

INVIVO CORP
Form 10-Q
November 14, 2003

Table of Contents

U.S. Securities and Exchange Commission
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2003

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 0-15963

INVIVO CORPORATION

(Exact name of Registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
Of incorporation)

77-0115161
(IRS Employer Identification No.)

4900 HOPYARD RD. SUITE 210, PLEASANTON, CALIFORNIA 94588
(Address of principal executive offices) (Zip Code)

TELEPHONE: (925) 468-7600
(Registrant's telephone number)

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 filing requirements for the past 90 days. Yes No

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares outstanding of the issuer's Common Stock, par value \$.01 per share, at November 13, 2003 was 5,891,893 shares.

TABLE OF CONTENTS

Consolidated Balance Sheets

Consolidated Statements of Income

Consolidated Statements of Cash Flows

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

ITEM 4. CONTROLS AND PROCEDURES

PART II - OTHER INFORMATION

ITEM 1: LEGAL PROCEEDINGS:

ITEM 2: CHANGES IN SECURITIES AND USE OF PROCEEDS:

ITEM 3: DEFAULTS UPON SENIOR SECURITIES:

ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS:

ITEM 5: OTHER INFORMATION:

ITEM 6: EXHIBITS AND REPORTS ON FORM 8-K

SIGNATURES

Exhibit 10.14

Exhibit 10.15

Exhibit 10.16

Exhibit 10.17

Exhibit 31.01

Exhibit 31.02

Exhibit 32.01

Exhibit 32.02

Table of Contents**INVIVO CORPORATION AND SUBSIDIARIES**

Consolidated Balance Sheets
(in thousands, except share data)
(Unaudited)

	<u>September 30, 2003</u>	<u>June 30, 2003</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 760	1,275
Short-term investments	8,811	8,258
Trade receivables, less allowance for doubtful accounts of \$599 as of September 30, 2003 and \$516 as of June 30, 2002	14,467	16,048
Inventories	11,064	12,016
Deferred income taxes	2,053	1,913
Prepaid expenses and other current assets	502	534
	<u> </u>	<u> </u>
Total current assets	37,657	40,044
Property and equipment, net	7,047	6,859
Goodwill	12,222	12,222
Other assets	208	208
	<u> </u>	<u> </u>
	<u>\$57,134</u>	<u>59,333</u>
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 2,712	3,747
Accrued expenses	5,810	7,208
Current portion of long-term debt and capital leases	113	113
Income taxes payable	722	1,709
Other current liabilities	348	394
	<u> </u>	<u> </u>
Total current liabilities	9,705	13,171
Long-term debt and capital leases, excluding current portion	1,322	1,351
Deferred income taxes	714	714
	<u> </u>	<u> </u>
Total liabilities	11,741	15,236
Commitments and contingencies		
Stockholders equity:		
Common stock, \$.01 par value; authorized shares totaling 20,000,000; issued and outstanding shares totaling 5,879,024 as of September 30, 2003 and 5,836,574 as of June 30, 2003	59	58
Additional paid-in capital	18,114	17,844
Retained earnings	27,163	26,211
Accumulated other comprehensive income (loss)	57	(16)
	<u> </u>	<u> </u>
Total stockholders equity	45,393	44,097
	<u> </u>	<u> </u>
	<u>\$57,134</u>	<u>59,333</u>

See accompanying notes to consolidated financial statements.

Table of Contents

INVIVO CORPORATION AND SUBSIDIARIES

Consolidated Statements of Income
For the Three Months Ended September 30, 2003 and 2002
(in thousands, except share and per share data)
(Unaudited)

	<u>2003</u>	<u>2002</u>
Sales	\$ 16,211	11,051
Cost of goods sold	8,205	5,260
	<u> </u>	<u> </u>
Gross profit	8,006	5,791
	<u> </u>	<u> </u>
Operating expenses:		
Selling, general, and administrative	5,472	4,150
Research and experimental	1,056	800
	<u> </u>	<u> </u>
Total operating expenses	6,528	4,950
	<u> </u>	<u> </u>
Income from operations	1,478	841
Other income (expense):		
Interest income	32	152
Interest expense	(12)	(17)
Other, net	(11)	
	<u> </u>	<u> </u>
Income before income taxes	1,487	976
Income tax expense	535	293
	<u> </u>	<u> </u>
Net income	\$ 952	683
	<u> </u>	<u> </u>
Basic net income per common share	\$ 0.16	0.10
	<u> </u>	<u> </u>
Weighted-average common shares outstanding (basic)	5,851,253	6,695,867
	<u> </u>	<u> </u>
Diluted net income per common share	\$ 0.15	0.10
	<u> </u>	<u> </u>
Weighted-average common shares outstanding (diluted)	6,522,432	7,045,068
	<u> </u>	<u> </u>

See accompanying notes to consolidated financial statements.

Table of Contents**INVIVO CORPORATION AND SUBSIDIARIES**

Consolidated Statements of Cash Flows
For the Three Months Ended September 30, 2003 and 2002
(in thousands)
(Unaudited)

	<u>2003</u>	<u>2002</u>
Cash flows from operating activities:		
Net Income	\$ 952	683
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	407	290
Deferred income taxes	(140)	(108)
Changes in operating assets and liabilities:		
Trade receivables	1,621	(14)
Inventories	1,014	(314)
Prepaid expenses and other current assets	32	(343)
Accrued expenses	(1,398)	(1,268)
Accounts payable	(1,035)	262
Income taxes payable	(987)	(747)
Other current liabilities	(46)	
	<u>420</u>	<u>(1,559)</u>
Cash flows from investing activities:		
(Purchase) sale of short-term investments, net	(520)	1,826
Restricted cash		83
Capital expenditures	(657)	(411)
	<u>(1,177)</u>	<u>1,498</u>
Cash flows from financing activities:		
Exercise of stock options	271	470
Payments under long-term debt and capital leases	(29)	(28)
	<u>242</u>	<u>442</u>
Net (decrease) increase in cash and cash equivalents	(515)	381
Cash and cash equivalents at beginning of period	1,275	1,006
	<u>760</u>	<u>1,387</u>
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Income taxes	\$ 1,662	1,147
Interest	\$ 12	17

See accompanying notes to consolidated financial statements.

Table of Contents

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. GENERAL

The consolidated balance sheets as of September 30, 2003 and June 30, 2003 and the related consolidated statements of income for the three-month periods ended September 30, 2003 and 2002, and the consolidated statements of cash flows for the three-month periods ended September 30, 2003 and 2002 of Invivo Corporation (the Company) are unaudited. The consolidated financial statements reflect, in the opinion of management, all adjustments necessary to present fairly the financial position and results of operations as of and for the periods indicated. Interim results are not necessarily indicative of results for a full year.

The financial statements and notes are presented as permitted by Form 10-Q, and do not contain certain information included in the Company's annual consolidated financial statements and notes.

2. DEBT AND BANK BORROWINGS

The Company renewed its \$1,000,000 bank line of credit on January 1, 2003. The Company's revolving bank line of credit is unsecured. At September 30, 2003, \$1,000,000 was available under the line of credit.

3. COMPREHENSIVE INCOME

The components of comprehensive income, net of tax, are as follows:

(in thousands)	THREE MONTHS ENDED SEPTEMBER 30,	
	2003	2002
Net income	\$ 952	\$ 683
Change in unrealized gain on short-term investments	33	28
Change in foreign currency translation	40	7

Table of Contents

4. NET INCOME PER COMMON SHARE

The following table presents the calculation for basic and diluted net income per common share:

	THREE MONTHS ENDED SEPTEMBER 30,	
	2003	2002
BASIC:		
Weighted average common Shares outstanding	5,851,253	6,695,867
Net Income	\$ 952	\$ 683
Basic net income per common share	\$ 0.16	\$ 0.10
DILUTED:		
Weighted average common Shares outstanding (basic)	5,851,253	6,695,867
Dilutive stock options	671,179	349,201
Weighted average common Shares outstanding (diluted)	6,522,432	7,045,068
Net Income	\$ 952	\$ 683
Diluted net income per common share	\$ 0.15	\$ 0.10

5. STOCK-BASED COMPENSATION DISCLOSURE

The Company has established stock option plans to provide for the granting of stock options to employees (including officers and directors) at prices not less than the fair market value of the Company's common stock at the date of grant. Options vest ratably over four years and expire in ten years. The Company accounts for those plans under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. In December 2002, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure, an amendment of FASB Statement No. 123*. SFAS No. 148 amends FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of Statement No. 123 to require prominent disclosures in both annual and interim financial statements.

Table of Contents

The following table illustrates the effect on net income and earnings per share for the interim periods presented if the Company had applied the fair value recognition provisions of SFAS No. 123, to stock-based employee compensation. The fair value of options issued under the plans was determined at the date of grant using a Black-Scholes option pricing model with the following assumptions: no dividend yield; volatility factor of the expected market price of the Company's stock of 78% and 74% for the years ended June 30, 2003 and 2002, respectively; a forfeiture rate of 5%; a weighted-average expected life of options of five years; and risk-free interest rates of 2.96% and 4.44% for the years ended June 30, 2003 and 2002, respectively. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period.

	Three Months Ended September 30, (in thousands, except per share data)	
	2003	2002
Net income, as reported	\$ 952	683
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(197)	(202)
Pro forma net income	\$ 755	481
Earnings per share:		
Basic as reported	.16	.10
Basic pro forma	.13	.07
Diluted as reported	.15	.10
Diluted pro forma	.12	.07

Table of Contents

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

The following information should be read in conjunction with the interim unaudited condensed consolidated financial statements and related notes.

This Quarterly Report on Form 10-Q contains forward-looking statements regarding the Company's plans, expectations, estimates and beliefs. These forward-looking statements are only predictions and involve risks and uncertainties, including among other things, statements regarding the Company's anticipated revenue, costs and expenses. Actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, will, or other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. The Company is not obligated to update or revise these forward-looking statements to reflect new events or circumstances. Factors that could cause actual results, events or circumstances to differ from forward-looking statements made in this report include those set forth in the following Risk Factors section. You are also urged to carefully review the risks described in other documents that the Company files with or furnishes to the Securities and Exchange Commission from time to time, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K.

On August 19, 2003, the Company's Board of Directors approved a three-for-two stock split of the outstanding shares of the Company's common stock. The stock split was effected in the form of a stock dividend pursuant to which one-half of one new share was issued on September 26, 2003 for each share outstanding on the close of business on the record date, September 12, 2003. Pursuant to the Company's 1994 stock option plan and 1986 stock option plan, the number of shares reserved under those plans and subject to outstanding options, and the exercise price per share of such options, were proportionately adjusted by reason of the stock split. The share and per share numbers provided in this Quarterly Report on Form 10-Q give effect to the stock split.

RESULTS OF OPERATIONS

Three Month Periods Ended September 30, 2003 and 2002

Sales

Sales for the first quarter of fiscal 2004 increased 46.7% to \$16,211,000 compared to sales of \$11,051,000 for the first quarter of fiscal 2003. The increase was primarily due to the growth in sales of general patient monitoring products along with growth in sales of the Company's magnetic resonance imaging, or MRI monitoring products. The increase in general patient monitoring was largely due to sales of products of Medical Data Electronics (MDE) which the Company acquired in April 2003. The growth in sales of the Company's MRI monitoring products in the first quarter of fiscal 2004 was primarily due to sales of the Magnitude AS anesthesia delivery system for the MRI introduced in the second quarter of fiscal 2003, which offset lower than expected growth in sales of MRI vital signs monitors.

Gross Profit

The gross profit margin for the first quarter of fiscal 2004 decreased to 49.4% from 52.4% in the first quarter of fiscal 2003. The decrease in the gross profit margin was primarily attributable to the increase in sales of the Magnitude AS anesthesia delivery system for the MRI and general patient monitoring products. The Magnitude AS is sold under an exclusive distributor agreement with Draeger Medical, Inc. providing for lower gross profit margins than the other monitors sold by the Company.

Operating Expenses

Selling, general and administrative expenses for the first quarter of fiscal 2004 increased 31.9% or \$1,322,000 from the year earlier fiscal period. Selling, general and administrative expenses were 33.8% of sales for the first quarter of fiscal 2004 compared with 37.6% in the first quarter of fiscal 2003. The increase in these expenditures was primarily due to expenditures on behalf of MDE. The decrease in selling, general and administrative expenses as a percentage of sales was primarily due to increased efficiencies from the integration of the MDE and Invivo Research sales forces in the quarter. The Company will incur additional administrative expense in the second quarter of fiscal 2004 due to fees paid to professional advisers assisting the Company in responding to an unsolicited proposal to negotiate a business combination that was received in October 2003.

Edgar Filing: INVIVO CORP - Form 10-Q

Research and experimental expenses for the first quarter of fiscal 2004 increased 32.0% or \$256,000 as compared to the same period in fiscal 2003. The increase was primarily attributable to research and development expenses on behalf of MDE. Research and experimental expenses were 6.5% of sales for the quarter ended September 30, 2003 compared to 7.2% for the quarter ended September 30, 2002. The Company plans to continue its efforts in developing new products and enhancing its existing ones and expects research and experimental expenditures as a percentage of sales to be in the 6.5% to 7.0% range throughout fiscal 2004.

Other Income and Expense

Interest income was \$32,000 for the first quarter of fiscal 2004 as compared to \$152,000 for the first quarter of fiscal 2003. The decrease was due to the decrease in cash and short-term investment balances in the quarter ended September 30, 2003 as compared to September 30, 2002.

Provision for Income Taxes

The effective tax rate for the first quarter of fiscal 2004 was 36.0% as compared to 30.0% the first quarter of fiscal 2003. The increase in the effective rate was primarily due to the decrease of federal tax-exempt interest income from short-term investments.

LIQUIDITY AND CAPITAL RESOURCES

Working capital at September 30, 2003 increased to \$27,952,000 from \$26,873,000 at June 30, 2003. Net cash provided by operating activities was \$420,000 for the three months ended September 30, 2003 compared with \$1,559,000 used in operating activities for the three months ended September 30, 2002. This increase in net cash provided by operating activities in the first quarter of fiscal 2004 was largely the result of decreases in accounts receivable and inventories and an increase in net income and depreciation, which more than offset the decrease in accrued expenses, accounts payable and income taxes payable.

Capital expenditures were \$657,000 for the first quarter of fiscal 2004 compared to \$411,000 for the first quarter of fiscal 2003. Capital expenditures in the first quarter of each of fiscal 2004 and fiscal 2003 were primarily related to sales demonstration equipment for the sales force.

Table of Contents

The Company believes that its remaining cash and short-term investments, along with its borrowing capacity, will be sufficient to support its working capital and capital expenditure requirements throughout fiscal 2004.

The Company renewed its \$1,000,000 revolving bank line of credit on January 1, 2003. The line of credit is unsecured. At September 30, 2003, \$1,000,000 was available under the line of credit.

A summary of future minimum lease payments required under noncancelable leases with terms in excess of one year as of September 30, 2003 follows:

	<u>Operating leases</u>
Fiscal year ending June 30:	
2004	\$ 712,200
2005	956,900
2006	551,500
2007	269,600
2008	250,500
Thereafter	732,100
	<u>\$3,472,800</u>

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and judgments that affect its reported amounts of assets and liabilities, revenues and expenses and related disclosures of contingent assets and liabilities. These estimates are based on the information that is currently available to the Company and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could vary from those estimates under different assumptions or conditions.

The Company believes that the following critical accounting policies involve the more significant judgments and estimates used in the preparation of its financial statements:

Revenue Recognition

The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred and title has transferred, the price is fixed and determinable, and collectibility is reasonably assured. The Company accrues for estimated sales returns and other allowances at the time of recognition of revenue, which is typically upon shipment, based on historical experience. If different assumptions were employed in making these estimates, the amount of reported revenue could be affected.

Allowance for Doubtful Accounts

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the failure of its customers to make required payments. On an on-going basis, the Company evaluates the collectibility of accounts receivable based on a combination of factors. In circumstances in which it is aware of a specific customer's inability to meet its financial obligation, it records a specific reserve of the bad debt against amounts due. In addition, the Company also makes judgments and estimates of the collectibility of accounts receivable based on historical bad debt experience, customers' creditworthiness, current economic trends, recent changes in customer payment trends, and deterioration in the customers' operating results or financial position. If circumstances change adversely, additional allowances may be required.

Inventory

Inventories are stated at lower of cost or market with cost determined by the first-in, first-out method. The Company reviews the components of inventory on a regular basis for excess, obsolete and impaired inventory based on estimated future usage and sales. The Company may be required to write-down inventory due to changes in competitive conditions, new product

Table of Contents

introductions by the Company or its competitors, or rapid changes in customer demand, in which event the Company's gross margins would be adversely affected.

Business Acquisitions and Valuation of Goodwill

The Company uses assumptions in establishing the carrying value of its goodwill. The determination of value of these components of a business combination, as well as associated asset useful lives, requires management to make various estimates and assumptions. Estimates using different, but each reasonable, assumptions could produce significantly different results.

On July 1, 2001 the Company adopted SFAS No. 142, *Accounting for Goodwill and Other Intangible Assets*. SFAS No. 142 addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. In accordance with SFAS No. 142, goodwill is no longer amortized over its estimated useful life; rather, goodwill will be subject to at least an annual assessment for impairment by applying a fair-value-based test. The Company continually reviews the events and circumstances related to its financial performance and economic environment for factors that would provide evidence of impairment of goodwill. The Company tests goodwill for impairment in accordance with SFAS No. 142 at least annually and more frequently upon the occurrence of certain events, as defined in SFAS No. 142. As of September 30, 2003, no events have occurred that would lead the Company to believe that there has been any impairment.

Warranty

The Company provides for the estimated cost of product warranties at the time the related revenue is recognized. The amount of this provision is determined by using historical experience and estimated future costs associated with the Company's different products. Should actual product failure rates or estimated costs to repair those product failures exceed the Company's estimates, revisions to the estimated warranty provision would be required and gross margins would be adversely affected.

Income Taxes

The Company bases its estimate of deferred tax assets and liabilities on current tax laws and rates. The Company's accounting for deferred tax consequences represents management's best estimate of future events that can be appropriately reflected in the accounting estimates.

RECENT ACCOUNTING PRONOUNCEMENTS

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*, to amend and clarify financial accounting and reporting for derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. SFAS No. 149 requires that contracts with comparable characteristics be accounted for similarly and clarifies under what circumstances a contract with an initial net investment meets the characteristics of a derivative as discussed in SFAS No. 133. In addition, it clarifies when a derivative contains a financing component that warrants special reporting in the statement of cash flows. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The Company believes that the adoption of SFAS No. 149 will not have an impact on its financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). The provisions of SFAS No. 150 are effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The Company believes that the adoption of SFAS No. 150 will not have an impact on its financial position or results of operations.

RISK FACTORS

THE COMPANY IS DEPENDENT ON A CONCENTRATED LINE OF PRODUCTS

The Company's future financial performance is dependent on its patient monitor product lines, which include a limited number of products. The growth of the market for the Company's MRI monitors is heavily dependent on the further acceptance of MRI technology as a diagnostic tool. In the general patient monitoring market, future growth of the Company's bedside monitors is dependent on the Company's ability to further penetrate an already competitive market. By virtue of its acquisition of MDE in April 2003, the Company acquired additional patient monitor products and therefore continues to be subject to the risk of concentration in this industry.

Table of Contents

In addition, the recent consolidation in the medical care provider market has resulted in a number of very large purchasers of medical devices. These large purchasers typically prefer to establish relationships with medical device manufacturers that have broad and diverse product lines, and therefore, may seek relationships with companies that are larger than the Company.

The failure of the Company's products to continue to gain market acceptance, the market's transition away from any existing line of products or a continued consolidation of the medical care provider market could have a material adverse effect on the Company's business and results of operations.

THE COMPANY FACES SUBSTANTIAL LEVELS OF COMPETITION

The Company has encountered and will continue to encounter significant competition in the sale of its products. The Company's general patient monitoring competitors include a number of large multinational corporations. Some of these competitors may be able to adapt more quickly to new or emerging technologies and changes in customer requirements, or to devote greater resources to the development, promotion and sale of their products than the Company can. In the MRI patient monitoring market, the Company has enjoyed a significant first-to-market advantage over its competitors. However, competitors have introduced products that compete with the Company's MRI vital signs monitoring products. In addition, as the market for MRI vital signs monitoring products expands it may attract competitors with greater resources.

Additionally, competition may increase if new companies enter the Company's markets or if existing competitors expand their product lines or intensify efforts within existing product lines. The introduction of competitive products may result in a decrease in the Company's market share and in a decrease in the prices at which the Company is able to sell its products. The Company's market share could also be adversely affected by increasing concentration in the medical care provider market. Any decrease in the Company's market share or decrease in the prices at which the Company is able to sell its products could have a material adverse effect on its business and results of operations.

THE COMPANY'S FINANCIAL RESULTS MAY FLUCTUATE

The Company's financial results may fluctuate significantly from period to period because of a variety of factors, many of which are beyond its control. These factors include:

- increased competition, including possible future competition in the MRI monitor market

- changes in the Company's pricing policies and those of its competitors

- changes in the Company's operating expenses or capital expenditures

- timing and market acceptance of new and upgraded product introductions by the Company and its competitors

- introduction of alternative technologies by the Company and its competitors

- effect of potential acquisitions

- other general economic factors

Fluctuations caused by these and other factors could have a material adverse effect on the Company's business and results of operations, and correspondingly, on the trading prices of the Company's common stock.

THE COMPANY IS SUBJECT TO A SIGNIFICANT RISK OF NEW LAWS RELATED TO HEALTH CARE

Changes in the law or new interpretations of existing laws may have a significant effect on the Company's costs of doing business and the amount of reimbursement the Company receives from both government and third-party payors. In addition, economic forces, regulatory influences and political initiatives are subjecting the health care industry to fundamental changes. Federal, state and local government representatives are likely to continue to review and assess alternative health care delivery systems and payment methods. The Company expects ongoing public debate on these issues. Any of these efforts or reforms could have a material adverse effect on the Company's business and results of operations.

Table of Contents

THE COMPANY'S BUSINESS IS SUBJECT TO TECHNOLOGICAL CHANGE AND INTRODUCTION OF NEW PRODUCTS

Technological change, evolving industry standards and new product introductions and enhancements characterize the markets for the Company's products. Many of the Company's existing products and products under development are technologically innovative, and therefore require significant planning, design, development and testing. These activities require the Company to make significant capital commitments and investments. In addition, industry standards may change on short notice and new products and technologies may render existing products and technologies uncompetitive. Additionally, the products that the Company is currently developing, and those that the Company develops in the future, may not be technologically feasible or accepted by the marketplace or they may not be completed in an acceptable time frame. Technological change could prevent the Company from achieving the benefits it expects from research initiatives and could also result in a loss from existing products.

THE COMPANY FACES RISKS ASSOCIATED WITH ACQUISITIONS

The Company acquired MDE in April 2003 and may make additional acquisitions in the future. Acquisitions involve numerous risks, including difficulties in the integration of the operations, services, technologies, products and personnel of the acquired companies, diversion of management's attention from other business concerns, overvaluation of the acquired companies, potential loss of key employees and customers of the acquired companies and lack of acceptance by the marketplace of the acquired companies' products or services. Some of the acquired products or technologies may require significant additional development before they can be marketed and may not generate sufficient revenue to offset expenses associated with the acquisitions. Future acquisitions may also result in dilution to existing stockholders, the use of a substantial portion of the Company's cash and investment balances, the incurrence of debt, large one-time write-offs and the creation of goodwill or other intangible assets that could result in significant impairment charges or amortization expense. Moreover, the Company may face exposure to litigation and other unanticipated contingent liabilities of the acquired companies. Any of these problems or factors with respect to the acquisition of MDE or any other acquisition completed by the Company could result in a material adverse effect to the Company's business, financial condition and results of operations.

THE COMPANY HAS RECEIVED AN UNSOLICITED PROPOSAL REGARDING THE ACQUISITION OF THE COMPANY AND CANNOT PREDICT THE OUTCOME OF THAT PROPOSAL OR ITS IMPACT ON THE COMPANY

In October 2003, a third party publicly announced that it had sought to engage the Company's Board of Directors in exclusive negotiations regarding a proposal that the third party acquire the Company. The Company has responded to the third party that the Company's Board had unanimously rejected the third party's proposal. Upon the public announcement of the third party's proposal, the trading price of the Company's common stock increased substantially. The Company cannot predict the next steps, if any, that will be taken by the third party or how the Board of Directors will react to any such steps. Nor can the Company predict the extent to which the trading price of the Company's common stock will be affected by any future developments, or the lack of any developments, in this matter. The Company is incurring fees to its advisors in connection with the response to and evaluation of the proposal, and these fees will have an adverse effect on fiscal 2004 operating results. If this unsolicited proposal is further pursued, it could have an adverse effect on employees, customers and suppliers of the Company.

THE COMPANY MAY FROM TIME TO TIME BE SUBJECT TO SIGNIFICANT LITIGATION

The Company may from time to time be subject to litigation and third party claims. In particular, because the Company does business in the critical healthcare setting, the Company may be subject to significant litigation arising from actual or alleged injuries to patients. Litigation is by its nature costly and may divert management's attention, either of which could adversely affect the Company's operating results. In addition, if any current or future litigation is determined adversely, the Company's operating results and financial condition could be adversely affected.

THE COMPANY FACES PRODUCT LIABILITY AND PRODUCT RECALL RISKS

With respect to all of its products, and particularly its medical devices, the Company faces the risk of potentially large product liability claims. The malfunction or misuse of its products could potentially result in serious harm to a patient. In addition, the Company may be required to indemnify its distributors and customers for similar claims made against them.

Claims could be made against the Company even if its products did not contribute to the injury that was sustained. Frequently, the Company's products are used with products developed by other manufacturers. Even if its products are not the cause of the injury, the Company may not be able to prove that some other product malfunction or human error caused a claimant's injury.

The Company has had product liability claims made against it in the past and may have further claims made against it in the future. While the Company is insured for certain product liability claims, not all claims will be covered and the level of its insurance may not be sufficient to protect it from the full amount of a successful claim. In addition, the Company may not be able to obtain adequate amounts of insurance at an

Edgar Filing: INVIVO CORP - Form 10-Q

acceptable cost. Claims made against the Company that are not insured, or that exceed the amount of the Company's coverage, could have a material adverse effect on its business and results of operations.

Similarly, the Company's products are subject to the potential of being recalled by government agencies for actual or potential deficiencies or problems. Any such recall would likely be expensive and would have a material adverse effect on the Company's business and results of operations.

Table of Contents

THE COMPANY FACES RISKS OF INTERNATIONAL OPERATIONS

International sales have accounted for at approximately 20% of the Company's sales for each of the past three years and may increase over time. International sales are subject to a number of risks, including the following:

fluctuations in exchange rates may affect the demand for products and services the Company provides in foreign markets

adverse changes in local economic conditions could depress the demand for the Company's products

agreements may be difficult to enforce and receivables 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 the Company's foreign income, impose tariffs, or adopt other restrictions on foreign trade

U.S. export licenses may be difficult to obtain

the protection of intellectual property in foreign countries may be more difficult than in the United States

acts of terrorism or war may have an adverse impact on foreign markets

Any of these factors could have a material adverse impact on the Company's business and results of operations.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company's sales are primarily denominated in U.S. dollars and as a result, the Company has relatively little exposure to foreign currency exchange risk with respect to its sales. The Company does not currently hedge against exchange foreign currency rate fluctuations. The effect of an immediate 10% change in exchange rates would not have a material impact on the Company's future operating results or cash flows.

The Company's exposure to market risk for a change in interest rates relates primarily to its investment portfolio. As of September 30, 2003, the Company's short-term investments consisted of available-for-sale securities of \$8.8 million. These fixed income marketable securities included corporate bonds, municipal bonds and mutual bond funds, all of which are of high investment grade. These securities are subject to interest rate risk and will decline in value if the market interest rates increase. If the market interest rates were to increase immediately and uniformly by 10% from levels as of September 30, 2003, the decline in the fair value of the portfolio would not be material to the Company's financial position.

ITEM 4. CONTROLS AND PROCEDURES

(a) **Evaluation of Disclosure Controls and Procedures.** The Securities and Exchange Commission defines the term "disclosure controls and procedures" to mean a company's controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. The Company's chief executive officer and chief financial officer have concluded, based on the evaluation of the effectiveness of the disclosure controls and procedures by its management, with the participation of the Company's chief executive officer and chief financial officer, as of the end of the period covered by this report, that the Company's disclosure controls and procedures were effective for this purpose.

(b) **Changes in Internal Controls Over Financial Reporting.** There was no change in the Company's internal control over financial reporting during the first quarter of fiscal 2003 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1: LEGAL PROCEEDINGS:

Not Applicable.

ITEM 2: CHANGES IN SECURITIES AND USE OF PROCEEDS:

On November 5, 2003, the Company's Board of Directors amended the by-laws of the Company. The amendment added a new Section 12 to Article II of the by-laws which requires that stockholders desiring to submit director nominations or other business for consideration at a meeting of stockholders must provide notice, and certain information, to the Company within a specified time period prior to the meeting.

ITEM 3: DEFAULTS UPON SENIOR SECURITIES:

Not Applicable.

ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS:

Not Applicable.

ITEM 5: OTHER INFORMATION:

Not Applicable.

ITEM 6: EXHIBITS AND REPORTS ON FORM 8-K

Exhibits:

Table of Contents

(a) Exhibits. The following exhibits are filed or furnished as part of this Quarterly Report on Form 10-Q:

Exhibit 10.14	Second Amended and Restated Employment Agreement for James Hawkins
Exhibit 10.15	Second Amended and Restated Employment Agreement for John Glenn
Exhibit 10.16	Second Amended and Restated Employment Agreement for Stuart Baumgarten
Exhibit 10.17	Second Amended and Restated Employment Agreement for Brent Johnson
Exhibit 31.01	Certification of the Company's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 31.02	Certification of the Company's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 32.01	Certification of the Company's Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 *
Exhibit 32.02	Certification of the Company's Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 *

Reports on Form 8-K:

Current Report on Form 8-K dated August 5, 2003 reporting the Company's fourth quarter and fiscal 2003 earnings results. This Form 8-K was furnished to, and not filed with, the U.S. Securities and Exchange Commission.

Table of Contents

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.

Date: November 14, 2003

INVIVO CORPORATION

By: /s/ JOHN F. GLENN

Vice President of Finance
and Chief Financial Officer
(Principal Financial and
Accounting Officer)