

ENDOCARE INC
Form 10-Q
November 09, 2004

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**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, 2004

OR

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

FOR THE TRANSITION PERIOD FROM TO .

COMMISSION FILE NUMBER: 000-27212

Endocare, Inc.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE
(State of Incorporation)

33-0618093
(I.R.S. Employer I.D. No.)

201 TECHNOLOGY DRIVE, IRVINE, CALIFORNIA 92618
(Address of Principal Executive Office, Including Zip Code)

(949) 450-5400
(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 filing requirements for the past 90 days.

(1) Yes ☒ No ☐; (2) 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 of the Registrant's common stock, par value \$.001 per share, outstanding at September 30, 2004 was 24,342,482

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(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Total revenues	\$ 8,365,118	\$ 8,041,119	\$ 24,059,102	\$ 23,193,270
Costs and expenses:				
Cost of revenues	4,273,836	4,093,747	12,821,216	11,559,295
Research and development	421,967	312,994	1,410,022	1,011,244
Selling, general and administrative	6,993,844	14,606,250	27,262,483	36,133,116
Impairment charge	15,809,632		15,809,632	
Total costs and expenses	27,499,279	19,012,991	57,303,353	48,703,655
Loss from operations	(19,134,161)	(10,971,872)	(33,244,251)	(25,510,385)
Gain on divestitures, net	53,550		104,073	9,944,424
Interest income	17,823	85,601	89,687	524,926
Interest expense		(6,870)		(34,168)
Loss before minority interests	(19,062,788)	(10,893,141)	(33,050,491)	(15,075,203)
Minority interests	(194,676)	(219,704)	(450,104)	(464,088)
Net loss	<u>\$(19,257,464)</u>	<u>\$(11,112,845)</u>	<u>\$(33,500,595)</u>	<u>\$(15,539,291)</u>
Net loss per share of common stock basic and diluted	\$ (0.80)	\$ (0.46)	\$ (1.38)	\$ (0.64)
Weighted average shares of common stock outstanding	24,174,982	24,182,004	24,262,868	24,163,235

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

Table of Contents**ENDOCARE, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

	September 30, 2004	December 31, 2003
ASSETS	(Unaudited)	
Current Assets:		
Cash and cash equivalents	\$ 10,162,485	\$ 23,374,910
Accounts receivable, net	3,167,037	2,973,518
Inventories	3,378,765	2,019,077
Prepaid expenses and other current assets	2,376,174	4,330,954
Assets held for sale	11,755,146	3,654,203
Total current assets	30,839,607	36,352,662
Property and equipment, net	2,729,532	3,661,551
Goodwill		9,877,910
Intangibles, net	4,554,358	5,162,445
Investments and other assets	1,852,624	1,852,624
Assets held for sale		15,089,723
Total assets	\$ 39,976,121	\$ 71,996,915
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,115,907	\$ 2,568,095
Accrued compensation	3,445,576	3,718,873
Other accrued liabilities	8,848,963	6,970,696
Liabilities held for sale	3,809,288	3,180,735
Total current liabilities	18,219,734	16,438,399
Minority interests	213,715	237,229
Total liabilities	18,433,449	16,675,628
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value; 1,000,000 shares authorized; none issued and outstanding	24,342	24,390

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Common stock, \$.001 par value; 50,000,000 shares authorized; 24,342,482 and 24,183,254 issued and outstanding as of September 30, 2004 and December 31, 2003, respectively

Additional paid-in capital	169,397,810	171,875,434
Accumulated deficit	(147,879,480)	(114,378,885)
Deferred compensation		(107,271)
Treasury stock at cost, 206,200 shares as of December 31, 2003		(2,092,381)
Total stockholders' equity	21,542,672	55,321,287
Total liabilities and stockholders' equity	\$ 39,976,121	\$ 71,996,915

The accompanying notes are an integral part of these condensed consolidated balance sheets.

Table of Contents**ENDOCARE, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
(Unaudited)

	Nine Months Ended September 30,	
	2004	2003
Net cash used in operating activities	\$(15,218,863)	\$(15,378,354)
Cash flows from investing activities:		
Sales of property and equipment	362,335	
Purchases of property and equipment	(522,378)	(533,241)
Proceeds from divestitures	2,604,073	6,980,000
Intangibles		(61,000)
Sale of available-for-sale securities		22,183,160
Other assets	274,858	(1,261,009)
Net cash provided by investing activities	2,718,888	27,307,910
Cash flows from financing activities:		
Stock options and warrants exercised	91,900	20,312
Partnership distributions to minority interests	(599,068)	(437,350)
Treasury stock received in litigation settlement	(503,729)	
Net cash used in financing activities	(1,010,897)	(417,038)
Net increase (decrease) in cash and cash equivalents	(13,510,872)	11,512,518
Cash and cash equivalents, beginning of period	23,976,539	18,177,825
Less: Cash transferred to assets held for sale	(303,182)	(978,987)
Cash and cash equivalents, end of period	\$ 10,162,485	\$ 28,711,356
Non-cash activities:		
Transfer of inventory to property and equipment	\$ 507,649	\$ 621,219
Retirement of treasury shares held	2,596,110	
Deferred compensation on options forfeited	93,905	
Unrealized loss on available-for-sale securities		12,466

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

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Operations of the Company

Endocare, Inc. (the Company) is a medical device company focused on developing, manufacturing and selling cryosurgical products with the potential to improve the treatment of cancer and other tumors. In addition, the Company offers vacuum therapy systems for non-pharmaceutical treatment of erectile dysfunction. The Company was formed in 1990 as a research and development division of Medstone International, Inc. (Medstone), a manufacturer of shockwave lithotripsy equipment for the treatment of kidney stones. Following its incorporation under the laws of the state of Delaware in 1994, the Company became an independent, publicly-owned corporation upon Medstone's distribution of the Company's stock to the existing stockholders on January 1, 1996.

Following the rules and regulations of the Securities and Exchange Commission (the SEC) the Company has omitted footnote disclosures in this report that would substantially duplicate the disclosures contained in the Company's annual audited financial statements. The accompanying condensed consolidated financial statements should be read together with the consolidated financial statements and the notes thereto included in the Company's December 31, 2003 Annual Report on Form 10-K, filed with the SEC on March 15, 2004.

The accompanying condensed consolidated financial statements reflect all adjustments, consisting solely of normal recurring accruals, needed to present fairly the financial results for these interim periods. The condensed consolidated results of operations presented for the interim periods are not necessarily indicative of the results for a full year. All intercompany transactions and accounts have been eliminated in consolidation.

2. Recent Operating Results and Liquidity

Since inception, the Company has incurred losses from operations and has reported negative cash flows. As of September 30, 2004, the Company had an accumulated deficit of approximately \$147.9 million and cash and cash equivalents of approximately \$10.2 million. In addition to the cash needed to fund the Company's ongoing operations, there will continue to be substantial demands on cash related to ongoing investigations of the Company's historical accounting and financial reporting. Regulators may fine the Company, or the Company may agree to make one or more settlement payments in order to resolve the matters under investigation. There may also be material cash payments required in connection with resolving a class action and a derivative law suit (see Note 5). The Company may be required to pay judgments or settlements and incur expenses in defending against these claims. Any judgment, settlement or expenses in excess of the Company's insurance coverage would have to be paid from the Company's cash reserves, to the extent of such excess.

The Company's operating results for the third quarter and for the first nine months of 2004 reflect the impact of divestitures in 2003 of certain non-core lines of business. In April 2003, the Company sold the Dura II penile implants line for approximately \$2.2 million, which resulted in an insignificant loss. The Company also sold the cardiac-related product manufacturing operations and licensed the related technology to CryoCath Technologies, Inc. for approximately \$10.0 million, resulting in a gain of the same amount. The Company receives a royalty based on net sales of the products incorporating the licensed technology (the Surgifrost System) at royalty rates which decrease from 10 percent to 3 percent over a nine year period from 2004 to 2012. Royalty income from sales of CryoCath products was \$150,000 and \$443,000 for the three-month and nine-month periods ended September 30, 2004, respectively. In October 2003, the Company sold its urinary incontinence product lines for a long-term note receivable of approximately \$2.7 million. Due to the uncertainty of the collectibility of the note, payments are recorded as gain

on divestiture on a cash basis. Payments received during the three and nine months ended September 30, 2004, were approximately \$54,000 and \$104,000 respectively. The sale of the urinary incontinence product line resulted in a loss of approximately \$1.3 million. Revenues associated with these divested product lines totaled approximately \$1.6 million during the nine months ended September 30, 2003.

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In June 2004, the Company initiated a cost reduction program, which included streamlining its corporate organizational structure, reduction in staffing, and elimination or deferral of some longer-term research and development, and clinical and marketing activities. While the Company has continued to make progress in lowering its recurring selling, general and administrative expenses throughout 2003 and 2004, it expects to record a loss for fiscal 2004 and has continued to experience significant non-recurring costs associated with ongoing investigations and other matters related to historical accounting and financial reporting.

These non-recurring costs, primarily legal, audit and accounting support fees, totaled approximately \$14.3 million during the fiscal year 2003, and approximately \$10.9 million and approximately \$5.4 million (net of insurance reimbursement) in the first nine months of 2003 and 2004, respectively. For the nine months ended September 30, 2004 approximately \$1.3 million of these costs also related to the Company's efforts to achieve compliance with section 404 of the Sarbanes-Oxley Act of 2002 ("Sarbanes 404") by the December 31, 2004 deadline.

The Company also faces potentially large cash expenditures in the future related to directors' and officers' liability insurance and indemnification obligations, delinquent state and local tax obligations, as well as additional investment needed to bring the Company into compliance with Sarbanes 404.

The Company will use cash reserves to finance its cash flow deficit throughout the remainder of 2004. In order to continue as a going concern, the Company will need to raise additional capital to fund operations and has engaged an investment banker to assist it in analyzing and evaluating various strategic alternatives to enhance stockholder value and raise capital. These alternatives include, among other things: debt financing, a strategic alliance, joint venture or other collaborative arrangement; a sale of some or all of the Company's assets (see Note 3); a business combination or similar transaction; or the issuance of additional equity securities. The Company is continuing to explore its strategic alternatives, and there can be no assurance that any such transaction will occur. Additional capital may not be available on terms acceptable to the Company, or at all. Any additional equity financing may be dilutive to stockholders, and debt financing may involve restrictive covenants. Collaborative arrangements may require the Company to relinquish rights to some of its technologies, products or marketing territories.

3. Assets Held for Sale

During the second quarter in 2004, the Company engaged an advisor to evaluate the potential divestiture of its wholly-owned subsidiary, Timm Medical Technologies, Inc. ("Timm Medical") and its equity interests in the mobile prostate treatment businesses (the "Partnerships"). Timm Medical and the Partnerships were acquired in February and September 2002, respectively (collectively the "Disposal Groups"). In July 2004, the Company began actively marketing the Disposal Groups to potential buyers. In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the assets and liabilities of Timm Medical and the Partnerships have been classified as assets held for sale in the accompanying consolidated balance sheets as of September 30, 2004. Assuming the Company is able to negotiate acceptable terms and conditions, it expects to complete the sale and collect the proceeds within 12 months. Therefore, these assets and liabilities have been classified as current as of September 30, 2004.

The assets and liabilities of the Disposal Groups as of December 31, 2003 have also been reclassified as assets held for sale (based on their classifications at that date) for comparative presentation. In accordance with SFAS No. 144, the assets and liabilities of Timm Medical and the Partnerships have been adjusted to fair value less estimated cost to sell. Depreciation of fixed assets and amortization of intangibles have also been suspended as of July 31, 2004. In

conjunction with the assessment of fair value, the Company performed an interim impairment test of the goodwill and amortizable intangibles related to the Disposal Groups in the third quarter of 2004, which resulted in total impairment charges of approximately \$15.8 million as discussed below.

Table of Contents**ENDOCARE, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Partnerships**

On September 30, 2002, the Company acquired certain general and limited equity interests in the Partnerships from a group of affiliated companies collectively known as USMD. USMD was an exclusive distributor of our cryosurgical products in certain states and operated the mobile businesses to provide support services for cryoablation procedures, including the use of a cryosurgical system, logistics and coordination, transport and technician services. Under service agreements with each Partnership, the Company pays a fixed fee per procedure, which is eliminated in consolidation.

In conjunction with the potential divestiture, the Company has reduced the net assets of the Partnerships to \$950,000 based on a purchase offer (net of \$50,000 in estimated selling costs), which approximated the carrying value of the net tangible assets to be sold. There were also approximately \$9.8 million in goodwill and \$80,000 in a covenant-not-to-compete (net of amortization) from the original acquisition. The goodwill primarily relates to the distribution network provided by the Partnerships, which allows the Company to further penetrate desired markets. Since investors in the mobile treatment businesses are comprised of urologists, the Partnerships facilitate the continued promotion of cryosurgery as the preferred treatment for prostate cancer. In addition, upon the Company's purchase of the Partnerships, USMD exited the cryosurgical operations and terminated its exclusive distribution agreement with the Company, allowing it to market directly to urologists previously served by USMD and to competitors of USMD who were precluded from purchasing from the Company under the exclusive arrangement. After the potential divestiture, the Company will retain access to the service and distribution network through its existing contracts and will continue to benefit from the strategic value of a non-exclusive distribution arrangement with the buyer. However, since this economic benefit cannot be quantified with reasonable accuracy, the Company has recorded an approximately \$9.8 million charge to write off the excess of the carrying value of the Partnerships' net assets (primarily goodwill and the covenant-not-to-compete) over the purchase offer, less selling costs, in the third quarter of 2004. The potential divestiture is not expected to have a significant impact on the Company's operating results and cash flows. The Partnerships are separately presented in the Assets/Liabilities Held for Sale captions in the condensed consolidated balance sheets.

Timm Medical

The Company acquired Timm Medical through a stock purchase in February 2002. There were approximately \$7.7 million in goodwill and approximately \$6.3 million in amortizable intangibles, net of amortization (developed technology and trade name) from the original acquisition. The goodwill primarily relates to enhancements in our product lines through complementary product offerings that provide non-pharmaceutical therapeutic treatments following cryosurgery and Timm Medical's distribution channels through its in-house sales force.

The Company used a third-party appraiser to assess the aggregate fair value of the Disposal Group based on a weighted combination of (i) the guideline company method that utilizes revenue multiples for comparable publicly-traded companies, and (ii) a discounted cash flow model that utilizes future cash flows, the timing of these cash flows, and a discount rate (or weighted average cost of capital which considers the cost of equity and cost of debt financing expected by a typical market participant) representing the time value of money and the inherent risk and uncertainty of the future cash flows. The Company then determined the implied fair value of the goodwill and amortizable intangibles. Based on this analysis, the Company recorded an impairment charge of approximately \$3.1 million and approximately \$2.1 million to reduce the carrying value of its goodwill and intangibles, respectively, to fair value and an additional charge of approximately \$700,000 for the estimated cost to sell. The impairment arose in 2004 due to declining revenues, turnover in sales force, and below average growth as compared to general industry

trends. Revenues for Timm Medical were approximately \$6.2 million and approximately \$8.7 million for the nine months ended September 30, 2004 and 2003, respectively. Net income (loss) was approximately \$(200,000) and approximately \$100,000 for the nine months ended September 30, 2004 and 2003, respectively, excluding the impairment charge.

Table of Contents**ENDOCARE, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Combined assets held for sale of Timm Medical and the Partnerships as of September 30, 2004 and December 31, 2003 include the following:

	September 30, 2004	December 31, 2003
Assets:		
Cash, inventories and other current assets	\$ 1,176,680	\$ 2,142,274
Property and equipment, net	1,641,923	1,977,028
Goodwill, net	4,660,423	7,660,314
Intangibles, net	4,170,000	6,583,333
Other assets	106,120	380,977
Total assets	11,755,146	18,743,926
Liabilities:		
Accounts payable and other current liabilities	633,951	606,801
Other accrued liabilities	2,445,197	2,573,934
Costs to sell	730,140	
Total liabilities	3,809,288	3,180,735
Net assets held for sale	\$ 7,945,858	\$15,563,191

4. Stock-Based Compensation

As of September 30, 2004, the Company had five stock-based compensation plans. On September 10, 2004, the Company's stockholders approved the 2004 Stock Incentive Plan. The Company accounts for the plans under the recognition and measurement principles (the intrinsic-value method) prescribed in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Compensation cost for stock options granted to employees is reflected in net loss and is measured as the excess of the market price of the Company's stock at the date of grant over the exercise price. Compensation costs for fixed awards that are subject to vesting are recognized prorata over the vesting period. In practice, the Company has only awarded stock options to its employees with exercise prices equal to the fair market value of the stock at the date of grant.

The Company has adopted the disclosure provisions required by SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure*. The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions to stock-based employee compensation.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net loss, as reported (a)	\$(19,257,464)	\$(11,112,845)	\$(33,500,595)	\$(15,539,291)
Reconciling items (net of related tax effects):				
Add: Stock-based employee compensation expense determined under the intrinsic-value-based method for all awards (b)	120,571	6,194	133,675	18,582
Less: Stock-based compensation expense determined under the fair-value-based method for all awards expense (c)	<u>(1,018,901)</u>	<u>873,196</u>	<u>(2,823,079)</u>	<u>(2,785,470)</u>
Net adjustment	<u>(898,330)</u>	<u>879,390</u>	<u>(2,689,404)</u>	<u>(2,766,888)</u>
Net loss, as adjusted	<u><u>\$(20,155,794)</u></u>	<u><u>\$(10,233,455)</u></u>	<u><u>\$(36,189,999)</u></u>	<u><u>\$(18,306,179)</u></u>
Basic and diluted loss per share:				
As reported	<u>\$ (0.80)</u>	<u>\$ (0.46)</u>	<u>\$ (1.38)</u>	<u>\$ (0.64)</u>
As adjusted	<u><u>\$ (0.83)</u></u>	<u><u>\$ (0.42)</u></u>	<u><u>\$ (1.49)</u></u>	<u><u>\$ (0.76)</u></u>

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(a) In the past, the Company had issued stock options and warrants to consultants for services performed. Compensation expense for the fair value of these options is determined by the Black-Scholes option-pricing model and is charged to operations over the service period or as performance goals are achieved. Such expense is included in net loss as reported.

(b) Since the Company issues options with exercise prices equal to or exceeding the fair values of the underlying common stock, no compensation expense is recorded for options issued to employees, except for compensation expense equal to the intrinsic value of unvested options assumed in the Company's 2002 acquisition of Timm Medical and amortized over the remaining vesting period. The 2004 amounts include a \$119,000 charge related to options held by the Company's then CFO, which will continue to vest for one year after separation in August 2004.

(c) Pursuant to APB No. 25, the \$1.7 million charge for replacement options was recorded upon termination of the then CFO on July 31, 2003. Pursuant to SFAS No. 148, the fair value of these options would have been recorded prorata between the option modification date of March 3, 2003 and termination date. The difference between the fair value allocation and the actual charge recorded resulted in a net reduction in reported compensation expense for the three months ended September 30, 2003.

On October 13, 2004, the FASB concluded that Statement No. 123R, *Share-Based Payments*, which requires all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value, would be effective for public companies for interim or annual periods beginning after June 15, 2005. SFAS No. 123R will eliminate the Company's ability to account for share-based compensation using the intrinsic value method permitted under Opinion No. 25. The Company will utilize the modified prospective method, recognizing compensation cost for share-based awards to employees based on their grant-date fair values from the beginning of the year in which the recognition provisions are first applied as if the fair value-based method had been used to account for all employee awards. Under this transition approach, compensation cost will be recognized for all awards granted, modified or settled after the date of adoption as well as for any awards that were not fully vested as of that date. Any adjustments to recognize share-based liabilities at fair value from the beginning of the year through the date of adoption will be recognized as a cumulative effect of a change in accounting principle. The Company intends to apply the new rules beginning July 1, 2005.

5. Commitments and Contingencies

In July 2003, the Company recorded severance charges of approximately \$775,500 and \$731,000 in connection with the termination of its then CEO and CFO, respectively. In addition, the Company recorded a non-cash charge of approximately \$1.7 million for the fair value of 385,000 options issued to the former CFO after his termination. The fair value was determined using the Black-Scholes option pricing model.

In August 2004, the Company entered into a severance agreement with its then CFO. In conjunction with this agreement, the Company recorded approximately \$200,000 in related severance payments. Since the former CFO continues to vest in her stock options for a period of one year after the termination of her employment, the Company recorded an additional \$119,000 in stock-based compensation expense.

Legal Matters

The Company is a party to lawsuits in the normal course of its business. Litigation and governmental investigation can be expensive and disruptive to normal business operations. Moreover, the results of complex legal proceedings are difficult to predict. The Company can provide no assurance that significant judgments or settlements in connection with the legal proceedings described below will not have a material adverse effect on the Company's business, financial condition, results of operations and cash flows. See Part I, Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations. Other than as described below, the Company is not a party to any material legal proceedings.

In November 2002, the Company was named as a defendant, together with certain former officers, one of whom is also a former board member, in a class-action lawsuit filed in the United States District Court for the Central District of California. On February 2, 2003, the court issued an order consolidating this action with various other similar complaints and ordering plaintiffs to file a consolidated complaint, which was filed on October 31, 2003. The consolidated complaint asserts two claims for relief, alleging that the defendants violated sections of the Securities Exchange Act of 1934 by purportedly issuing false and misleading statements regarding the Company's revenues and expenses in press releases and SEC filings. Plaintiffs seek class certification and unspecified damages from the Company, as well as forfeiture and reimbursement of bonus compensation received by two of the individual defendants. On April 26, 2004, the court issued an order denying the Company's motion to dismiss the consolidated complaint. The Company has executed a settlement agreement with the lead plaintiffs and their counsel which will be submitted to the court for its preliminary approval and for authorization to provide notice of its terms to class members. Under the agreement, in exchange for release of all claims, the Company and certain individuals will pay a total of \$8.95 million in cash. The Company's directors and officers' liability insurance carriers will fund the total amount of \$8.95 million, subject to reservations of rights by the carriers in connection with the rescission arbitration described below. Consummation of the settlement is subject to the court approval. The Company believes it has properly accrued for its share of the settlement cost.

On December 6, 2002, Frederick Venables filed a purported derivative action against the Company and certain former officers, certain former board members and one current board member in the California Superior Court for

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the County of Orange alleging breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment. Pursuant to a stipulation filed on or about April 23, 2004 and approved by the court, the deadline to respond to the complaint has been stayed until 2005. The complaint seeks unspecified monetary damages, equitable relief and injunctive relief based upon allegations that the defendants issued false and misleading statements regarding the Company's revenues and expenses in press releases and SEC filings. We are currently engaged in settlement discussions in an effort to resolve this matter.

While the Company carries \$20 million of directors and officers' liability insurance coverage, the three excess carriers, representing \$15 million of the \$20 million of coverage, have filed arbitration complaints seeking rescission of the policies. The primary carrier has agreed to reimburse the Company's defense costs up to the limits of its \$5 million policy subject to a \$0.5 million deductible. The amount of estimated settlement accruals, net of reimbursement from the primary carrier for prior defense-related costs, was not material to selling, general and administrative expenses and net loss for the three-month and nine-month periods ended September 30, 2004. Management's evaluation of the likely impact of these actions could change in the future and an unfavorable outcome, depending upon the amount and timing, could have a material adverse effect on the Company's consolidated financial position, results of operations or cash flows for a future quarter.

The SEC is currently conducting an investigation to determine whether any federal securities laws were violated in connection with the filing of the Company's financial statements for 2001 and the first two quarters of 2002, including investigation into allegations that the Company and certain of the Company's current and former officers and directors issued or caused to be issued false and misleading statements regarding the Company's revenues and expenses in those SEC filings. On June 30, 2004, the Company reported receipt of a Wells Notice from the SEC and the issuance of Wells Notices to former members of its senior management, former sales personnel, and its current head of sales and marketing. On July 23, 2004, the Company reported the receipt of Wells Notices from the SEC by two former members and one then-current member of its board of directors, all of whom are former members of the audit committee. The Company is cooperating fully with this investigation, but there can be no assurance that this matter will be resolved in its favor.

The Department of Justice (DOJ) is currently conducting an investigation into allegations that the Company and certain of its current and former officers and directors intentionally issued, or caused to be issued, false and misleading statements regarding the Company's revenues and expenses in SEC filings. The Company is cooperating fully with this investigation but there can be no assurance that this matter will be resolved in its favor.

6. Related Party Transactions

In January 2003, the Company extended a \$344,000 non-recourse loan to an individual who is a shareholder and consultant. The Company previously entered into an asset purchase agreement with the shareholder in February 2002 to acquire certain patents and a covenant-not-to-compete for 100,000 shares of the Company's common stock valued at approximately \$1.4 million. The Company extended the loan to the shareholder to assist with the payment of related federal income taxes arising from the 2002 purchase transaction. The loan is secured by the shares issued, bears interest at 1.8 percent and is due at the earlier of January 2005 or 30 days after the borrower ceases to be a consultant to the Company. The Company intends to extend the maturity date to December 2005.

7. Capital Stock and Earnings Per Share

During the first quarter of 2004, the Company retired 326,222 of its common shares held in treasury, including 120,022 shares purchased from BioLife Solutions, Inc. for approximately \$504,000 in February 2004, in connection with settlement of its litigation with this company.

Table of Contents**ENDOCARE, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the respective periods. Diluted loss per share, calculated using the treasury stock method, gives effect to the potential dilution that could occur upon the exercise of certain stock options that were outstanding during the respective periods presented. For periods when the Company reported a net loss, these potentially dilutive common shares were excluded from the diluted loss per share calculation because they were antidilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net loss, as reported	\$(19,257,464)	\$(11,112,845)	\$(33,500,595)	\$(15,539,291)
Basic and diluted loss per common share	\$ (0.80)	\$ (0.46)	\$ (1.38)	\$ (0.64)
Basic and diluted weighted average shares	24,174,982	24,182,004	24,262,868	24,163,235

8. Income Taxes

The Company reported no income tax expense for each of the nine months ended September 30, 2004 and 2003 due to its operating losses. The continuing operating losses resulted in an increase in the valuation allowance of approximately \$12.2 million and approximately \$6.2 million during the nine months ended September 30, 2004 and 2003, respectively. Due to the Company's history of operating losses, management has determined that it is more likely than not that the Company's deferred tax assets will not be realized through future earnings. Accordingly, valuation allowances were recorded to fully reserve the deferred tax assets as of September 30, 2004 and 2003. As of December 31, 2003, the Company had federal and state net operating loss carry forwards of approximately \$85.4 million and approximately \$53.7 million, respectively.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Part I Item 1 of this report, and the audited consolidated financial statements and notes thereto, and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in the Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

This discussion contains forward-looking statements based on our current expectations. There are various factors many beyond our control that could cause our actual results or the occurrence or timing of expected events to differ materially from those anticipated in these forward-looking statements. Some of these factors are described below and other factors are described elsewhere in this Quarterly Report on Form 10-Q or in our Annual Report on Form 10-K referred to above. In addition, there are factors not described in this Quarterly Report on Form 10-Q or in our Annual Report on Form 10-K that could cause our actual results or the occurrence or timing of expected events to differ materially from those anticipated in these forward-looking statements. All forward-looking statements included in this Quarterly Report on Form 10-Q are based on information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statements.

Overview

We are an innovative medical device company focused on the development of minimally invasive technologies for tissue and tumor ablation through cryoablation. We develop and manufacture devices for the treatment of prostate cancer and we believe that our proprietary technologies have broad applications across a number of markets, including the ablation of tumors in the kidney, lung, liver and bone.

In addition to our cryosurgery products, we sell other products we acquired when we purchased Timm Medical in the first quarter of 2002. The primary products are our ErecAid vacuum therapy systems. In 2003 we either divested or discontinued certain non-strategic urological product lines acquired in the Timm Medical purchase. The reduction in year-over-year sales of our Timm Medical products is largely attributable to these divestitures.

Currently, our cryosurgical products are sold chiefly to hospitals for the treatment of prostate cancer. In addition, we are exploring the application of our cryosurgical technologies for ablation of other tumors, specifically in the treatment of tumors of the kidney, lung and liver, and for pain management related to metastatic bone cancer. We sell our vacuum therapy products for treatment of erectile dysfunction primarily to individual patients on a prescription basis.

Results of Operations

Three Months Ended September 30, 2004 Compared to Three Months Ended September 30, 2003

Revenues. Revenues for the three months ended September 30, 2004 increased 4.0 percent to approximately \$8.4 million compared to \$8.0 million for the three months ended September 30, 2003. The increase in revenues was primarily attributable to growth in sales of disposables and procedure fees related to our cryosurgical business, partially offset by lower revenues from Timm Medical.

The number of cryosurgical procedures performed, and related sales of disposable products used in these procedures, grew significantly in the three months ended September 30, 2004 compared to the same period in 2003. Procedures increased 17.6 percent to approximately 1,134 in the third quarter of 2004 from approximately 964 in the third quarter of 2003, while the related revenues increased 12.4 percent to approximately \$5.4 million in the third quarter of 2004 from approximately \$4.8 million in the third quarter of 2003. Contributing to growth in sales of

cryosurgical products was an increase in sales with a lower average selling price to a market served by interventional radiologists (Interventional Radiology Market), treating tumors in the lung, liver and bone.

Sales of our Timm Medical product lines decreased 15.4 percent to approximately \$2.2 million in the three months ended September 30, 2004 from approximately \$2.6 million in the three months ended September 30, 2003. This was primarily due to an approximate \$287,000 decrease from the divestiture of the Dura II line of implantable penile prostheses and the divestiture of the urinary incontinence product lines in the second and fourth quarter of 2003, respectively.

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Cost of Revenues. Cost of revenues for the three months ended September 30, 2004 increased 4.4 percent to approximately \$4.3 million compared to approximately \$4.1 million for the three months ended September 30, 2003. The increase in cost of revenues resulted primarily from growth in sales of cryosurgical probes and procedures, offset by elimination of costs related to the Dura II and urinary incontinence product lines. Cost of revenues related to our cryosurgical probes and procedures increased approximately \$500,000 to approximately \$3.0 million for the third quarter of 2004 from approximately \$2.5 million, compared to the same period in the prior year. This increase was also partly driven by an increase in the number of cryosurgical procedures for which we subcontract a portion of the service to third party service providers at an additional cost.

Gross Margins. Gross margins on revenues declined to 48.9 percent for the three months ended September 30, 2004 compared to 49.1 percent for the three months ended September 30, 2003, due to increased use of third party service providers in our cryosurgical procedures, and offset by the divestiture in 2003 of higher margin product lines acquired in our purchase of Timm Medical.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2004 increased 34.8 percent to approximately \$422,000 compared to approximately \$313,000 for the three months ended September 30, 2003. The increase was primarily attributable to increased costs associated with several new development projects that we have undertaken in our efforts to reduce the manufacturing costs of the disposable components used in cryoablation surgical procedures. As a percentage of revenues, research and development expenses increased to 5.0 percent in the third quarter of 2004 from 3.9 percent during the three months ended September 30, 2003.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the three months ended September 30, 2004 decreased 52.1 percent to approximately \$7.0 million compared to approximately \$14.6 million for the three months ended September 30, 2003. Non-recurring legal and accounting costs incurred in connection with investigations into our historical accounting and financial reporting, declined to approximately \$102,000 (net of reimbursement) in the quarter ended September 30, 2004 from approximately \$4.3 million in the same period in 2003. The prior year quarter included total charges of approximately \$3.2 million for severance and stock compensation expense related to the termination of the then chief executive and chief financial officers. The remaining approximately \$700,000 decrease reflects the results of our June 2004 cost reduction program. We consolidated certain sales functions and territories, streamlined our corporate organizational structure, reduced staff, eliminated marketing activities and restructured our sales and marketing programs.

Impairment charge. During the quarter ended September 30, 2004, we recorded \$15.8 million in impairment charges to write down the goodwill and amortizable intangibles in conjunction with Timm Medical and our mobile prostate treatment businesses. The charge represents the excess of the carrying value of these entities compared to their fair value, less estimated costs to sell. Fair value for the mobile prostate treatment businesses was based on a proposed purchase offer. Fair value for Timm Medical was based on an independent appraisal using a weighted combination of the publicly-traded peer group company valuations and discounted cash flow analyses.

Interest Income, Net. Interest income, net, for the three months ended September 30, 2004 was \$17,800 compared to \$85,600 for the three months ended September 30, 2003. The decrease in net interest income in 2004 compared to 2003 resulted from a decline in our average cash balance.

Minority Interests. Minority interests represent earnings attributable to minority investors in the mobile prostate treatment businesses we acquired in 2002. The amounts recorded for minority interests were approximately \$195,000 for the three months ended September 30, 2004 compared to approximately \$220,000 for the three months September 30, 2003. Revenues and earnings from these businesses remained consistent with our overall operations.

Net Loss. Net loss for the three months ended September 30, 2004 was approximately \$19.3 million or \$0.80 per basic and diluted share on 24,174,982 weighted average shares outstanding, compared to a net loss of approximately \$11.1 million, or \$0.46 per basic and diluted share on 24,182,004 weighted average shares outstanding for the same period in 2003.

Table of Contents***Nine Months Ended September 30, 2004 Compared to Nine Months Ended September 30, 2003***

Revenues. The number of cryosurgical procedures performed, and related sales of disposable products used in these procedures, grew significantly in the nine months ended September 30, 2004 compared to the same period in 2003. Procedures increased 38.7 percent to approximately 3,487 in the nine months ended September 30, 2004 from approximately 2,514 in the nine months ended September 30, 2003. Revenues for the nine months ended September 30, 2004 increased 3.7 percent to approximately \$24.1 million compared to approximately \$23.2 million for the nine months ended September 30, 2003. The increase in revenue is primarily due to growth in sales of cryosurgical disposables and procedure fees, including an increase in cases from the Interventional Radiology Market which has a lower average selling price per case, partially offset by divestitures of the urinary incontinence products and the Dura II line. Sales of cryosurgical probes and procedures grew 31.7 percent to approximately \$15.8 million for the nine months ended September 30, 2004 from approximately \$12.0 million for the same period in 2003. Revenues from Timm Medical decreased \$2.5 million to approximately \$6.2 million in the nine months ended September 30, 2004 compared to approximately \$8.7 million in the prior year period primarily due to the divestitures of certain product lines. Sales of Cryocare Surgical Systems also decreased to \$457,000 for the first nine months of 2004 from \$568,000 in the first nine months of 2003, due to a reduction in the number of units sold.

Cost of Revenues. Cost of revenues for the nine months ended September 30, 2004 increased 10.9 percent to approximately \$12.8 million compared to approximately \$11.6 million in the prior-year period. The increase is due to growth in the number of cryosurgical procedures and sale of disposables and increased use of third party service providers, offset by elimination of costs of the divested product lines in Timm Medical. Cost of revenues for cryosurgical probes and procedures for the first nine months of 2004 was approximately \$9.5 million compared to approximately \$6.5 million for the first nine months of 2003.

Gross Margins. Gross margins on revenues for the nine months ended September 30, 2004 decreased to 46.7 percent compared to 50.2 percent for the same period in 2003 due to increased use of third party service providers and the divestiture in 2003 of certain higher margin product lines at Timm Medical.

Research and Development Expenses. Research and development expense for the nine months ended September 30, 2004 increased 39.4 percent to approximately \$1.4 million compared to approximately \$1.0 million for the same period in 2003. As a percentage of revenues, research and development expenses increased to 5.9 percent from 4.4 percent. The increase is attributable to costs associated with several new development projects that we have undertaken in our efforts to reduce the manufacturing costs of the disposable components used in cryoablation surgical procedures.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the nine months ended September 30, 2004 decreased 24.5 percent to approximately \$27.3 million compared to approximately \$36.1 million for the same period in 2003. Legal, audit and accounting support fees related to regulatory investigations of our historical accounting and financial reporting and related litigation, were approximately \$4.1 million for the nine months ended September 30, 2004 compared to approximately \$7.7 million for the same period in 2003 due to a reduction in accounting support expenses and audit fees. The Company streamlined its corporate organizational structure, reduction in staffing, and elimination or deferral of some longer-term research and development, and clinical and marketing activities reducing expenses by \$1.6 million for the nine months ended September 30, 2004. The first three quarters of 2003 also included total charges of approximately \$3.2 million for severance and stock compensation expenses related to the termination of the then chief executive and chief financial officers. In addition, for the nine months ended September 30, 2004 there were approximately \$1.3 million of accounting support expenses related to the Company's efforts to achieve compliance with Sarbanes 404.

Impairment charge. During the quarter ended September 30, 2004, we recorded \$15.8 million in impairment charges to write down the goodwill and amortizable intangibles in conjunction with Timm Medical and our mobile prostate treatment businesses. The charge represents the excess of the carrying value of these entities compared to their fair value, less estimated costs to sell. Fair value for the mobile prostate treatment businesses was based on a proposed purchase offer. Fair value for Timm Medical was based on an independent appraisal using a weighted combination of the publicly-traded peer group company valuations and discounted cash flow analyses.

Interest Income. Interest income, net for the nine months ended September 30, 2004 was \$90,000 compared to \$525,000 for the nine months ended September 30, 2003. The decrease was due to our declining average cash balances.

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Net Loss. Our net loss for the nine months ended September 30, 2004 was approximately \$33.5 million, or \$1.38 per basic and diluted share, on 24,262,868 weighted average shares outstanding, compared to a net loss of approximately \$15.5 million, or \$0.64 per basic and diluted share, on 24,163,235 weighted average shares outstanding for the same period in 2003.

Liquidity and Capital Resources

Since inception, we have incurred losses from operations and have reported negative cash flows. As of September 30, 2004, we had an accumulated deficit of approximately \$147.9 million, and cash and cash equivalents of approximately \$10.2 million. We currently have no long-term debt, and no long-term financial obligations other than under operating leases and purchase commitments for raw materials used in manufacturing our products. Although we believe that our existing cash balances will be sufficient to fund our working capital requirements, capital expenditures and other obligations at least through 2004, there are certain risks and uncertainties that could, in the future, change our opinion regarding the adequacy of our capital resources. During the nine months ended September 30, 2004, approximately \$15.2 million of our cash was used to fund operating activities.

In February 2004 we paid approximately \$1.5 million in directors' and officers' liability insurance premiums, and we paid approximately \$1.9 million to settle litigation. In addition, during the first nine months of 2004 we incurred approximately \$4.1 million in non-recurring legal and accounting fees associated with the ongoing investigations into possible irregularities in our accounting and financial reporting in earlier periods. In addition, for the nine months ended September 30, 2004 there were approximately \$1.3 million of accounting support expenses related to the Company's efforts to achieve compliance with Sarbanes 404.

We face the possibility that there will be additional material cash payments required in connection with resolving matters related to the investigations into our historical accounting and financial reporting. We and certain former officers, one of whom is also a former board member have been named as defendants in a pending class action lawsuit. We and certain former officers, certain former board members and one current board member, also have been named as defendants in a pending derivative lawsuit. In addition, we, former board members, former members of our senior management, former sales personnel, and our current head of sales and marketing have received Wells Notices from the SEC (see Note 5 to our condensed consolidated financial statements contained in this report). We are generally obliged, to the extent permitted by law, to indemnify our directors and officers who are named defendants in litigation related to their service. At this time we are unable to provide a reasonable estimate of our potential liability in these cases.

We may be required to pay judgments or settlements and to incur expenses in defending against these claims that could be material. While we carry \$20 million of directors' and officers' liability insurance coverage, this coverage may not be adequate to cover all costs related to these lawsuits, including any resulting judgments or settlements. As described below under Risks Related to Our Business, for claims asserted during the period from June 10, 2002 through June 10, 2003, our three excess carriers have filed arbitration complaints, contending our former management made misstatements or omissions in the applications for insurance coverage and seeking rescission of the policies. Any judgment, settlement or expenses in excess of our insurance coverage would have to be paid out of our cash reserves, to the extent of such excess, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Beyond the factors described above, we expect to face significant demands on our capital resources related to the execution of our 2004 operating plan, maintaining compliance with the SEC rules and regulations required of publicly traded companies, including Sarbanes 404, and fulfilling requirements prerequisite to becoming relisted on a national stock exchange or market. We are currently projecting an operating loss for fiscal 2004, as well as a net use of cash.

While we have continued to experience growth in cryosurgical probe and procedure revenues through the first nine months of 2004 and have reduced our selling, general and administrative costs through this period compared to the same period in 2003, we do not expect to reach break-even or cash flow positive in 2004. We will use cash reserves to finance our cash flow deficit in 2004.

In order to continue as a going concern, we will need to raise additional capital to fund operations. We have engaged an investment banker to assist us in analyzing various strategic alternatives to enhance stockholder value and raise capital. These alternatives include, among other things: debt financing; a strategic alliance, joint venture or

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other collaborative arrangement; the sale of Timm Medical and the Partnerships; a business combination or other similar transaction; or issuing equity securities. We are continuing to explore our strategic alternatives, and there can be no assurance that any such transaction will occur. Additional capital may not be available on terms acceptable to us, or at all.

Risks Related to Our Business

*The risks and uncertainties described below are not the only ones we face. For information regarding other risks related to our business, please see **Risks Related to Our Business** in our Annual Report on Form 10-K for the fiscal year ended December 31, 2003. Furthermore, additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations. The occurrence of any of these risks could harm our business. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.*

We face risks relating to our liquidity.

Since the fourth quarter of 2002, we have incurred significant costs related to, among other things, legal, accounting and other professional fees associated with our internal reviews of various accounting and other matters, the ongoing investigation of us by the SEC and DOJ, various shareholder class-action and derivative lawsuits and other legal proceedings described below. We are generally obliged, to the extent permitted by law, to indemnify our directors and officers who are named defendants in litigation related to their service. At this point in time we are unable to provide a reasonable estimate of our potential liability in these cases.

In addition we are making significant investments in the development and implementation of sound internal controls and corporate governance policies and procedures designed to enhance the accuracy, quality and consistency of our financial information and reporting and to achieve compliance with Sarbanes 404. We will continue to incur significant related expenses in the future.

We expect that we will require additional financing in order to continue operating our business beyond 2004. We have engaged an investment banker to assist us in analyzing various strategic alternatives to enhance stockholder value and raise capital. These alternatives include, among other things: debt financing; a strategic alliance, joint venture or other collaborative arrangement; a sale of some or all of our assets; a business combination or other similar transaction; or issuing equity securities. We are continuing to explore our strategic alternatives, and there can be no assurance that any such transaction will occur. Additional capital may not be available on terms acceptable to us, or at all. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve interest expense and restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to some of our technologies, products or marketing territories. Our failure to raise capital would have a material adverse effect on our business, financial condition, results of operations and cash flows, and could cause us to discontinue operations or declare bankruptcy.

In addition, if we fail to adequately address our liquidity concerns, then our independent auditors may issue a qualified opinion, to the effect that there is substantial doubt about our ability to continue as a going concern. A qualified opinion could itself have a material adverse effect on our business, financial condition, results of operations and cash flows.

For a further description of the nature of the risks relating to our liquidity see, **Part I, Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources.**

We face risks related to investigations by the SEC and DOJ and related to other legal proceedings.

The SEC and the DOJ are conducting investigations into allegations that we and certain of our current and former officers and directors issued, or caused to be issued, false and misleading statements regarding our revenues and expenses in press releases and SEC filings. Although we have fully cooperated with these governmental agencies in these matters and intend to continue to fully cooperate, these agencies may determine we have violated federal securities laws. We cannot predict when these investigations will be completed or their outcomes. If it is determined that we have violated federal securities laws or other laws or regulations, we may face sanctions, including, but not limited to, significant monetary penalties and injunctive relief.

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We and certain former officers, one of whom is also a former board member, have been named as defendants in a pending class-action lawsuit. In addition, we and certain former officers, certain former board members and one current board member, have been named defendants in a pending derivative lawsuit. The findings and outcome of the SEC and DOJ investigations described above may affect the class action and the derivative lawsuit. We are generally obliged, to the extent permitted by law, to indemnify our directors and officers who are named defendants in litigation related to their service. We are unable to estimate what our liability in these matters may be, and we may be required to pay judgments or settlements and incur expenses in aggregate amounts that could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We have \$20 million of directors' and officers' liability insurance coverage. The coverage is provided in four \$5 million policies issued by a primary insurance carrier and three excess insurance carriers. For claims asserted during the period from June 10, 2002 through June 10, 2003, the three excess carriers have filed arbitration complaints, contending our former management made misstatements or omissions in the applications for insurance coverage and seeking rescission of the policies. Any judgment, settlement or expenses in excess of our insurance coverage would have to be paid out of our cash reserves, to the extent of such excess, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We may be unable to satisfy the requirements of Sarbanes 404, or we or our auditors may identify significant deficiencies or material weaknesses in our internal controls.

Pursuant to Sarbanes 404, we will be required to furnish a report of our management's assessment of the effectiveness of our internal controls over financial reporting as part of our Annual Report on Form 10-K for the fiscal year ending December 31, 2004. In addition, our auditors will be required to provide an attestation report on management's assessment. We have prepared an internal plan of action for compliance, and we are in the process of evaluating, enhancing and testing our internal controls to provide the basis for our report. However, we may be unable to satisfy the requirements of Sarbanes 404, or our internal control report or the related attestation report may identify significant deficiencies or material weaknesses in our internal controls, either of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our management members have spent considerable time and effort dealing with internal and external investigations and re-auditing of financial statements.

In addition to the challenges of the SEC investigation, the DOJ investigation, a shareholder class-action and a derivative lawsuit and other legal proceedings described above, our new management members have spent considerable time and effort dealing with internal and external investigations involving our previous internal controls, accounting policies and procedures, disclosure controls and procedures and corporate governance policies and procedures. The significant time and effort spent has adversely affected our operations and may continue to do so in the future.

Our success will depend on our ability to attract and retain key personnel.

In order to execute our business plan, we need to attract, retain and motivate a significant number of highly qualified managerial, technical, financial and sales personnel. If we fail to attract and retain skilled scientific and marketing personnel, our research and development and sales and marketing efforts will be hindered. Our future success depends to a significant degree upon the continued services of key management personnel, including Craig T. Davenport, our Chief Executive Officer, William J. Nydam, our President and Chief Operating Officer, and Michael R. Rodriguez, our Senior Vice President, Finance and Chief Financial Officer. None of our key management personnel is covered by an insurance policy of which we are the beneficiary.

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Item 3. *Quantitative and Qualitative Disclosures About Market Risk*

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. Our financial instruments include cash, cash equivalents, accounts receivable, accounts payable and accrued liabilities. At September 30, 2004, the carrying values of our financial instruments approximated their fair values. Our policy is not to enter into derivative financial instruments. In addition, we do not enter into any futures or forward contracts and therefore, we do not have significant market risk exposure with respect to commodity prices.

Although we transact our business in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products. However, we do not believe that we currently have any significant direct foreign currency exchange rate risk and have not hedged exposures denominated in foreign currencies or any other derivative financial instruments.

Item 4. *Controls and Procedures*

(a) *Evaluation of Disclosure Controls and Procedures.* We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports pursuant to the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Securities Exchange of 1934, as amended, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not yet effective at the reasonable assurance level.

Since March 2003, management has implemented and continues to implement significant changes in organization, policies and procedures designed to enhance our disclosure controls and procedures and the related internal controls, and to achieve compliance with Sarbanes 404. Nevertheless, during much of 2003, many of these enhancements to our disclosure controls and procedures and the related internal controls were not yet in place, or were only partially in place. In addition, until the recent filing of our past due reports on Form 10-Q, we have not been current in our reporting under Section 15(d) of the Securities Exchange Act of 1934. For this reason, management has undertaken an extensive and substantive review and evaluation of all financial transactions that, individually or collectively, could have a material impact on the information contained in this Form 10-Q. These review procedures, in combination with the changes in internal control that have been implemented as of the end of the period covered by this report, form the basis for our determination that the financial statements and other information contained in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the nine months ended September 30, 2004 and 2003.

We are continuing a detailed assessment of our internal controls as required for Sarbanes 404 compliance. We are beginning the testing phase of our project. We have supplemented our internal project team with the services of several outside specialists. Although we have made this project a top priority, there can be no assurances that all

control deficiencies identified and validated will be remediated before the end of our fiscal year or that any control deficiencies found as a result of our testing will not rise to the level of significant deficiencies or material weaknesses.

(b) *Changes in Internal Controls.* Except as described above in subsection (a) of this Item 4, there was no change in our internal control over financial reporting during our third fiscal quarter for 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. *Legal Proceedings*

We are a party to lawsuits in the normal course of our business. Litigation and governmental investigation can be expensive and disruptive to normal business operations. Moreover, the results of complex legal proceedings are difficult to predict. We can provide no assurance that significant judgments or settlements in connection with the legal proceedings described below will not have a material adverse effect on our business, financial condition, results of operations and cash flows. See Part I, Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations. Other than as described below, we are not a party to any material legal proceedings.

In November 2002, we were named as a defendant, together with certain former officers, one of whom is also a former board member, in a class-action lawsuit filed in the United States District Court for the Central District of California. On February 2, 2003, the court issued an order consolidating this action with various other similar complaints and ordering plaintiffs to file a consolidated complaint, which was filed on October 31, 2003. The consolidated complaint asserts two claims for relief, alleging that the defendants violated sections of the Securities Exchange Act of 1934 by purportedly issuing false and misleading statements regarding our revenues and expenses in press releases and SEC filings. Plaintiffs seek class certification and unspecified damages from us, as well as forfeiture and reimbursement of bonus compensation received by two of the individual defendants. On April 26, 2004, the court issued an order denying our motion to dismiss the consolidated complaint. We have executed a settlement agreement with the lead plaintiffs and their counsel which will be submitted to the court for its preliminary approval and for authorization to provide notice of its terms to class members. Under the agreement, in exchange for release of all claims, we and certain individuals will pay a total of \$8.95 million in cash. Our directors and officers' liability insurance carriers will fund the total amount of \$8.95 million, subject to reservations of rights by the carriers in connection with the rescission arbitration described in Note 5 in Part I, above. Consummation of the settlement is subject to the court approval. We believe we have properly accrued for our share of the settlement cost.

On December 6, 2002, Frederick Venables filed a purported derivative action against us and certain former officers, certain former board members and one current board member in the California Superior Court for the County of Orange alleging breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment. Pursuant to a stipulation filed on or about April 23, 2004 and approved by the court, the deadline to respond to the complaint has been stayed until 2005. The complaint seeks unspecified monetary damages, equitable relief and injunctive relief based upon allegations that the defendants issued false and misleading statements regarding our revenues and expenses in press releases and SEC filings. We are currently engaged in settlement discussions in an effort to resolve this matter.

The SEC is currently conducting an investigation to determine whether any federal securities laws were violated in connection with the filing of our financial statements for 2001 and the first two quarters of 2002, including investigation into allegations that we and certain of our current and former officers and directors issued, or caused to be issued, false and misleading statements regarding our revenues and expenses in those SEC filings. On June 30, 2004, we reported our receipt of a Wells Notice from the SEC and the issuance of Wells Notices to our former senior management, former sales personnel and our current head of sales and marketing. On July 23, 2004, we reported the receipt of Wells Notices from the SEC by two former members and one then-current member of our board of directors, all of whom are former members of our audit committee. We are cooperating fully with this investigation. We cannot assure you that this matter will be resolved in our favor.

The DOJ is currently conducting an investigation into allegations that we and certain of our current and former officers and directors intentionally issued, or caused to be issued, false and misleading statements regarding our revenues and expenses in SEC filings. We are cooperating fully with this investigation. We cannot assure you that this

matter will be resolved in our favor.

Item 2. *Unregistered Sales of Equity Securities and Use of Proceeds*

In addition to the 275,000 stock option grants that we previously reported in the Form 8-K that we filed on August 10, 2004, during the quarter ended September 30, 2004 we granted an aggregate of 709,000 stock options to 19 employees, at exercise prices ranging from \$2.72 to \$2.97 per share. The terms of these stock options provide that they cannot be exercised until they vest over our standard four-year vesting term and until we file a registration statement on Form S-8 to register these stock options, which we filed on October 19, 2004.

In August 2004, we issued 10,000 shares to a former employee upon his exercise of stock options granted to him while he was an employee. The exercise price of these options was \$0.18 per share, for an aggregate exercise price of \$1,800. In September 2004 our former CEO exercised 325,000 options at an exercise price of \$0.18 for aggregate proceeds of \$58,500. We issued these shares in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, in that the issuance did not involve a public offering. The issuees represented to us their intention to acquire the shares for investment only and not with a view to sell in connection with any distribution thereof and appropriate legends were affixed to the certificate evidencing the shares.

Table of Contents**Item 3. Defaults Upon Senior Securities**

Not applicable.

Item 4. Submission of Matters to a Vote of Security Holders

We held our Annual Meeting of Stockholders on Friday, September 10, 2004. Our stockholders approved the following matters at the Annual Meeting by the votes indicated:

1. The stockholders elected the following five directors to our Board of Directors to serve during the ensuing year or until their respective successors are duly elected and qualified:

	Number of Shares	
	For	Withheld
John R. Daniels, M.D.	21,304,274	660,340
Craig T. Davenport	21,653,365	311,249
Terrence A. Noonan	21,605,274	359,340
Michael J. Strauss, M.D	18,279,374	3,685,240
Thomas R. Testman	21,605,674	358,940

2. The stockholders approved our 2004 Stock Incentive Plan:

	Number of Shares
For	5,869,306
Against	5,264,667
Abstain	43,422
Broker Non-Votes	10,787,219

3. The stockholders ratified the selection of Ernst & Young LLP as our independent auditors for the fiscal year ended December 31, 2004:

	Number of Shares
For	21,929,245
Against	28,712
Abstain	6,657

Item 5. Other Information

None.

Item 6. Exhibits.

Exhibit No.	Description
2.1(1)	Agreement and Plan of Reorganization dated February 21, 2002, by and among the Company, Technologies, Inc., TMT Acquisition Corporation and certain stockholders of Timm Medical Technologies, Inc. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.2(2)	Agreement and Plan of Merger dated June 30, 1999, by and among the Company, Advanced Medical Procedures, Inc., Advanced Medical Procedures, L.L.C., Gary M. Onik, M.D., Robert F. Byrnes and Jerry Anderson. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.3(3)	Asset Purchase Agreement, dated February 6, 2002, by and between the Company and Gary M. Onik, M.D. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.

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Exhibit No.	Description
2.4(3)	Asset Purchase Agreement dated May 28, 2002, by and among the Company and Cryomedical Sciences, Inc. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.5(4)	Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of August 12, 2002, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C. Certain schedules and exhibits referenced in this exhibit have been omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.6(5)	Amendment No. 1 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of August 12, 2002, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C.
2.7(6)	Agreement of Purchase and Sale, dated as of April 7, 2003, by and among American Medical Systems, Inc., the Company and Timm Medical Technologies, Inc.
2.8(7)	Asset Purchase and Technology License Agreement, dated as of April 29, 2003, by and between the Company and CryoCathTechnologies Inc.
2.9(8)	Agreement of Purchase and Sale, dated as of October 15, 2003, by and between SRS Medical Corp. and Timm Medical Technologies, Inc.
2.10(9)	Amendment No. 2 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of February 27, 2004, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C.
2.11(9)	Service Fee Agreement, dated as of February 26, 2004, by and among Endocare, Inc. and the Limited Partners of Mid-America Cryotherapy, L.P.
2.12(9)	First Amendment to Agreement of Purchase and Sale, dated as of March 25, 2004, by and between SRS Medical Corp. and Timm Medical Technologies, Inc.
2.13	First Amendment to Asset Purchase Agreement, dated as of August 18, 2005, by and between Endocare, Inc. and Gary Onik, M.D.
3.1(2)	Certificate of Amendment of Restated Certificate of Incorporation of the Company.
3.2(2)	Certificate of Designation of Series A Junior Participating Preferred Stock of the Company.
3.3(2)	Restated Certificate of Incorporation.
3.4(10)	Amended and Restated Bylaws of the Company.

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- 10.1(11) Employment Agreement, dated as of August 11, 2004, by and between Endocare, Inc. and Michael R. Rodriguez.
 - 10.2(12) General Release of All Claims, dated as of August 10, 2004, by and between Endocare, Inc. and Katherine G. Greenberg.
 - 10.3(13) 2004 Stock Incentive Plan.
 - 31.1 Certification under Section 302 of the Sarbanes-Oxley Act of 2002 for Craig T. Davenport.
 - 31.2 Certification under Section 302 of the Sarbanes-Oxley Act of 2002 for Michael R. Rodriguez.
 - 32.1 Certification under Section 906 of the Sarbanes-Oxley Act of 2002 for Craig T. Davenport.
 - 32.2 Certification under Section 906 of the Sarbanes-Oxley Act of 2002 for Michael R. Rodriguez.
-

* We have requested confidential treatment with respect to certain portions of these documents.

Management contract or compensatory plan or arrangement

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- (1) Previously filed as exhibits to our Form 8-K filed on March 5, 2002.
- (2) Previously filed as exhibits to our Registration Statement on Form S-3 filed on September 20, 2001 and October 31, 2001.
- (3) Previously filed as exhibits to our Form 10-Q filed on August 14, 2002.
- (4) Previously filed as exhibits to our Form 8-K filed on August 16, 2002.
- (5) Previously filed as an exhibit to our Form 8-K filed on October 15, 2002.
- (6) Previously filed as an exhibit to our Form 8-K filed on April 22, 2003.
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- (12) Previously filed as an exhibit to our Form 8-K filed on September 1, 2004.
- (13) Previously filed as an appendix to our Definitive Proxy Statement filed on August 6, 2004.

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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.

ENDOCARE, INC.

By: /s/ CRAIG T. DAVENPORT

Craig T. Davenport
*Chief Executive Officer and
Chairman of the Board
(Duly Authorized Officer)*

By: /s/ MICHAEL R. RODRIGUEZ

Michael R. Rodriguez
*Senior Vice President, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)*

Date: November 8, 2004

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2.5(4)	Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of August 12, 2002, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C. Certain schedules and exhibits referenced in this exhibit have been omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
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