportive, then applications will not be filed. If we choose to seek additional clearances or approvals by filing one or more applications, we cannot be certain that we would obtain any further regulatory clearances or premarket approvals in a timely manner or at all, and delays in obtaining clearances or approvals may adversely affect our revenue growth, future profitability and ability to penetrate what otherwise might be lucrative markets for our products.

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

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

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

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

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

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

We currently manufacture substantially all of our *KyphX* instruments in our facilities located in Sunnyvale, California. We plan to devote significant resources to expand our manufacturing capacity at this facility. We could experience difficulties and disruptions in the manufacture of our *KyphX* instruments. We could also face the inability to procure and install the necessary manufacturing equipment, a shortage of components we use in our products, a lack of availability of qualified manufacturing personnel to work in our Sunnyvale facility, difficulties in achieving consistent quality control from new manufacturing lines and an inability to maintain sufficient manufacturing capacity. We may experience delays, disruptions, capacity constraints and other problems in our manufacturing operations, and, as a result, product shipments to our customers could be delayed, which would negatively impact our revenues, competitive position and reputation. If we are unable to expand our manufacturing capacity in a timely manner, or if we do not accurately project demand, we will have excess capacity or insufficient capacity, either of which could seriously harm our profitability.

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

product liability lawsuits. If we are sued in a product liability action, we could be forced to pay substantial damages.

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

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

Sales outside of the United States account for a significant percentage of our revenues and we intend to continue to expand our presence in international markets. International net sales accounted for \$31.8 million, or approximately 14% of total net sales, for the nine months ended September 30, 2005. Our international operations and sales are subject to a number of further risks in addition to those faced for our business, generally including:

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

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

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

In July 2003, the Medicines and Healthcare Products Regulatory Agency (“MHRA”) of the United Kingdom issued a Medical Device Alert entitled, “Injectable polymeric cements in percutaneous vertebroplasty, kyphoplasty and pedicle screw augmentation procedures.” The United Kingdom MHRA has received reports of bone cement leaking during vertebroplasty and pedicle screw augmentation procedures leading to patient complications. The Alert noted that there have been no complications reported to MHRA from kyphoplasty procedures, but stated that it was including kyphoplasty procedures in the Alert due to similarities the MHRA perceived exist between kyphoplasty procedures and the other procedures it identified in its Alert. We believe the MHRA’s Alert concerning kyphoplasty pertains directly to our *KyphX* products, since our products are the only balloons presently available in Europe to perform kyphoplasty. The notification asks physicians to consider alternatives before performing procedures using bone

cement in the spine, to use the manufacturer's instructions in preparing bone cements for use in the spine, and to take specific precautions before and during those procedures. So far, despite the FDA's April 2004 clearance of our bone cement and other cements for use in kyphoplasty procedures in the United States and the FDA's subsequent modification of its own Web Notification concerning the use of bone cement in the spine to acknowledge its clearance of our bone cement, the MHRA has declined to update its own notification. If the MHRA notification is not modified or retracted in light of the FDA's clearance of our proprietary *KyphX HV-R* bone cement for specific use in the spine, then the notification may raise concerns with our customers, potential customers and reimbursement organizations, which could negatively impact our ability to sell and promote our instruments in geographic markets that follow MHRA's guidance. In addition, an increase in reports of deaths or serious injuries could lead the FDA or foreign regulatory agencies to issue safety alerts, health advisories, or mandated labeling changes restricting the use of our instruments, including new warnings regarding their use or contraindicating their use with bone cement, which could also harm our business and cause our revenues to decline.

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

With the present exception of some of the larger countries in Europe and in Canada, we sell our *KyphX* instruments in foreign markets through distributors and sales agents. To the extent we rely on distributors, our success will depend upon the efforts of others, over which we may have little control. We recently terminated our relationship with distributors in several foreign jurisdictions and are in the process of establishing, or have already established, new relationships in those and other geographic regions. We may also terminate or modify other distribution relationships in further geographic locations in the future. If we lose a distributor or a distributor fails to perform, our revenues will be harmed in those geographies, and the market for our products may also be harmed in those geographies as a result of the distributor's or agent's actions.

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

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

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

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

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

Our world-wide direct sales organization has increased from approximately 31 employees in October 2000 to over 400 employees in September 2005, which we believe represents significant growth over a relatively short period of time. Our world-wide organization as a whole has increased from approximately 131 employees in October 2000 to approximately 850 employees in September 2005. We intend to continue growing rapidly. The growth that we have experienced, and in the future likely will experience, provides challenges to our organization, requiring us to rapidly expand our personnel and manufacturing operations. We may not be able to hire sufficient personnel to meet our growth goals or may have difficulty managing such rapid growth. As a result, our failure to recruit additional sales and other personnel may result in our inability to meet our projections. Future growth may strain our infrastructure, operations, product development and other managerial and operating resources. If our business resources become strained, we may not be able to deliver instruments in a timely manner.

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

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

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

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

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

As of September 30, 2005, we had \$131.7 million of cash and cash equivalents and \$39.5 million of short and long-term investments. We currently believe that our current cash, cash equivalents, investments, and cash generated from operations will be sufficient to meet our anticipated cash needs for at least the next 12 months. If existing cash, cash equivalents, and cash generated from operations are insufficient to satisfy our cash requirements, whether as a result of possible investment in new markets or businesses through both internal or external business development, expansion of product lines, increased capital expenditures, additional clinical trials, expansion of product lines or investment in new markets or businesses, or for other reasons related to our business, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or the sale of convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock, and could contain covenants that would restrict our operations. Additional financing may not be available to us when we need it or it may not be available on favorable terms, if at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or eliminate our business development activities.

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

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

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

Our basic corporate documents and Delaware law contain provisions that enable our management to attempt to resist a takeover unless it is deemed by management and our Board of Directors to be in the best interests of our stockholders. Those provisions might discourage, delay or prevent a change in the control of our company or a change in our management. Our Board of Directors may also choose to adopt further anti-takeover measures without stockholder approval. The existence and adoption of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

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

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

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

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

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

While we expended significant resources in developing the necessary documentation and testing procedures required by Section 404, given the risks inherent in the operation of internal controls over financial reporting, we can provide no assurance as to our, or our independent auditor's, conclusions after December 31, 2004 with respect to the effectiveness of our internal control over financial reporting. Although we received unqualified opinions as of December 31, 2004, if we are unable to maintain compliance with all of the requirements imposed by Section 404, or if we are unable to complete any assessment of our internal controls, or if our internal controls are not designed or operating effectively, our external auditors may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal control or may issue a qualified opinion on the effectiveness of our internal controls. Investors may lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and which could affect our business and financial condition.

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

In December 2004, the FASB issued SFAS No. 123(R), pursuant to which we must measure all stock-based compensation awards, including grants of employee stock options, using a fair value-based method and record such expense in our consolidated financial statements. This requirement to expense stock-based compensation awards is effective for public companies for annual periods beginning after June 15, 2005. Accordingly, SFAS No. 123(R) will be effective January 1, 2006 for us. Currently, we disclose such expenses on a pro forma basis in the notes to our consolidated financial statements, but we do not record a charge for employee stock option expense in the financial statements. Once we begin to comply with SFAS No. 123(R) as of the beginning of fiscal year 2006, our reported earnings will decrease, which may affect our stock price.

Our facilities are located near known earthquake fault zones, much of our United States revenue is dependent on business from areas of the United States prone to hurricanes, and the occurrence of an earthquake, one or more hurricanes or other natural disasters or any other catastrophic event could cause damage to our facilities

and equipment and could substantially impact many of our customers' operations, which could require us to cease or curtail operations and could hurt our revenues.

Our facilities are located near known earthquake fault zones and are vulnerable to significant damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fires, floods, power loss, communications failures and similar events including the effects of war or acts of terrorism. In addition, many of our customers in the southeastern United States have been adversely affected by one or more hurricanes during the past several years, and may be so affected in the future, which has adversely affected, and could in the future adversely affect, our revenues due to those customers' decreased ability to continue their operations uninterrupted. If any disaster of this sort were to occur, our ability to operate our business at our facilities could be seriously or completely impaired or destroyed and our United States revenues could be significantly impacted. The insurance we maintain may not be adequate to cover our own losses resulting from disasters or other business interruptions.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest-rate risk as of September 30, 2005 is related primarily to our investment portfolio. Our investment portfolio includes fixed-rate debt instruments of the United States government and its agencies and high quality corporate issuers. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk, investments are generally held to maturity and the weighted average duration of our investments is 12 months or less. Due to the short-term nature of these investments, we believe we have no material exposure to interest-rate risk arising from our investments.

We have operated mainly in the United States, and 86%, and 90% our sales were made in United States dollars for the nine months ended September 30, 2005 and 2004, respectively. The majority of our international 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 for the month and balance sheets are translated using rates in effect on the balance sheet date. Differences are recorded within stockholders' equity as a component of accumulated other comprehensive income or to the income statement, as applicable. We believe we have no material exposure to foreign currency exchange rate risk arising from these circumstances.

ITEM 4. CONTROLS AND PROCEDURES

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

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

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In April 2004, we filed two patent infringement suits against Disc-O-Tech, an Israel-based company doing business in the United States. This is the first time we have enforced our patent rights against any entity. We filed suit in the United States District Court in Delaware and in the ITC in Washington, D.C. In September 2004, the ITC entered an Order barring Disc-O-Tech from all further importation of its SKy Bone Expander device into the United States and from engaging in any further sales activities and uses of such imported products, thereby terminating the ITC proceeding in our favor. In June 2005, the Delaware District court entered a Consent Judgment permanently enjoining

Disc-O-Tech from further infringing our patent rights with its SKy Bone Expander device or products not colorably different from the SKy Bone Expander, which took effect on July 22, 2005. This Judgement bars further importation or selling of Disc-O-Tech's SKy Bone Expander device or colorable variations of that device for performing kyphoplasty in the U.S. market. This concluded the litigation in our favor without the possibility of further trial or appeal. Disc-O-Tech, however, remains a competitor abroad, in other jurisdictions where we have not pursued them to date, or may not be able to pursue them with our foreign patent rights.

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

ITEM 5. OTHER INFORMATION

(a) On September 28, 2005, we entered into an amendment to our lease agreement dated September 18, 2003 with Moffett Office Park Investors LLC, a Delaware limited liability company. Set forth below is a brief description of the terms and conditions of the amendment, which summary is qualified in its entirety by reference to the full text of the underlying amendment which has been filed as an exhibit hereto.

Pursuant to the amendment, we will lease 43,434 square feet of space in the building located at 441 Moffett Park Drive, which is located within the Sunnyvale Corporate Campus, which also includes our principal executive offices at 1221 Crossman Avenue and our leased facilities at 480 Java Drive, all in the City of Sunnyvale, California. The lease of the additional space is effective as of the later of January 1, 2006 and three months following the date on which the landlord delivers possession of the additional space to us. Under the terms of the amendment, we increased the amount of the irrevocable standby letter of credit previously provided to the landlord pursuant to the lease agreement to \$1.1 million. The lease term for the additional space extends until August 2014. Except as set forth in the Amendment, all terms and conditions of the Lease remain in full force and effect.

(b) 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 independent registered public accounting firm. Non-audit services are defined in the Act as services other than those provided in connection with an audit or a review of the financial statements of a company. The Audit Committee has approved the engagement of PricewaterhouseCoopers LLP for the following non-audit services: (1) various tax matter consultations concerning foreign, U.S. federal and state taxes; and (2) the preparation of federal and state income tax returns.

ITEM 6. EXHIBITS

Number	Description
3.2 (1)	Amended and Restated Certificate of Incorporation of the registrant.
3.4 (1)	Bylaws of the registrant.
4.1 (1)	Specimen common stock certificate of the registrant.
10.1* (1)	Form of Indemnification Agreement for directors and executive officers.
10.2* (1)	1996 Stock Option Plan, including form of option agreement.
10.3* (1)	2002 Stock Plan, including form of option agreement.
10.4* (1)	2002 Employee Stock Purchase Plan, including form of employee stock purchase plan subscription agreement.
10.5* (1)	2002 Director Option Plan, including form of option agreement.
10.8 (1)	Lease dated January 27, 2000 for office space located at 1350 Bordeaux Drive, Sunnyvale, CA 94089 and Second Amendment to Lease dated November 29, 2001.

- 10.8.1 (1) Third Amendment to Lease dated March 29, 2002 for office space located at 1350 Bordeaux Drive, Sunnyvale, CA 94089.
- 10.9* (1) Employment Agreement between the registrant and Gary L. Greuter dated July 16, 2001.
- 10.10 (1) Promissory Note Secured by Deed of Trust between the registrant and Gary L. Greuter dated December 31, 2001.
- 10.11 (1) Amended and Restated Stockholder Rights Agreement effective as of December 14, 1999, among the registrant and certain stockholders of the registrant.
- 10.12* (2) Employment Agreement between the registrant and Richard W. Mott dated September 3, 2002.
- 10.13†(2) Sublicense Agreement effective as of August 19, 2002, between the registrant and Bonutti Research, Inc.
- 10.14 (3) Stock Purchase Agreement by and between Kyphon and the shareholders of Sanatis GmbH, dated February 15, 2003.
- 10.15 (4) Lease dated September 18, 2003 for office spaces located at 1221 Crossman Avenue and 480 Java Drive, Sunnyvale, California.
- 10.16*(5) Form of Severance Agreement entered into by and between Kyphon Inc. and its executive officers.
- 10.17*(5) Severance Agreement, dated January 28, 2005, entered into by and between Kyphon Inc. and Richard W. Mott.
- 10.18 First Amendment to Lease Agreement, made as of September 28, 2005, by and between Moffett Office Park Investors LLC, a Delaware limited liability company, and Kyphon Inc.
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-83678), which was declared effective on May 16, 2002.

(2) Incorporated by reference from our Quarterly Report on Form 10-Q as filed with the Securities Exchange Commission on November 13, 2002.

(3) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities Exchange Commission on March 7, 2003.

(4) Incorporated by reference from our Quarterly Report on Form 10-Q as filed with the Securities Exchange Commission on November 14, 2003.

(5) Incorporated by reference from our Current Report on Form 8-K as filed with the Securities Exchange Commission on February 7, 2005.

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

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Kyphon Inc.

Date: November 1, 2005

By: /s/ Richard W. Mott

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

Date: November 1, 2005

By: /s/ Arthur T. Taylor

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

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

I, Richard W. Mott certify that:

1. I have reviewed this quarterly report on Form 10-Q of Kyphon Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as designed in the Exchange Act Rules 13a-15(d) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2005

By: /s/ Richard W. Mott
Richard W. Mott
President, Chief Executive Officer and Director
(Principal Executive Officer)

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

I, Arthur T. Taylor certify that:

1. I have reviewed this quarterly report on Form 10-Q of Kyphon Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as designed in the Exchange Act Rules 13a-15(d) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 1, 2005

By: /s/ Arthur T. Taylor

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

**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, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Kyphon Inc.

Date: November 1, 2005

By: /s/ Richard W. Mott

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

I, Arthur T. Taylor, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Kyphon Inc. on Form 10-Q for the fiscal quarter ended September 30, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Kyphon Inc.

Date: November 1, 2005

By: /s/ Arthur T. Taylor

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