

ENDOCARE INC  
Form 10-Q  
June 28, 2004

**Table of Contents**

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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, 2002**

**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 May 31, 2004 was 24,007,482.

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ENDOCARE, INC. AND SUBSIDIARIES

FORM 10-Q, QUARTER ENDED SEPTEMBER 30, 2002

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Condensed Consolidated Financial Statements</u>	2
<u>Condensed Consolidated Statements of Operations (Unaudited)</u>	2
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Cash Flows (Unaudited)</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	37
<u>Item 4. Controls and Procedures</u>	38
<u>PART II OTHER INFORMATION</u>	38
<u>Item 1. Legal Proceedings</u>	38
<u>Item 2. Changes in Securities</u>	40
<u>Item 3. Defaults Upon Senior Securities</u>	40
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	40
<u>Item 5. Other Information</u>	40
<u>Item 6. Exhibits and Reports on Form 8-K</u>	40
<u>SIGNATURE PAGE</u>	42
<u>EXHIBIT INDEX</u>	43
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	
<u>EXHIBIT 32.2</u>	

**Table of Contents**

**EXPLANATORY NOTE:** We are filing this past due quarterly report on Form 10-Q for the quarter ended September 30, 2002 concurrently with our filing of past due quarterly reports on Form 10-Q for the quarters ended March 31, 2003, June 30, 2003 and September 30, 2003. Except as otherwise noted, this quarterly report on Form 10-Q speaks as of the date of filing. Accordingly, statements in this report on Form 10-Q containing the words (i) now, currently, present, to date, and words of similar import, or (ii) believes, intends, anticipates, expects, estimates, should, could, may, plans, planned, and words of similar import, are based on conditions existing on the date of filing of this quarterly report on Form 10-Q.

**PART I FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements****ENDOCARE, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001 (Restated)	2002	2001 (Restated)
Revenues	\$ 8,381,793	\$ 3,783,075	\$ 23,807,706	\$ 9,522,511
Costs and expenses:				
Cost of revenues	4,525,786	1,580,084	12,018,692	4,377,149
Research and development	489,890	526,029	2,051,744	1,907,343
Selling, general and administrative	8,408,328	4,397,892	24,075,011	11,891,740
Total costs and expenses	13,424,004	6,504,005	38,145,447	18,176,232
Loss from operations	(5,042,211)	(2,720,930)	(14,337,741)	(8,653,721)
Other income (expense):				
Interest income, net	317,314	46,996	934,511	12,004
Loss on minority investment				(250,000)
Net loss	\$ (4,724,897)	\$ (2,673,934)	\$ (13,403,230)	\$ (8,891,717)
Net loss per share of common stock, basic and diluted	\$ (.19)	\$ (.16)	\$ (.57)	\$ (.56)
Weighted average shares of common stock outstanding, basic and diluted	24,279,000	16,920,505	23,695,667	15,892,333

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, 2002	December 31, 2001
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 23,779,675	\$ 81,886,801
Available-for-sale securities	20,200,893	
Accounts receivable, net	8,068,301	4,832,963
Inventories	5,061,434	2,129,797
Prepaid expenses and other current assets	824,190	362,951
	<hr/>	<hr/>
Total current assets	57,934,493	89,212,512
Property and equipment, net	8,017,831	1,749,126
Goodwill	35,081,479	
Intangibles, net	16,127,822	656,374
Investments and other assets	3,784,835	3,475,594
	<hr/>	<hr/>
Total assets	\$ 120,946,460	\$ 95,093,606
	<hr/>	<hr/>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,414,364	\$ 1,807,500
Accrued compensation	2,394,333	1,020,462
Other accrued liabilities	6,213,717	1,385,078
	<hr/>	<hr/>
Total current liabilities	13,022,414	4,213,040
	<hr/>	<hr/>
Minority interests	1,281,287	
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.001 par value; 1,000,000 shares authorized; none issued and outstanding		
Common stock, \$.001 par value; 50,000,000 shares authorized; 24,280,620 and 22,051,826 issued and outstanding	24,329	22,079
Additional paid-in capital	169,534,717	138,337,026
Accumulated deficit	(60,429,377)	(46,945,837)
Receivable from stockholder	(278,542)	(471,292)
Accumulated other comprehensive income, net of tax	17,590	
Deferred compensation	(154,327)	
Treasury stock at cost, 201,200 and 27,000 shares	(2,071,631)	(61,410)
	<hr/>	<hr/>
Total stockholders' equity	106,642,759	90,880,566
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Total liabilities and stockholders' equity	\$ 120,946,460	\$ 95,093,606
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The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

## ENDOCARE, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2002	2001
		(Restated)
Net cash used in operating activities	(11,851,408)	(8,839,344)
Cash flows from investing activities:		
Acquisitions, net of cash acquired	(24,092,497)	
Purchases of property and equipment	(1,815,754)	(544,742)
Intangibles		(50,000)
Loan made to investee		(250,000)
Repayment of loan made to investee		250,000
Purchases of available-for-sale securities	(20,183,303)	
Other assets	(119,443)	
Net cash used in investing activities	(46,210,997)	(594,742)
Cash flows from financing activities:		
Payments on credit facility and note payable		(1,032,603)
Stock options and warrants exercised	1,965,500	1,772,528
Repurchase of treasury stock	(2,010,221)	
Net cash (used in) provided by financing activities	(44,721)	739,925
Net decrease in cash and cash equivalents	(58,107,126)	(8,694,161)
Cash and cash equivalents, beginning of period	81,886,801	22,016,448
Cash and cash equivalents, end of period	\$ 23,779,675	\$ 13,322,287
Non-cash activities:		
Convertible debentures and accrued interest converted to common stock, net of unamortized deferred financing costs	\$	\$ 7,241,641
Transfer of inventory to property and equipment for placement at customer sites	1,872,571	35,280
Common stock exchanged for investment in USMD		2,837,293
Common stock issued and options assumed in the acquisition of Timm Medical	25,741,128	
Common stock issued for patents and covenant-not-to-compete	3,257,139	150,000
Change in unrealized gain on available-for-sale securities	17,590	

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

**Table of Contents**

**ENDOCARE, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Operations of the Company**

Endocare, Inc. ( Endocare or 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, through its wholly-owned subsidiary, Timm Medical Technologies, Inc. ( Timm Medical ), 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., a manufacturer of shockwave lithotripsy equipment for the treatment of kidney stones. The Company was incorporated under the laws of the state of Delaware in 1994 and 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 unaudited condensed consolidated financial statements should be read together with the consolidated financial statements and the notes thereto included in the Company's December 31, 2002 and 2003 Annual Reports on Form 10-K, filed with the SEC on December 3, 2003 and March 15, 2004, respectively.

Additionally, the condensed consolidated financial statements for the quarter ended September 30, 2001 contained in this report reflect various restatement adjustments made as a result of a review by management of historical financial statements previously filed with the SEC, including the report filed for that period. For a further description of the nature and status of these adjustments see Note 4 below, Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 3 to our consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2002 filed with the SEC on December 3, 2003.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and 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**

The Company's operating results for the nine months ended September 30, 2002 reflect sales and gross profits, as well as operating expenses, associated with certain non-core product lines divested during 2003. While these divestitures have allowed the Company to better concentrate on its core businesses, they have also eliminated some sources of revenue and gross profit for the Company going forward. In addition, while the Company lowered certain operating costs in 2003 by consolidating functions at its Irvine, California headquarters that were formerly performed by its subsidiaries, the Company has also incurred significant one-time charges associated with ongoing investigations related to its historical accounting and financial reporting. These costs amounted to approximately \$20.2 million from the fourth quarter of 2002 through the first quarter of 2004 (including executive severance charges of \$3.2 million in the third quarter of 2003). In addition to charges for executive severance payments, these non-recurring expenses have included legal fees and settlements, audit fees and accounting support fees.

Since inception, the Company has incurred losses from operations and has reported negative cash flows. As of September 30, 2002, the Company had an accumulated deficit of \$60.4 million and cash and available-for-sale securities of \$44.0 million. For all periods since September 30, 2002, the Company has continued to incur operating losses. As discussed above, commencing in the fourth quarter of 2002, the

**Table of Contents**

**ENDOCARE, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Company incurred, and continues to incur, significant costs in connection with internal and regulatory investigations into its historical accounting and financial reporting. The Company also faces potentially large costs related to directors' and officers' liability insurance, delinquent state and local tax obligations, as well as additional expenditures needed to bring the Company into compliance with SEC rules and regulations, including with Section 404 of the Sarbanes-Oxley Act of 2002, and efforts to regain listing on a national exchange or market.

There may also be material cash payments required in connection with resolving a class action and a derivative law suit (see Note 7). The Company may be required to pay judgments or settlements and to incur expenses in defending against these claims that could exceed the Company's directors' and officers' liability insurance coverage. Regulators may fine the Company when the investigations are complete.

The Company continued to experience growth in cryosurgical probe and procedure revenues during 2003 and into the first quarter of 2004. Costs and expenses have also grown through this period. Management plans continued investment in sales and marketing to increase market penetration and in research and development to improve existing products and develop new ones. The Company will continue to use cash reserves to finance its cash flow deficit. If the Company is unable to generate cash flows from operations, it may need to raise additional capital to fund operations through the sale of equity securities to public or private investors, debt or the sale or licensing of its assets. Additional capital, if needed, might not be available on terms acceptable to the Company, or at all. If additional capital were raised through the issuance of equity securities, the percentage of the Company's stock owned by its then-current stockholders would be reduced.

The Company has no long-term debt and no other material financial commitments other than those under operating lease agreements and purchase commitments for raw materials used in manufacturing its products.

**3. Goodwill and Intangible Assets**

The excess of the purchase price over the fair value of net assets acquired has been allocated to goodwill and identifiable intangible assets. The Company had no reported goodwill prior to January 1, 2002. The Company does not amortize goodwill, which is consistent with the provisions of Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and other Intangible Assets*, but goodwill is subject to impairment tests on an annual basis or more frequently if impairment indicators exist. Under the guidance of SFAS No. 142, the Company uses a discounted cash flow methodology to assess the fair values of its reporting units. Impairment is measured by comparing the goodwill derived from the hypothetical purchase price allocation to the carrying value of the goodwill balance. During the fourth quarter of 2002, the Company recorded an impairment charge of \$18 million to reduce the carrying value of goodwill acquired in the Timm Medical acquisition resulting from the termination or abandonment of three of the acquired distribution agreements for urological products following the acquisition.

Intangible assets that are deemed to have finite useful lives are recorded at cost and amortized using the straight-line method over their estimated useful lives. Estimated useful lives of such intangible assets are as follows:

Trade name	15 years
Domain name	5 years
Covenant-not-to-compete	3 to 5 years
Developed technology	15 years
Patents	3 to 15 years

Changes in circumstances (for example, changes in laws or regulations to which the Company is subject, technological advances or changes in the Company's strategies) may result in changes to the useful lives from



**Table of Contents**

**ENDOCARE, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

initial estimates. Factors such as changes in the planned use of intangibles may result from changes in customer base, contractual agreements, or regulatory requirements and may result in shorter useful lives. In such circumstances, the Company will revise the useful life of the long-lived asset and amortize the remaining net book value over the adjusted remaining useful life. There were no changes in estimated useful lives during 2002 and 2003.

**4. Restatement of Financial Statements**

On October 24, 2002, the former General Manager of Timm Medical reported to the Board of Directors his concerns regarding the accounting for several transactions. The Company's Audit Committee promptly directed outside legal counsel to investigate the accounting concerns. On October 31, 2002, the Audit Committee's legal counsel engaged an accounting firm independent of the Company's then auditors, KPMG LLP (KPMG), to investigate the complaints. On December 11, 2002, KPMG notified the Company that their audit report on the Company's consolidated financial statements as of December 31, 2001, and for the year then ended, had been withdrawn and could no longer be relied upon. In addition, KPMG advised that the consolidated financial statements for the quarters ended March 31, 2002 and June 30, 2002 should not be relied upon. Trading of the Company's stock on The Nasdaq Stock Market was halted on December 12, 2002. The Company was delisted effective January 16, 2003 and has been trading in the so-called "pink-sheets" since that date.

The Company hired a new President and Chief Operating Officer and a new Chief Financial Officer in March 2003. The Company's Board of Directors, upon recommendation of the Audit Committee, approved dismissal of KPMG as the Company's independent auditors effective March 7, 2003. On April 1, 2003, the Company appointed new independent auditors and engaged them to re-audit the Company's consolidated financial statements for the years ended December 31, 2000 and 2001 and to audit its consolidated financial statements for the year ended December 31, 2002. In September 2003, the Company's former auditors notified the Company that they were withdrawing their reports on the Company's consolidated financial statements for the years ended December 31, 1999 and 2000 and that these financial statements could no longer be relied upon.

To address the matters discovered in the investigations, the Company has implemented remedial actions, including improved processes for and controls over all financial transactions and the employees involved in them. These remedial actions included the development and implementation of policies and procedures governing sales personnel and sales orders, new and more stringent credit approval practices, the adoption of improved expense recognition and approval policies, improved controls and documentation over the issuance of options and warrants in financial transactions, and new internal financial reporting procedures.

The discovery of accounting errors required the Company to restate previously issued financial statements. Following are explanations of the restatement adjustments and presentation of affected accounts in the condensed consolidated statements of financial position and results of operations as previously reported and as restated.

***Revenues***

The Company discovered that its revenues had been overstated relating to the sale of Cryocare Surgical System units and cryoprobes because certain sales did not meet all revenue recognition criteria required under Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*. The Company restated previously recognized revenues related to certain Cryocare Surgical Systems and cryoprobes transactions by

**Table of Contents**

**ENDOCARE, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

\$432,000 and \$986,000 for the quarter and nine months ended September 30, 2001 respectively. These adjustments primarily relate to the following:

- a. Revenues previously recorded in the period in which certain Cryocare Surgical Systems were shipped to a company-controlled facility. These revenues were restated to record such revenues in the period the customer actually took possession.
- b. Concessions provided to certain customers purchasing Cryocare Surgical Systems that were not accounted for in the period the revenues were recorded. Restated revenues include recording concessions for advertising allowances, grants, interest buy-downs, extended warranties, free equipment and upgrades in the period the Cryocare Surgical Systems were sold.
- c. Guarantees made to certain customers for minimum procedure fee revenue from the use of purchased Cryocare Surgical Systems for which the future cost of providing the guarantee was not appropriately accrued. Restated revenues reflect the deferral of the portion of Cryocare Surgical Systems revenues associated with the minimum procedure fees until the minimum procedure fee guarantees were fulfilled.
- d. Revenues previously recorded for certain Cryocare Surgical Systems sales where the customers' commitment or ability to pay was contingent upon the customer's arranging financing, the sale to a newly formed partnership, or the re-sale by a distributor to a third-party. Restated revenues reflect the recording of Cryocare Surgical Systems sales in the period the contingency was removed or payment received.
- e. The sale of a Cryocare Surgical System to a customer where the Company failed to record a customer trade-in of a competitor's equipment at the appropriate value and in the proper period. Restated revenues and property and equipment reflect the customer trade-in at the lower fair-value of the equipment received in the period of the exchange.
- f. Sale of cryoprobes in June 2002 to USMD pursuant to a pre-existing distribution agreement and subsequent repurchase of the unused inventory following the acquisition of interests in certain cryosurgical partnerships in September 2002 (see Note 5). The repurchased cryoprobes are reported as a reduction in June 2002 revenues, and reductions in cost of sales for September 2002 and subsequent periods.
- g. Receipt of certain licensing fees and milestone payments where these licensing fees were recorded as revenue in the period received, and payments for volume discounts determined on a retrospective basis where these payments were recorded as cost of sales when paid. Licensing fees and milestone payments are recorded net of volume discounts as restated revenues in the period they were earned.

***Cost of Revenues***

The Company made certain adjustments to increase cost of revenues, which totaled \$291,000 and \$641,000 for the quarter and nine months ended September 30, 2001, respectively. These adjustments primarily relate to the following:

- a. Failure to properly apply standard costing to its inventory, or to allow for shrinkage, excess and obsolescence. Additionally, depreciation of Cryocare Surgical Systems placed at hospital locations was not consistently recorded. Restated cost of revenues reflects the effects of properly valuing inventory and depreciating placed Cryocare Surgical Systems.
- b. Incorrect omission from the preliminary purchase price allocation for the Timm Medical acquisition of certain amortizable developed technology (see Note 5). Restated cost of revenues reflects increased amortization since the date of the Timm Medical acquisition.

**Table of Contents**

**ENDOCARE, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

c. Reclassification to cost of revenues certain research and development and quality assurance expenses related to routine manufacturing operations.

***Selling, General and Administrative Expenses and Research and Development Costs***

The Company made certain adjustments to increase selling, general and administrative expenses, which totaled \$870,000 and \$1,900,000 for the quarter and nine months ended September 30, 2001, respectively, and to reduce research and development costs by \$240,000 and \$685,000 for the quarter and nine months ended September 30, 2001, respectively. These adjustments primarily relate to the following:

a. Failure to consistently accrue expenses in the periods when the obligations were incurred, including accrual of expenses in the period invoices were received rather than in the period the expenses were incurred; capitalization of legal, transactional and advertising expenses normally expensed; and establishing and recording unsupported general reserves.

b. Insufficient accrual of capital, sales and use taxes, and state and local taxes, which are assessed on a basis other than taxable income.

c. Incorrect recording of: (1) expenses associated with stock options and warrants issued as compensation to consultants; (2) the assets and related amortization where warrants were issued to acquire certain patents; and (3) the deferred financing costs and related amortization expense for warrants issued to lenders in connection with debt financings. Adjustments were recorded to expense the fair value of consultant stock options and warrants in the period services were provided, and capitalize and amortize the fair value of warrants issued to acquire patents and finance debt.

d. Forgiveness of an interest-bearing loan made to a Company executive (see Note 8) for the purchase of Company common stock. Adjustments were recorded to write-off the principal and interest over a 4-year period as compensation expense.

e. Reclassification from research and development to S,G&A of certain expenses related to collection of clinical data for marketing purposes, consulting and patent litigation. (see Cost of Revenues, paragraph c. above).

f. Incorrect capitalization of certain costs related to acquisition activities which should have been expensed as incurred.

g. Absence of substantiation for the existence and/or carrying values of certain property and equipment.

***Other Income and Loss***

The Company made certain adjustments to decrease other income, net, which totaled \$64,000 and \$136,000 for the quarter and nine months ended September 30, 2001, respectively. These adjustments primarily relate to the following:

a. Recording an impairment in the value of a minority investment in the second quarter of 2002, when the investment was actually impaired in 2001.

b. Incorrect recording of interest income related to a forgivable loan to a Company executive (see S,G&A paragraph d. above).

The consolidated financial statements for the three months and nine months ended September 30, 2002 and 2001, and notes thereto have been restated to include the items described above.

**Table of Contents****ENDOCARE, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Consolidated Statements of Operations**

	As Previously Reported Three Months Ended September 30, 2001	Restated Three Months Ended September 30, 2001	As Previously Reported Nine Months Ended September 30, 2001	Restated Nine Months Ended September 30, 2001
Revenues	\$ 4,214,766	\$ 3,783,075	\$ 10,508,202	\$ 9,522,511
Cost of revenues	1,289,414	1,580,084	3,735,707	4,377,149
Research and development	766,417	526,029	2,592,681	1,907,343
Selling, general and administrative	3,527,527	4,397,892	9,992,021	11,891,740
Total costs and expenses	5,583,358	6,504,005	16,320,409	18,176,232
Loss from operations	(1,368,592)	(2,720,930)	(5,812,207)	(8,653,721)
Loss on minority investment				(250,000)
Interest income, net	110,546	46,996	148,087	12,004
Net loss	(1,258,046)	(2,673,934)	(5,664,120)	(8,891,717)
Net loss per share of common stock basic and diluted	(.07)	(.16)	(.36)	(.56)
Weighted average shares of common stock outstanding basic and diluted	16,921,000	16,921,000	15,892,000	15,892,000

**5. Acquisitions*****Timm Medical Technologies, Inc.***

On February 21, 2002, the Company entered into an agreement and plan of reorganization to acquire Timm Medical for total consideration of \$37,350,000 (including \$838,000 in legal, accounting and other acquisition-related costs). In connection with the merger, all outstanding shares of the capital stock of Timm Medical were exchanged for \$10,770,000 in cash and 1,620,530 shares of the Company's common stock valued at \$23,806,000 (of which 63,412 shares were held in escrow, all of which have now been released).

In addition, the Company assumed certain outstanding options of Timm Medical, which were exercisable into 168,162 shares of Endocare common stock at \$7.25 per share. These options were valued at \$1,935,000 using the Black-Scholes option pricing model, of which \$1,770,000 related to vested options and \$165,000 related to unvested options. Except for the adjustment in the number of exercisable shares and the corresponding exercise price per share based on the conversion ratio as defined in the purchase agreement, all other option terms and vesting periods remained unchanged. The value of the unvested options was recorded as deferred compensation on the acquisition date to be amortized over the remaining vesting period.

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

This transaction was accounted for under the purchase method of accounting and the consolidated financial statements of the Company include the financial results of Timm Medical from February 21, 2002 through subsequent periods. The total purchase price of \$37,350,000 (including transaction costs and the amount recorded as deferred compensation) was allocated to the tangible and intangible assets acquired based on their respective fair values as follows:

Total purchase consideration and related costs	\$ 37,350,000
Fair value of tangible net assets acquired	(1,041,000)
Fair value of amortizable intangibles:	
Developed technology	(10,000,000)
Trademark	(500,000)
Unearned compensation	(165,000)
	<hr/>
Goodwill (non-tax deductible)	\$ 25,644,000
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Factors contributing to the origination of goodwill include the enhancement of the product line and projected growth in urology sales through collaborative distribution agreements with other medical device companies and the sales force which the Company believed would be valuable assets as the Company divested non-core product lines and redeployed existing resources in the area of cancer treatment. Intangible assets relating to developed technology and trade name are amortized over estimated useful lives of 15 years.

Net cash paid in the acquisition is as follows:

Total purchase consideration and related costs	\$ 37,350,000
Fair value of common stock issued	(23,806,000)
Fair value of options assumed	(1,935,000)
	<hr/>
Cash paid	11,609,000
Cash acquired	(1,127,000)
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Net cash paid	\$ 10,482,000
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Subsequent to the acquisition date, the Company decided to divest certain non-core product lines, including the Dura II penile implants line sold in April 2003, and the urinary incontinence and urodynamics lines sold in October 2003 (see Note 6).

***Mobile Prostate Treatment Businesses***

On September 30, 2002, the Company completed the acquisition of certain general and limited equity interests in the mobile prostate and benign prostatic hyperplasia ( BPH ) treatment businesses ( Mobile Prostate Treatment Businesses ) from a group of affiliated companies collectively known as USMD. Under the terms of the original agreement, the Company agreed to forgive \$7.7 million, consisting of a \$6.8 million loan and a \$900,000 earnest money deposit, if the Mobile Prostate Treatment Businesses achieved \$12 million in gross revenues during the period from October 1, 2002 to December 31, 2005 (the Forgiveness Period ). At the time of the acquisition, the Company assumed the loans would be forgiven and, therefore, included them in the total purchase consideration of \$11,734,000.

In February, 2004, the purchase agreement was amended to extend the Forgiveness Period to December 31, 2008. In addition, effective January 1, 2004, the Company reduced the service fee it pays to one of the partnerships for the use of their Cryocare Surgical Systems from \$2,500 to \$2,000 per procedure, representing an adjustment to a market rate. As a result, the reduction in service fee does not require a

reallocation of goodwill.

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

In late 2003 and early 2004, the Company initiated the dissolution of five of the 13 partnerships acquired from USMD, two of which were engaged in BPH treatment and three of which were engaged in cryosurgical procedures for prostate cancer (see Note 6).

The total purchase price was allocated to the tangible and intangible assets acquired based on their respective fair value as follows:

Total purchase consideration (includes \$549,000 in acquisition related costs)	\$ 11,734,000
Fair value of tangible net assets acquired (primarily property and equipment)	(1,616,000)
Covenant-not-to-compete	(240,000)
	<hr/>
Goodwill (non-tax deductible)	\$ 9,878,000
	<hr/>

The goodwill is primarily related to the distribution network provided by the Mobile Prostate Treatment Businesses, which allows the Company to further penetrate desired markets. The tangible assets acquired include 11 Cryocare Surgical Systems previously purchased from the Company by USMD and resold to the partnerships. These systems were recorded at their fair value of \$2,109,000 on the acquisition date, which approximated the carrying value recorded by USMD, and are depreciated over their remaining useful lives not to exceed three years. The covenant-not-to-compete is amortized over three years.

Net cash paid in the acquisition is as follows:

Total purchase consideration and related costs	\$ 11,734,000
Cash acquired	(396,000)
	<hr/>
Net cash paid	\$ 11,338,000
	<hr/>

Endocare is the general partner or member in each of the Mobile Prostate Treatment Businesses and generally holds over 20% in combined general and limited equity interests. The Company has sole responsibility for the management of the Mobile Prostate Treatment Businesses and exercises exclusive control over their operations. Other equity holders have limited participation rights, which are protective in nature. As such, the Mobile Prostate Treatment Businesses have been consolidated with the Company's operations since September 30, 2002.

***Pro Forma Results of Operations***

The following table presents pro forma results of operations for the nine month periods ended September 30, 2002 and 2001, assuming the Timm Medical and Mobile Prostate Treatment Business acquisitions occurred as of January 1, 2001:

	Nine Months Ended September 30,	
	2002	2001
Net revenues	\$ 26,097,000	\$ 21,198,000
	<hr/>	<hr/>

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Net loss	(15,191,000)	(10,698,000)
Net loss per share, basic and diluted	(0.63)	(0.61)
Weighted average shares outstanding, basic and diluted	23,927,000	17,510,000

The pro forma results of operations reflect adjustments for additional amortization expense for intangible assets acquired, reduction in interest income due to net cash paid in acquisitions, stock compensation expense related to employee options assumed, and increased weighted average shares outstanding to reflect the issuance of common stock in the Timm Medical acquisition.



**Table of Contents**

**ENDOCARE, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Asset Purchases***

The Company has acquired intangible assets from time to time, including patents and intellectual property as follows:

On May 28, 2002, pursuant to an asset purchase agreement, the Company agreed to acquire the cryosurgical assets of Cryomedical Sciences, Inc., now known as BioLife Solutions, Inc. ( BioLife ), consisting primarily of a portfolio of patents, for \$2,200,000 in cash and 120,022 shares of the Company's common stock valued at \$1,847,000. This transaction was accounted for under the purchase method of accounting. The total purchase consideration of \$4,119,000 (including \$72,000 in acquisition-related costs) was allocated to the patents since other assets acquired had de minimis value. Pursuant to a Registration Rights Agreement, the Company was required to file a registration statement with the SEC to register the shares issued to BioLife. In November 2002, BioLife filed suit against the Company for failing to register the shares in a timely manner, seeking damages for breach of contract (see Note 7).

In February 2002, the Company entered into an asset purchase agreement with a cryosurgeon inventor of certain technologies related to the Company's business to acquire certain patents and a covenant-not-to-compete for 100,000 shares of the Company's common stock valued at \$1,410,000. Of this amount, \$1,058,000 (75,000 shares) was allocated to the patent and is amortized over 15 years and the remaining \$352,000 (25,000 shares) was allocated to the covenant-not-to-compete and is amortized over five years. The agreement also requires the seller to provide certain consulting services over 15 years for the consideration received. No consideration was allocated to the consulting agreement since the value of such services could not be accurately determined. In January 2003, the Company extended a \$344,000 loan to the seller to finance tax payments related to the gain on the sale (see Note 8).

**6. Dispositions and Restructuring Activities**

In 2003, the Company refocused its strategy on its core technological competence and primary market emphasis in the area of minimally invasive technologies for tissue and cancer ablation. Part of this strategy entailed divestiture of certain product lines unrelated to the Company's core businesses. The Company also undertook a review of its strategic plans and operational infrastructure in order to maximize efficiency and promote optimal use of resources. In addition to the divestiture of a Florida billing and contracting subsidiary in December 2002, which reduced headcount by 12 employees, the Company downsized Timm Medical's Eden Prairie, Minnesota, operations in June 2003, consolidating many administrative functions at its Irvine, California, headquarters and reducing headcount by 26 employees. The Company's Board of Directors also approved the divestiture of certain non-core product lines and assets in the first quarter of 2003, including the sale of the Dura II penile implants, the cardiac-related product manufacturing operations and license of related technology, and the urinary incontinence and urodynamics product lines.

***Dura II Penile Implants***

On April 7, 2003, Timm Medical sold certain assets related to the Dura II positionable urological prostheses product line to American Medical Systems, Inc. for approximately \$2.15 million in cash. Assets sold include developed technology, intellectual property, customer lists, production equipment and Dura II inventory. The sale resulted in a loss of \$35,000 in the second quarter of 2003.

***Cryosurgical Products for Cardiac Applications***

On April 14, 2003, the Company sold its cardiac-related product manufacturing operations and licensed the related intellectual property to CryoCath Technologies, Inc. ( CryoCath ) for \$10 million and a nine-year descending royalty based on net sales of products incorporating the licensed technology. Upon consummation of the sale, the Company terminated its pre-existing distribution agreement with CryoCath. CryoCath was the

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

exclusive distributor for cryoprobes and consoles in connection with the SurgiFrost system, a cryoablation system designed to treat cardiac arrhythmias. Since the technology was internally developed and the tangible assets sold had de minimus value, the sale resulted in a 2003 second quarter gain of \$10 million. The \$10 million was collected in four installments, three in 2003 and one in the first quarter of 2004. The royalty stream decreases from 10% to 3% of net sales from the SurgiFrost system during the period from 2004 to 2012. The first royalty payment of \$131,000 was collected and recorded in the first quarter of 2004, based on CryoCath revenues for that period.

***Minnesota Facility***

Subsequent to the acquisition of Timm Medical, the Company undertook a review of the Company's operational and financial infrastructure. To maximize operational efficiency and resource utilization, the Board of Directors approved a plan in the first quarter of 2003 to downsize Timm Medical's operations in Minnesota. With the exception of certain marketing and financial functions, all of Timm Medical's operations were transferred to the Company's Irvine, California, headquarters in June 2003 or were outsourced. The cost of the restructuring totaled \$386,000, which included \$266,000 in severance payments and \$120,000 in lease losses for vacating the unused leased space. These losses were recorded in the second quarter of 2003 upon the communication of the separation terms to the affected employees. In addition, Timm Medical had \$465,000 in property and equipment, a portion of which may be abandoned or sold for salvage value at a future date. These assets are classified as held and used until they are disposed or abandoned. In the first quarter of 2003, management had adjusted the useful life of the assets to be abandoned to amortize their carrying value, less estimated salvage, through the scheduled abandonment date of April 2004.

***Urinary Incontinence and Urodynamics***

On October 15, 2003, Timm Medical agreed to sell the manufacturing assets related to its urodynamics and urinary incontinence product lines to SRS Medical Corp. (SRS) for a \$2,694,000 note. The note bears interest at 7.5% and is secured by the assets sold, which consist of certain patents, trademarks, inventory, customer lists and technical know-how. Under the terms of the original agreement, quarterly payments were to begin on March 31, 2004, equal to the higher of (a) minimum quarterly payments as defined or (b) 15% of the net revenues related to the urinary incontinence assets acquired and 15% of the net revenues related to SRS's existing urodynamics business, including the urodynamics assets acquired. These minimum quarterly payments were to commence at \$112,500 for the quarter ended March 31, 2004, and increase to \$298,406 for the quarter ended March 31, 2007. Amounts which remain outstanding at March 31, 2007 were to be payable at \$250,000 per quarter thereafter until fully paid. The carrying values of the urodynamics and urinary incontinence related assets were \$1,314,000 on the date of sale. Management concluded that collection of the note from SRS was not reasonably assured. As a result, a loss of \$1,314,000 was recorded in the fourth quarter of 2003 equal to the carrying value of the assets sold. Collections on the note, if any, will be reported as gain in the period received. In March 2004, the Company agreed to amend the purchase agreement to reduce the minimum quarterly payments to \$45,000, increasing to \$60,000 for the quarter ended December 31, 2005. Amounts which remain outstanding at December 31, 2005 will be payable at \$60,000 per quarter until the outstanding principal and accrued interest are paid in full.

***Mobile Prostate Treatment Businesses***

In late 2003 and early 2004, the Company initiated the dissolution of five of the 13 partnerships acquired from USMD, two of which were engaged in BPH treatment and three of which were engaged in cryosurgical procedures for prostate cancer. The BPH partnerships discontinued operations beginning in the first quarter of 2003 due to significant reduction in payor reimbursements and the Company's desire to exit the non-core BPH business. The Company elected to terminate the cryosurgical partnerships due to decisions by certain of the limited partner physicians to withdraw from these partnerships. After the dissolution, the Cryocare Surgical

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

Systems held by these partnerships were redeployed to other markets as placement units. The assets held by the BPH partnerships will be liquidated.

**7. Commitments and Contingencies*****Former Chief Executive Officer and Chairman of the Board***

The Company entered into a Separation Agreement and a one-year Consulting Agreement with the Company's former Chief Executive Officer and Chairman of the Board (the former CEO), each effective as of July 31, 2003. Under the Separation Agreement, the former CEO was entitled to receive a \$375,000 severance payment and a \$375,000 upfront payment for a one-year covenant-not-to-compete and an agreement to provide consulting services. The Company recorded a charge of \$775,500 in the third quarter of 2003 for the severance and related benefits. The total severance payment was deposited into an escrow account held by the Company and released to the former CEO in March 2004.

***Former Chief Financial Officer***

The Company entered into an employment agreement, dated March 3, 2003 (the Employment Agreement), with the Company's former Chief Financial Officer (former CFO). Under the Employment Agreement, upon any Qualified Termination (as defined) the former CFO was entitled to receive a cash payment of \$616,000, continued participation in the Company's benefit plans for 24 months, a \$50,000 relocation allowance and an additional payment to cover the tax liabilities relating to the allowance. In addition, the Employment Agreement also provided that all of the former CFO's options to purchase outstanding common stock (385,000 shares) would be cancelled and replaced by immediately exercisable options to be granted between September 4, 2003 and November 3, 2003. Effective July 31, 2003, the Company terminated the former CFO's employment other than for cause. The Company recorded a charge of \$731,000 in the third quarter of 2003 for the severance and related benefits due under the Employment Agreement. In addition, the Company recorded a third quarter charge for \$1,715,000 for the fair value of the 385,000 replacement options issued to the former CFO on October 30, 2003 determined using the Black-Scholes option-pricing model. The total severance payments due of \$616,000 were deposited into an escrow account held by the Company. In March 2004, all amounts due to the former CFO under the Employment Agreement were released from the escrow account.

***2002 Executive Separation Benefits Plan***

Effective July 17, 2002, the Company adopted the 2002 Executive Separation Benefits Plan (Separation Plan) to provide separation benefits to certain designated employees upon or following a change in control, as defined. In February 2004, the Board of Directors voted to terminate the Separation Plan effective July 18, 2004. In February 2004, the Board of Directors voted to terminate the Separation Plan effective July 18, 2004. On February 13, 2004, Craig T. Davenport (Chairman and Chief Executive Officer), William J. Nydam (President and Chief Operating Officer) and Katherine Greenberg (Chief Financial Officer) were added as Eligible Employees as defined in the Separation Plan.

***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 and Part II,

**Table of Contents**

**ENDOCARE, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Item 1 Legal Proceedings. ) 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 intends to defend the case vigorously, but cannot assure you that it will be resolved in the Company's favor.

On November 26, 2002, BioLife Solutions, Inc. ( BioLife ) filed an action against the Company in the Delaware Court of Chancery seeking damages for alleged breaches of contract stemming from the Company's acquisition, pursuant to an asset purchase agreement dated May 28, 2002, of the tangible and intangible assets related to BioLife's cryosurgical business. In the action, styled as BioLife Solutions, Inc. v. Endocare, Inc., Del. Ch., C.A. No. 20057-NC, BioLife alleged that the Company failed to timely register 120,022 shares of its common stock that were provided to BioLife in connection with the asset purchase agreement, in violation of a registration rights agreement relating to the shares that was executed in conjunction with the asset purchase agreement. BioLife sought damages of approximately \$1.6 million. The Company defended the action on the grounds that its obligation to register the shares was excused for various reasons, including as a consequence of BioLife's failure to transfer assets in accordance with the asset purchase agreement. Trial on all but one of the claims in the action was held during the week of March 31, 2003. On October 1, 2003, the Delaware Court ruled in favor of BioLife, awarding BioLife \$1,648,000, plus pre-judgment interest and costs (including legal fees), and requiring BioLife to surrender the 120,022 shares of the Company's common stock to the Company. That ruling became an appealable final order and judgment on October 10, 2003. On February 20, 2004, the Company agreed with BioLife to settle all claims. As part of the settlement the Company paid to BioLife \$1,887,000, which represented a discount of \$150,000 from the total judgment amount (including accrued interest and costs), BioLife returned to the Company the 120,022 shares of the Company's common stock referred to above and the Company agreed to abandon its appeal.

On December 6, 2002, Frederick Venables filed a purported derivative action against the Company and certain former officers and certain current and former board members 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. On April 23, 2004, the parties filed a stipulation agreeing to a conditional stay of the action for 270 days, continuing the deadline to respond to the complaint until after expiration of the stay. 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. The Company intends to defend the case vigorously, but cannot assure you that it will be resolved in the Company's favor.

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. The Company is cooperating fully with this investigation. The Company cannot assure you that this matter will be resolved in its favor.

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

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. The Company cannot assure you that this matter will be resolved in its favor.

In December 2002, the Company filed a demand for arbitration before the American Arbitration Association in Minnesota against a former employee. The complaint included various claims in response to which the employee made several counterclaims. In March 2003, the Company was notified by the United States Department of Labor that counsel for the employee had presented a letter of complaint alleging that the Company, its former CEO and former CFO violated 18 U.S.C. § 1514A by improperly retaliating against the employee. In December 2003, the Company and the employee agreed to settle all claims on mutually acceptable terms without the admission of liability by any party for an amount that is not significant. Pursuant to the settlement, the employee withdrew his letter of complaint, and the Department of Labor has indicated that it considers the matter closed.

In June 2003, the Company was awarded a favorable judgment for \$351,000 in a litigation matter previously initiated by Timm Medical against a third party. Since collection is not assured, any amount recovered in connection with this judgment will be recorded in the period when it is actually paid to the Company.

**8. Related Party Transactions***Loans to Officers*

In November 1999, the Company received a full recourse promissory note for \$1,028,125 in connection with the sale of 175,000 common shares at fair value to the Company's then-Senior Vice President, Sales and Marketing. The four-year note bore interest at 5.99% per annum, payable annually, and was recorded as a reduction in stockholders' equity. The Company agreed to forgive the principal on the note ratably over four years subject to performance of certain objectives that were to be mutually agreed upon by the borrower and the Company and subject to the borrower remaining an employee of the Company. The outstanding principal balance at September 30, 2002 and December 31, 2001 totaled \$278,542 and \$471,292, respectively. The Company forgave \$64,250 and \$192,750, respectively, for the three months and nine months ended September 30, 2002, which was recorded as compensation expense (included in selling, general and administrative expense). As of September 30, 2003, the full value of the note had been written off.

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. The Company extended the loan to the shareholder to assist with the payment of federal income taxes arising from the 2002 purchase transaction. The loan is secured by the shares issued, bears interest at 1.8% and is due at the earlier of January 2005 or 30 days after the borrower ceases to be a consultant to the Company (see Note 5).

**9. Collaborative and Other Agreements***Sanarus Medical Inc.*

In October 1999, the Company entered into a strategic alliance with Sanarus Medical, Inc. ( Sanarus ), a privately held medical device company. The Company received 200,041 Series A voting convertible Preferred Shares or 6.8% of the total outstanding voting securities at the investment date in exchange for \$300,000. The Company also received a warrant to acquire 3,166,000 common shares (approximately 52.0% of Sanarus' voting stock on an as-converted, fully-diluted basis at that time) for \$.01 per share in consideration for entering into a manufacturing, supply and license agreement (the 1999 Agreement ). The 1999

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

Agreement provided Sanarus an exclusive, royalty-free, worldwide non-sublicensable right to develop, manufacture and sell products using cryoablation technology developed by Endocare for use in the field of gynecology and breast diseases. The 1999 Agreement expires at the earlier of the 30th anniversary, expiration of the patents underlying the licensed technology or a change in control event (as defined) at Sanarus. The warrant is exercisable at any time through October 12, 2009.

In June 2001, the Company and Sanarus entered into a license agreement (the 2001 Agreement ) amending the terms and conditions of the 1999 Agreement to provide for, among other things: (i) the termination of Sanarus' exclusive, royalty-free, worldwide non-sublicensable right under the 1999 Agreement; (ii) Sanarus' grant to Endocare of an exclusive (even as to Sanarus), worldwide, irrevocable, fully paid-up right to develop, manufacture and sell products using certain Sanarus technology for use in the diagnosis, prevention and treatment of prostate, kidney and liver diseases, disorders and conditions; and (iii) Endocare's grant to Sanarus of an exclusive (even as to Endocare), worldwide, irrevocable, fully paid-up right to develop, manufacture and sell products using certain Endocare technology for use in the diagnosis, prevention and treatment of gynecological and breast diseases, disorders and conditions.

Also in June 2001, the Company provided a bridge loan to Sanarus in the amount of \$250,000 and received a warrant to purchase 36,210 shares of Series B voting Preferred Stock. The loan was repaid in July 2001 upon receipt of additional equity funding by Sanarus. In April 2003, the Company and other investors entered into a second bridge loan financing in which Sanarus issued to the Company a convertible promissory note in the aggregate amount of \$600,000 and a warrant to purchase equity shares in Sanarus with an aggregate exercise price of up to \$300,000. Upon completion of a \$19,100,000 equity financing by Sanarus in October 2003, the \$600,000 bridge loan and warrant were canceled in exchange for 908,025 shares of Series C voting Preferred Stock and a warrant to purchase 308,823 Series C shares at \$.68 per share. This and other financings changed the Company's current voting percentage from 1.8% on an as converted basis (20% on an as converted, fully diluted basis) at December 31, 2002 to 2.7% on an as converted basis (7.9% on an as converted, fully diluted basis) at December 31, 2003.

Under the 1999 and 2001 Agreements, the Company manufactured customized cryoprobes for the treatment of breast diseases for Sanarus at cost plus a profit margin. Certain proprietary components were purchased directly from Sanarus and were included in cost of revenues. These revenues and cost of revenues were not significant. Effective December 31, 2002, the Company no longer supplied or manufactured products for Sanarus.

Total investment in Sanarus of \$300,000 and \$917,000 at December 31, 2002 and 2003, respectively, is included in investments and other assets. The investment is recorded at cost since the Company does not have significant influence over the operations of Sanarus.

***U.S. Medical Development, Inc.***

On June 30, 2001, the Company issued 213,010 shares of its common stock with a fair value of \$2,837,293 as consideration for a membership interest in U.S. Medical Development, Inc., formerly U.S. Therapies, LLC, in the form of 1,134,922 Class A units. The investment represents approximately 9% of the total issued and outstanding Class A Units of U.S. Medical Development, Inc. and approximately 5% of the Class A Units on a fully diluted basis. U.S. Medical Development, Inc. is a privately held national urology services company based in Dallas, Texas, representing more than 150 urologists across the nation. In a related distributor agreement, U.S.M.D., Ltd., formerly U.S. Medical Devices, Ltd., a subsidiary of U.S. Medical Development, Inc. was appointed a distributor and given exclusive sales rights to the Company's Cryocare Surgical System and associated disposable products in 16 states. U.S.M.D., Ltd. also had the exclusive right to distribute the Cryocare Surgical System to HealthTronics Surgical Services, Inc. and its affiliates, a company that provides urologic and orthopedic services to patients in 35 states through physician partnerships. The investment in U.S. Medical Development, Inc. is included in investments and other assets and is carried using

**Table of Contents**

**ENDOCARE, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

the cost method of accounting as the Company does not have significant influence over the operations of U.S. Medical Development, Inc. The Company has recorded sales of Cryocare Surgical Systems and cryoprobes to U.S.M.D., Ltd. totaling \$4,105,000 and \$2,257,000 in 2001 and 2002, respectively. The distributor agreement was terminated upon the Company's acquisition of certain Mobile Prostate Treatment Businesses from USMD on September 30, 2002.

The Company recorded an other-than-temporary loss of \$2,327,000 in its investment in U.S. Medical Development, Inc. during the fourth quarter of 2002, reducing the carrying value of the investment to \$510,000.

***CryoCath***

In September 2001, the Company entered into a strategic alliance with CryoCath pursuant to an exclusive global market access and supply agreement whereby CryoCath and the Company would co-develop a new, advanced line of surgical probe systems to treat cardiac arrhythmias. CryoCath would purchase the newly developed systems from Endocare and market them on a global basis under the CryoCath trademark, SurgiFrost. CryoCath paid the Company \$125,000 in license fees upon execution of the agreement. Additional fees were due upon the availability of a malleable cryoprobe and for the sale of a fixed number of cryo-consoles. However, these amounts were never received since the performance targets had not been met. The agreement also provided volume purchase discounts to CryoCath to be determined annually on a retrospective basis. The agreement had an initial term of five years and with renewals for two additional three-year periods if certain conditions were met. As discussed in Note 5, the distribution agreement was terminated in April 2003 upon the sale of the cardiac product line and related assets to CryoCath. Purchase discounts due to CryoCath of \$433,000 at September 30, 2002 (included in other accrued liabilities) were settled as part of the sale of the cardiac product line to CryoCath in April 2003.

**10. Other Investments**

Material equity investments in companies acquired through collaboration agreements include the following:

a. 833,333 common shares (approximately 14% interest) in Medical Resource Management, Inc. ( MRM ), a publicly traded company that provides mobile surgical equipment rental, certified technician training and support services to hospitals and medical facilities on a fee per procedure basis (acquired September 2000 for cash of \$250,000). MRM specializes in laser surgery, cryosurgery, brachytherapy and other capital-intensive medical equipment. In June 2001, Emergent Group, Inc. acquired the outstanding stock of MRM in a share exchange. The Company wrote off the \$250,000 carrying value of this investment as a loss on minority investment in the second quarter of 2001 since the shares received in exchange have de-minimus value.

b. 33,945 common shares in Matritech, Inc., a publicly traded company that develops proteomics-based diagnostic products for early detection of cancer (acquired February 2001 for cash of \$150,000). Timm Medical was the exclusive United States distributor of bladder cancer diagnostic test kits manufactured by Matritech, Inc. The distribution agreement was terminated in June 2002. Purchases from Matritech, Inc. were immaterial. The carrying value of the investment at September 30, 2002 was \$72,000.

**11. Income Taxes**

The Company reported no income tax expense for each of the nine months ended September 30, 2002 and 2001 due to its operating losses. The continuing operating losses resulted in an increase in the valuation allowance of \$5.4 million and \$3.6 million during the nine months ended September 30, 2002 and 2001,

**Table of Contents**

**ENDOCARE, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

respectively. Due to the Company's history of operating losses, management cannot conclude that it is more likely than not that the Company's deferred tax asset will be realized through future earnings. Accordingly, valuation allowances were recorded to fully reserve the Company's deferred tax assets as of September 30, 2002 and 2001.

**12. Subsequent Events**

During the first quarter ended March 31, 2004, the Company retired 326,222 of its common shares held in treasury, including 120,022 shares re-purchased from BioLife for \$503,729 in February 2004 in connection with the settlement of its litigation with this company.

Through its acquisition of Timm Medical in February 2002, the Company obtained offices, manufacturing and research facilities for its erectile dysfunction products in a 28,066 square foot building in Eden Prairie, Minnesota. This lease expired on April 30, 2004. Due to the net downsizing of its Minnesota operations and divestiture of several product lines acquired in the purchase of Timm Medical, the Company decided not to renew its existing lease and instead negotiated a lease for a smaller facility. In May 2004, the Company agreed to enter into a new lease on 8,919 square feet in the existing facility to house its Minnesota operations. The monthly rental payment during the term of the lease will range from \$0.61 to \$0.67 per square foot, excluding common area maintenance costs. The aggregate rental obligation over the term of the lease will be approximately \$343,000. The lease for this office and warehouse facility expires in 2009.



**Table of Contents**

**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 Reports on Form 10-K for the fiscal years ended December 31, 2003 and 2002.*

*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. In addition, there are factors not described in this Quarterly Report on Form 10-Q 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 a medical device company focused on developing, manufacturing and selling cryosurgical products with the potential to improve the treatment of cancer and other tumors and on manufacturing and marketing vacuum technology as a non-pharmacological option for treatment of erectile dysfunction. Our cryosurgical products include a computerized device (the Cryocare Surgical System), and disposable cryoprobes and temperature probes used to safely and effectively freeze cancerous tissue or other tumors through our proprietary argon gas-based technology. We recently introduced the next generation of our Cryocare Surgical System, the Cryocare CS. Our erectile dysfunction products, sold through our wholly-owned subsidiary, Timm Medical, include the ErecAid Esteem and the ErecAid Classic for treatment of impotence as well as the RigiScan for diagnostic evaluation of this condition.

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. Our RigiScan products are sold to physicians.

We have incurred significant operating losses and negative cash flows from operations in each full fiscal year since January 1, 1996. We incurred a net loss of approximately \$4.7 million and \$13.4 million, respectively, for the quarter and nine months ended September 30, 2002. As of September 30, 2002, we had an accumulated deficit of \$60.4 million. We expect to incur additional losses as we expand our sales and marketing efforts, strengthen our infrastructure, improve our financial reporting processes and controls and continue to develop new products.

In addition to the cash needed to fund our ongoing operations, there have been and will continue to be substantial demands on cash in connection with ongoing investigations by the SEC and DOJ of our historical accounting and financial reporting and related matters, including restatements of our consolidated financial statements filed in our Annual Reports on Form 10-K for the years 2000 and 2001 and in our Quarterly Reports on Form 10-Q for the first and second quarters of 2002, as well as expenses related to shareholder litigation. (See Notes 1 and 2 to the condensed consolidated financial statements included in this report and below under Liquidity and Capital Resources.)

**Results of Operations**

A major factor contributing to the fluctuation in our operating results in the three and nine months ended September 30, 2002 compared to the same periods in 2001 was the acquisition of Timm Medical on February 21, 2002. We also acquired the mobile prostate treatment businesses previously owned by USMD on

**Table of Contents**

September 30, 2002. Both acquisitions brought with them increases in costs and expenses. The Timm Medical acquisition also brought with it additional sales.

***Three and Nine Months Ended September 30, 2002 Compared to Three and Nine Months Ended September 30, 2001***

*Revenues.* We generate revenues from sales of our Cryocare Surgical Systems, disposable cryoprobes and other disposable devices used in cryoablation procedures. We also contract with hospitals and other health care providers for the use of our Cryocare Surgical Systems in cryoablation treatments for which we charge a per-procedure fee.

The procedure fee typically includes a procedure kit containing cryoprobes and other disposables needed to perform a cryosurgical procedure, in addition to a service component. The service component of the procedure fee generally consists of rental and transport of a Cryocare Surgical System as well as the services of a technician to assist the physician with the set-up, use and monitoring of the equipment. In certain instances, we will provide the service component of the procedure to the hospital as well as the devices. At other times, we will contract with third parties to perform the service component of the procedures and will remit a service fee to the third party upon invoicing the hospital. We also sell just the disposable devices to hospitals, without the service component, where the hospital either owns the equipment or independently contracts with a service provider.

We sell Cryocare Surgical Systems to distributors and to independent cryosurgical service providers. In addition, we sell disposable cryoprobes and temperature probes directly to distributors, hospitals or independent service providers. Disposables are sometimes packaged and sold in a procedure kit containing the usual number of probes consumed in a single cryosurgical procedure plus the service component.

In addition to our cryosurgery products, we sell other urological products acquired when we purchased Timm Medical, a urological device manufacturer, in February 2002. We continue to sell our ErecAid vacuum therapy systems and RigiScan monitors, although in 2003 we either divested or discontinued the remaining product lines acquired in the Timm Medical purchase.

A portion of our revenues also comes from sales of the SurgiFrost cryosurgical line which we developed for treatment of cardiac arrhythmia. In 2002 and through the first quarter of 2003, we sold these products to CryoCath under the terms of a distribution agreement. In April 2003, we licensed to CryoCath the manufacturing and intellectual property rights to these products and sold them the related assets. Beginning with the first quarter of 2004, we are entitled to royalty income based on CryoCath's sales of these products.

Revenues for the three months ended September 30, 2002 increased 121.6% to \$8,382,000 compared to \$3,783,000 for the three months ended September 30, 2001. The increase in revenues was partly attributable to an increase in sales of cryosurgical probes and procedures into the urology market. There were approximately 665 cryosurgical procedures performed in the third quarter of 2002 compared to approximately 300 for the same period in the prior year. In addition we had sales of new products in the first nine months of 2002 that we did not have during the same period in 2001, including the SurgiFrost cardiac products we manufactured and sold under the terms of our September 21, 2001 Global Supply and Market Access Agreement with CryoCath and products we acquired through our acquisition of Timm Medical. Sales to CryoCath totaled \$1,060,000 for the quarter ended September 30, 2002. Sales of Timm Medical products, including those later divested, were \$3,863,000 for the three months ended September 30, 2002.

Offsetting these increases in revenues were reductions in sales of Cryocare Surgical Systems. We sold 14 systems in the third quarter of 2001 compared to two systems during the same period in 2002 for a \$2,033,000 reduction in revenues. Correspondingly, we sold 35 systems in the first nine months of 2001 compared to 20 systems in the first nine months of 2002, a decline of \$2,151,000. The decline in sales of Cryocare Surgical Systems is primarily due to the decrease in sales of these units to USMD. During 2001 and prior to our acquisition of the mobile prostate treatment businesses from USMD in September 2002, we sold Cryocare Surgical Systems and our disposable cryosurgical devices to USMD under the terms of a distribution agreement that provided for minimum purchase quotas in each quarter. During the nine months ended

**Table of Contents**

September 30, 2001 and 2002, we sold 16 and five units, respectively, to USMD totaling approximately \$3.3 million and \$1.0 million, respectively, in revenues. Following the acquisition, the distribution agreement was terminated.

Revenues for the nine months ended September 30, 2002 increased 150% to \$23,808,000 compared to \$9,523,000 in 2001. Reasons for this increase in sales are consistent with the explanations above. Products we acquired or obtained a right to distribute from Timm Medical contributed revenues of approximately \$9,700,000 for the nine months ended September 30, 2002. Sales of our cardiac products to CryoCath were \$1,589,000 for the first nine months of 2002.

*Cost of Revenues.* Cost of revenues consists of fixed and variable costs incurred in the manufacture of our products in addition to depreciation of Cryocare Surgical Systems placed in the field with customers under our placement program or with our sales and service personnel. We incur an additional cost of revenues in the form of a fee for equipment usage and other services when a procedure is performed on a Cryocare Surgical System owned by an unrelated service provider. That portion of the procedure fee remitted to the third-party service provider is charged to cost of revenues when the procedure is performed and billed. We retain a larger profit on procedures performed on systems owned by us where no outside service fees are incurred.

In addition, charges for product warranties as well as excess and obsolete inventory, shrinkage and other inventory carrying costs are included in our cost of revenues as are costs of maintaining patents or other intellectual property rights to processes or technologies related to our products, royalties on product sales and amortization of developed technology acquired in connection with our acquisition of Timm Medical.

Cost of revenues for the three months ended September 30, 2002 increased 186.4% to \$4,526,000 compared to \$1,580,000 for the three months ended September 30, 2001. The increase in cost of revenues resulted primarily from sales of new products acquired in the Timm Medical purchase and sales of our cardiac products to CryoCath under the agreement referenced above. Costs related to the manufacture and sale of products we acquired from Timm Medical and related to the SurgiFrost products we sold to CryoCath, contributed approximately \$1,541,000 and \$679,000, respectively, to the cost of revenues for the quarter ended September 30, 2002. Another factor in the increase in cost of revenues for the quarter ended September 30, 2002 was the fact that we recorded cost of revenues related to five Cryocare Surgical Systems, which had been shipped during the period but for which we could not recognize revenue. There were only two Cryocare Surgical System shipped in the third quarter of 2001 for which we could not recognize revenue in the period. Finally, there was an increase in cost of revenues due to growth in the number of cryosurgical procedures overall, as well as in the number of procedures where we contracted with third-party service providers, to perform the service component of the procedure. In these instances, we billed the hospital for the procedure and remitted up to half of the amount billed to the third-party service provider. We include fees paid to the service providers in our cost of revenues. Finally, we increased the number of Cryocare Surgical Systems we loaned or placed with hospitals in an effort to encourage them to adopt cryosurgery. We depreciate these systems ratably over a three-year period and include the depreciation charge in cost of revenues.

Cost of revenues for the nine months ended September 30, 2002 increased 174.6% to \$12,019,000 compared to \$4,377,000 in 2001. Reasons for this increase in sales are consistent with the explanations above.

*Gross Margins.* Gross margins on revenues decreased to 46.0% for the three months ended September 30, 2002 compared to 58.2% for the three months ended September 30, 2001. Gross margins on revenues for the nine months ended September 30, 2002 decreased to 49.5% compared to 54.0% for the same period in 2001. The reduction in our gross margins is significantly due to the factors described above under cost of revenues, primarily to 1) an increase in the fees paid to third party service providers, 2) an increase in depreciation on Cryocare Surgical Systems loaned to or placed with our customers 3) the inclusion in cost of revenues of the manufacturing cost of five Cryocare Surgical Systems shipped to our customers for which we could not record the corresponding revenue and 4) reduction in sales of Cryocare Surgical Systems which have a higher profit margin than sales of disposable devices and procedure fees.

*Research and Development Expenses.* Research and development expenses include expenses associated with the design and development of new products as well as significant enhancements to existing products.

**Table of Contents**

These expenses consist primarily of salaries and related benefits and overhead costs for staff engaged in research and development activities, costs for materials and supplies used in performing research and development activities, costs of clinical trials conducted for the purpose of obtaining regulatory approval of our products, consulting and advisory fees for outside service providers directly involved in research and development activities, and depreciation on equipment used directly for research and development activities. We expense research and development expenses when incurred. Our research and development efforts are periodically subject to significant non-recurring expenses and fees that can cause some variability in our quarterly research and development expenses.

Research and development expenses for the three months ended September 30, 2002 decreased 6.9% to \$490,000 compared to \$526,000 for the three months ended September 30, 2001. The lower cost in third quarter of 2002 was primarily attributable to the winding down of development of cryosurgical products for the cardiac and gynecology markets created under strategic alliances formed with CryoCath and with Sanarus, a company for which we developed cryosurgical products for treatment of benign and malignant breast diseases. We completed most of the development work in 2001 and commercialized these products in 2002. These reductions in spending were partly offset by investment in development of the Horizon Prostatic Stent and the ThermaStent for treatment of BPH and costs incurred for research and development related to products acquired in the Timm Medical purchase. As a percentage of revenues, research and development expenses decreased from 13.9% in the third quarter of 2001 to 5.8% during the third quarter of 2002, due to the combination of reduced spending levels and increased revenues.

Research and development expense for the nine months ended September 30, 2002 increased 7.6% to \$2,052,000 compared to \$1,907,000 for the same period in 2001. As a percentage of revenues, research and development expenses dropped from 20.0% in the first nine months of 2001 to 8.6% for the same period in 2002.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses primarily consist of salaries, commissions and related benefits and other overhead costs for employees and activities in the areas of sales, marketing, customer service, clinical services, finance, information technology, human resources and administration. Fees for attorneys, independent auditors and certain other outside consultants and suppliers are included where their services or products are related to selling, general and administrative activities. The costs of our insurance premiums, including those for directors and officers liability and products liability coverage are also included in this category. Expenses associated with advertising, trade shows, promotional and training costs related to marketing our products are also classified as selling, general and administrative expenses as are the costs of conducting clinical research studies for the purpose of collecting clinical data used in promoting our products.

Selling, general and administrative expenses for the three months ended September 30, 2002 increased 91.2% to \$8,408,000 compared to \$4,398,000 for the three months ended September 30, 2001. The increase is primarily attributable to our acquisition of Timm Medical in the first quarter of 2002 and relates to significant additions to staffing, particularly in the sales and marketing area, and to administrative costs incurred in connection with running our operations in Eden Prairie, Minnesota, and to marketing our newly-acquired urology products.

Headcount following the Timm Medical acquisition more than doubled from 94 employees at year-end 2001 to 202 employees at the end of first quarter 2002. At September 30, 2002, our headcount of 194 employees included 63 sales and marketing personnel (up from 23 at year-end 2001), 25 customer service employees (up from 10 at year-end 2001), and corporate administrative staff of 28 (up from 16 at year-end 2001). We also acquired the lease on a 28,000 square foot facility in Eden Prairie, Minnesota.

Selling, general and administrative expenses for the nine months ended September 30, 2002 increased 102.5% to \$24,075,000 compared to \$11,892,000 for the same period in 2001. Reasons for this increase are consistent with the explanations above for the quarter. In addition, we incurred significantly higher costs related to training new cryosurgeons in the first nine months of 2002, compared to the earlier period, as well as higher marketing costs related to product promotional literature and increased trade show activity.

**Table of Contents**

*Interest Income, Net.* Interest income, net for the three months ended September 30, 2002 was \$317,000 compared to \$47,000 for the three months ended September 30, 2001. The change was due to the reduction of interest expense associated with the reduction of debt in 2001 and increased cash and investment balances following our secondary public offering in November of 2001.

Interest income, net for the nine months ended September 30, 2002 was \$935,000 compared to \$12,000 for the nine months ended September 30, 2001. The increase is primarily due to reasons stated above.

*Loss on Minority Investment.* Loss on investment for the nine months ended September 30, 2001, relates to a charge taken to reflect a decline, other than temporary, for the Company's investment in Medical Resources Management, Inc.

*Net Loss.* Net loss for the three months ended September 30, 2002 was \$4,725,000 or \$0.19 per diluted share on 24,279,000 weighted average shares outstanding, compared to a net loss of \$2,674,000, or \$0.16 per share on 16,920,505 weighted average shares outstanding for the same period in 2001. The loss for the three months ended September 30, 2002, compared to the net loss for the same period in 2001, increased as a result of lower gross margins and higher selling, general and administrative expenses.

Our net loss for the nine months ended September 30, 2002 was \$13,403,000 or \$0.57 per diluted share on 23,695,667 weighted average shares outstanding, compared to a net loss of \$8,892,000 or \$0.56 per diluted share on 15,892,333 weighted average shares outstanding for the same period in 2001.

**Liquidity and Capital Resources**

Since inception, we have incurred losses from operations and have reported negative cash flows. As of September 30, 2002, we had an accumulated deficit of \$60.4 million and cash, cash equivalents and available-for-sale securities of \$44.0 million.

After September 30, 2002, our cash reserves continued to decline. From October 1, 2002 through March 31, 2004, our cash was principally used to fund a total of \$52.4 million in operating losses (excluding impairment charges and gains on divestiture). The losses include \$15.3 million in non-recurring legal and accounting fees associated with the on-going investigations of our historical accounting and financial reporting, \$3.6 million in executive severance costs related primarily to our former Chief Executive Officer and Chief Financial Officer and \$1.5 million for the settlement of the BioLife litigation (see Note 7 to our condensed consolidated financial statements). These expenses were partially offset by \$10 million in proceeds from the sale of our cardiac related product manufacturing operations to CryoCath and \$2 million from the sale of the Dura II penile implant product line.

In February 2004 we paid approximately \$1.5 million in directors' and officers' liability insurance premiums, and we paid approximately \$1.9 million to BioLife to settle litigation and repurchase common shares previously issued to BioLife. During the first quarter of 2004 we incurred approximately \$3.3 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.

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 and certain current and former board members have been named defendants in a class action and a derivative lawsuit. We are generally obliged, to the extent permitted by law, to indemnify our directors and officers who are named defendants in these lawsuits. At this point in time we are unable to provide a reasonable estimate of our potential liability in these lawsuits.

We may be required to pay judgments or settlements and to incur expenses in defending against these claims that could be material. Further, 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

## **Table of Contents**

insurance coverage and seeking rescission of the policies. A claim in excess of our insurance coverage would have to be paid out of cash reserves, 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, regaining compliance with the SEC rules and regulations required of publicly traded companies, including Section 404 of the Sarbanes-Oxley Act of 2002, and fulfilling requirements prerequisite to becoming re-listed on a national stock exchange or market. We incurred net losses of \$25.4 million and \$42.0 million in 2003 and 2002, respectively, and are currently projecting an operating loss for fiscal 2004, as well as a net use of cash.

We will continue to use cash reserves to finance our projected 2004 cash flow deficit. Our 2004 forecast provides for an increase in revenues and improvement in gross profit as well as a reduction in general and administrative expenses. The reduction in general and administrative costs is due partly to the winding down of certain activities related to various investigations of accounting and financial reporting matters and reductions in both staffing and marketing programs. In addition, we have trimmed general and administrative costs through the elimination of redundant functions at our subsidiaries and centralizing them at our Irvine, California headquarters, and plan to continue cost reduction programs aimed at improving the financial health of the Company.

At the same time, however, we have planned certain strategic investments in sales and marketing activities to increase our market penetration as well as in inventory related to the introduction of our new Cryocare CS System. We have also planned expenditures on staffing and infrastructure improvements in finance and information technology to ensure that we will be able to comply with internal control and other SEC requirements.

### **Risks Related to Our Business**

*The risks and uncertainties described below are not the only ones we face. 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 the following 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.*

#### ***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 Katherine Greenberg, our Senior Vice President and Chief Financial Officer. None of our key management personnel is covered by an insurance policy of which we are the beneficiary.

#### ***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 below, 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.

**Table of Contents**

***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. 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. We will continue to incur significant related expenses in the future.

If we are not able to significantly grow market share, improve our gross margins and reduce our operating expenses, or if we become subject to significant judgments or settlements in connection with the legal proceedings described in Part II, Item 1 of this Quarterly Report on Form 10-Q, we will require additional financing. Additional equity or debt financing may not be available on acceptable terms, or at all, in part because our common stock was de-listed from The Nasdaq Stock Market. If we are unable to obtain additional capital, we may be required to reduce our sales and marketing activities, reduce the scope of or eliminate our research and development programs, relinquish rights to technologies that we might otherwise seek to develop or commercialize, or sell certain assets.

We recently made several significant payments that have reduced our cash reserves. On March 8, 2004, we paid to our former Chief Executive Officer an aggregate of \$750,000, which we owed to him under a separation agreement and consulting agreement that we previously executed. Also on March 8, 2004, we paid to our former Chief Financial Officer an aggregate of \$616,000, which we owed to him under an employment agreement we previously executed. At the request of the SEC, these payments were deposited into escrow accounts during the fourth quarter of 2003; the funds were released upon termination of the related escrow agreements. Additionally, on February 20, 2004, we paid approximately \$1.5 million in directors and officers liability insurance premiums. Furthermore, as described below in Part II, Item 1 of this Quarterly Report on Form 10-Q, in February 2004 we paid approximately \$1.9 million to BioLife to settle litigation.

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 have limited operating experience and a history of net losses, and we may never reach or maintain profitability.***

We have limited experience in manufacturing, marketing and selling our Cryocare Surgical System in commercial quantities. In addition, during 2002, we completed our acquisitions of Timm Medical, the cryosurgical assets of BioLife, and our acquisition of the mobile prostate treatment businesses owned by USMD. As a result, we have a short history in marketing and selling the products we acquired or have rights to commercialize through these acquisitions or to market our products on the scale required by these acquisitions. In addition, we have limited experience in managing the complex demands of a business with multiple entities and locations, a large workforce and diverse information technology systems.

We have incurred annual operating losses each year since our inception. For the quarter ended March 31, 2004, we had losses from operations of approximately \$8.6 million. As of March 31, 2004, our accumulated deficit was approximately \$123.0 million. It is possible that we will not generate sufficient revenues from product sales and service revenues to achieve or sustain profitability. Even if we do achieve significant

**Table of Contents**

revenues from our product sales and service revenues, we expect that increased operating expenses will result in significant operating losses over the next several quarters, as we, among other things:

expand our infrastructure to support more robust internal controls, including policies and procedures related to our accounting practices, disclosure controls and corporate governance;

incur costs related to legal proceedings, including ongoing government investigations;

expand our sales and marketing activities as we attempt to gain market share for our Cryocare Surgical System; and

continue our research and development efforts to improve our existing products and develop new products.

We will need to significantly increase the revenues we receive from sales of our products and services as a result of these increased operating expenses. We may be unable to do so, and therefore, may not achieve profitability. Even if we do achieve profitability, we cannot be certain that we will be able to sustain or increase profitability on a quarterly or annual basis.

***If we require future capital, we may not be able to secure additional funding in order to expand our operations and develop new products.***

If we fail to achieve and maintain profitability and positive cash flow, or if we undertake or accelerate significant research and development projects for new products or pursue corporate acquisitions, we may need additional outside financing. We may raise these additional funds by selling one or more lines of business or products, selling our equity securities, incurring debt or entering into collaborative arrangements. 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 when needed could have a material adverse effect on our business, financial condition, results of operations and cash flows.

***We cannot assure you that we will not discover additional instances of historical breakdowns in controls, policies and procedures affecting our previously issued financial statements.***

We have made significant changes in our internal controls, accounting policies and procedures, disclosure controls and procedures and corporate governance policies and procedures. While we believe that our newly implemented controls, policies and procedures will help to prevent the occurrence of financial reporting problems in the future, it is possible that we may discover additional instances of historical breakdowns in our internal controls, policies and procedures of the types that led to restatements of our financial statements for the years 2000 and 2001 and for the first two quarters of 2002. In the event such breakdowns are discovered they could impact both historical financial statements and future reported results.

***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.

In addition, we and certain former officers and certain current and former board members have been named defendants in a class action and a derivative lawsuit. The findings and outcome of the investigations described above may affect the class action and the derivative lawsuit that are pending. We are generally



**Table of Contents**

obliged, to the extent permitted by law, to indemnify our directors and officers who are named defendants in some of these lawsuits. 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. A claim in excess of our insurance coverage would have to be paid out of cash reserves, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

***Our investors, customers, vendors and suppliers may react adversely to the restatement of our historical financial statements and our inability to timely file all of our SEC filings.***

Our future success depends in large part on the support of our investors, customers, vendors, and suppliers. The restatement of our historical financial statements and our inability to timely file all of our SEC filings has resulted in negative publicity about us and has, and may continue to have, a negative impact on the market price of our common stock. The restatement of our historical financial statements and our inability to timely file all of our SEC filings also could cause some of our customers or potential customers to refrain from purchasing or to defer or cancel purchases of our products. Additionally, our current and potential vendors and suppliers may re-examine their willingness to do business with us, to develop critical interfaces for us or to supply products and services if they lose confidence in our ability to fulfill our commitments.

***Our common stock was de-listed from the Nasdaq Stock Market and, as a result, trading of our common stock has become more difficult.***

Our common stock was de-listed from The Nasdaq Stock Market on January 16, 2003. One result of this action is a limited public market for our common stock. Trading is now conducted in the over-the-counter market in the so-called Pink Sheets. Consequently, selling our common stock is more difficult because smaller quantities of shares can be bought and sold, transactions can be delayed and security analyst and news media coverage of us may be reduced. These factors could result in lower prices and larger spreads in the bid and ask prices for shares of our common stock as well as lower trading volume. Although we will seek to have our common stock re-listed on a national stock exchange or market once we are in full compliance with our obligations as a reporting company, we can provide no assurance that we will be re-listed.

As a result of the delisting of our common stock from The Nasdaq Stock Market, our common stock has become subject to the penny stock regulations, including Rule 15g-9 under the Securities Exchange Act of 1934. That rule imposes additional sales practice requirements on broker-dealers that sell low-priced securities to persons other than established customers and institutional accredited investors. For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to sale. Consequently, the rule may affect the ability of broker-dealers to sell our common stock and affect the ability of holders to sell their shares of our common stock in the secondary market. To the extent our common stock remains subject to the penny stock regulations, the market liquidity for the shares will be adversely affected.

***We expect to derive a significant portion of our future revenues from our cryosurgical products, which could fail to achieve market acceptance or generate significant revenue.***

We introduced our Cryocare Surgical System to the market in July 1999. We derived a significant portion of our revenues in 2001 and 2002 from sales of Cryocare Surgical Systems and related disposable cryoprobes and temperature probes, as well as from per-procedure fees. In 2003, we shifted our business model to focus on sales of procedures and disposable devices rather than on sales of Cryocare Surgical Systems. We expect sales of cryosurgical products and the related procedure fees will constitute a significant portion of our revenues for

## **Table of Contents**

the foreseeable future, although we expect revenue from system sales to fluctuate from quarter to quarter and decrease, over time, as a percentage of our revenue.

Our success is reliant on the acceptance by doctors and patients of the Cryocare Surgical System as a preferred treatment for tumor ablation. Cryosurgery has existed for many years, but has not been widely accepted primarily due to concerns regarding safety and efficacy and widespread use of alternative therapies. Because the technology previously lacked precise monitoring capabilities, cryosurgical procedures performed in the 1970s resulted in high cancer recurrence and negative side effects, such as rectal fistulae and incontinence, and gave cryosurgical treatment negative publicity. To overcome these negative side effects, we have developed ultrasound guidance and temperature sensing to enable more precise monitoring in our Cryocare Surgical System. Nevertheless, we will need to overcome the earlier negative publicity associated with cryosurgery in order to obtain market acceptance for our products. In addition, use of our Cryocare Surgical System requires significant physician education and training. As a result, we may have difficulty obtaining recommendations and endorsements of physicians and patients for our Cryocare Surgical System. We may also have difficulty raising the brand awareness necessary to generate interest in our Cryocare Surgical System. Any adverse side effects, including impotence or incontinence, recurrence of cancer or future reported adverse events or other unfavorable publicity involving patient outcomes from the use of cryosurgery, whether from our products or the products of our competitors, could adversely affect acceptance of cryosurgery. In addition, emerging new technologies and procedures to treat cancer, prostate enlargement and other prostate disorders may negatively affect the market acceptance of cryosurgery. If our Cryocare Surgical System does not achieve broad market acceptance, we will likely remain unprofitable.

### ***If we are unable to continue to develop and enhance our Cryocare Surgical System, our business will suffer.***

Our growth depends in part on our continued ability to successfully develop enhancements to our Cryocare Surgical System. We may experience difficulties that could delay or prevent the successful development and commercialization of these products. Our products in development may not prove safe and effective in clinical trials. Clinical trials may identify significant technical or other obstacles that must be overcome before obtaining necessary regulatory or reimbursement approvals. In addition, our competitors may succeed in developing commercially viable products that render our products obsolete or less attractive. Failure to successfully develop and commercialize new products and enhancements would likely have a significant negative effect on our financial prospects.

### ***Our strategy of divesting non-core product lines may not be successful.***

We are refocusing our business on the development of minimally invasive technologies for tissue and tumor ablation. As part of this strategy, we have begun divesting certain non-core product lines, as evidenced by our sale of our Dura II Penile Prosthesis product line, our sale of our urodynamics and urinary incontinence product lines and our licensing of our cardiac technology and sale of related assets. We can provide no assurance that our strategy of focusing on our core technologies for tumor ablation applications and our divestitures of non-core technologies and product lines will be successful.

### ***There is uncertainty relating to third-party reimbursement, which is critical to market acceptance of our products.***

Hospitals and other health care providers in the United States generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to reimburse all or part of the cost of medical procedures involving our products. While private health insurers in some areas of the United States provide reimbursement for procedures in which our products are used, we can provide no assurance that private insurance reimbursement will be adopted nationally or by additional insurers. Furthermore, those private insurance companies currently paying for procedures in which our products are used may terminate such coverage. If reimbursement levels from Medicare, Medicaid, other governmental health care programs or private insurers are not sufficient, physicians may choose not to recommend, and patients may not choose, procedures utilizing our products.

**Table of Contents**

Previously, reimbursement under Medicare for our cryosurgical disposable products used in outpatient procedures was provided on a so-called pass-through basis. This enabled the hospital or other health care provider to obtain separate reimbursement for our disposable devices in addition to reimbursement for the procedure fee. Pass-through status was terminated on December 31, 2003. As a result, the cost of our disposable products now is incorporated into the Hospital Outpatient Prospective Payment System and there will be no separate reimbursement for the disposables.

Given the end to pass-through status for our disposable cryoprobes and temperature probes, we expect Medicare reimbursement for our products used in outpatient settings to continue to fluctuate. This may influence reimbursement rates for our products by private insurers as well. We can provide no assurance that changes in outpatient reimbursement rates will not affect our ability to negotiate favorable charges for our products to hospitals.

International market acceptance of our products may depend, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government sponsored health care and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. Our failure to receive international reimbursement approvals may negatively impact market acceptance of our products in the international markets in which those approvals are sought.

Furthermore, from time to time significant attention has been focused on reforming the health care system in the United States and other countries. Any changes in Medicare, Medicaid or third-party medical expense reimbursement, which may arise from health care reform, may have a material adverse effect on reimbursement for our products or procedures in which our products are used and may reduce the price we are able to charge for our products. In addition, changes to the health care system may also affect the commercial acceptance of products we are currently developing and products we may develop in the future. Potential approaches that have been considered include controls on health care spending and price controls. Several proposals have been made in the United States Congress and various state legislatures recently that, if adopted, would potentially reduce health care spending, which may result in a material adverse effect on our business, financial condition, results of operations and cash flows.

***We have limited sales and marketing experience with our Cryocare Surgical System and any failure to significantly expand sales of this product will negatively impact future revenue.***

We primarily handle the marketing, distribution and sales of our Cryocare Surgical Systems through our own work force. We have limited experience marketing and selling our Cryocare Surgical System in commercial quantities or on a nationwide basis. We will face significant challenges and risks in training, managing and retaining our sales and marketing teams, including managing geographically dispersed efforts and adequately training our people in the use and benefits of our Cryocare Surgical System. We may not be able to hire significant additional personnel or deploy sufficient other resources needed to create increased demand for our Cryocare Surgical System. In addition, we have distribution arrangements, some of which are exclusive, for the sale of our Cryocare Surgical System both domestically and internationally, and we are dependent upon the sales and marketing efforts of our third-party distributors. These distributors may not commit the necessary resources to effectively market and sell our Cryocare Surgical System. If we are unable to expand our sales and marketing capabilities or if our senior sales and marketing personnel are not retained, we may not be able to effectively commercialize our Cryocare Surgical System.

***We acquired Timm Medical, the cryosurgical assets of BioLife and the mobile prostate treatment businesses of USMD and face risks associated with integrating these businesses into our existing business operations.***

We continue to face numerous risks and expenses related to integration of the businesses we acquired from Timm Medical, BioLife and USMD. In addition, the acquired businesses have suffered because management's resources have been consumed by, among other things, the internal and external investigations involving various accounting and related matters as well as the work involved in re-auditing and restating our

**Table of Contents**

consolidated financial statements for the years ended December 31, 2000 and 2001 and for the first two quarters of 2002. The businesses acquired from Timm Medical have suffered because resources have been diverted in divesting certain non-core product lines and in downsizing our Eden Prairie operations. The businesses we acquired from USMD have suffered for many of the same reasons in addition to the fact that we recently assumed administrative responsibility for management of these complex businesses. If we do not successfully integrate and grow the acquired businesses, our business will suffer.

***Introduction of alternative therapies may affect our revenues.***

We sell medical devices for the treatment of certain urological disorders. If physicians and patients do not accept our products, our sales will decline. Patient acceptance of our products depends on a number of factors, including the failure of other therapies, the degree of invasiveness involved, the rate and severity of complications from the procedures, and other adverse side effects. Patients are more likely first to consider non-invasive alternatives to treat their urological disorders. The introduction of new oral medications or other less-invasive therapies may cause our sales to decline in the future.

***We could be difficult to acquire due to anti-takeover provisions in our charter, our stockholders rights plan and Delaware law.***

Provisions of our certificate of incorporation and bylaws, as amended, may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. In addition, in April 1999, our Board of Directors adopted a stockholder rights plan in which preferred stock purchase rights were distributed as a dividend. These provisions may make it more difficult for stockholders to take corporate actions and may have the effect of delaying or preventing a change in control. We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Subject to specified exceptions, this section provides that a corporation may not engage in any business combination with any interested stockholder during the three-year period following the time that such stockholder becomes an interested stockholder. This provision could have the effect of delaying or preventing a change of control of us. The foregoing factors could limit the price that investors or an acquiror might be willing to pay in the future for shares of our common stock.

***If we fail to protect our intellectual property rights, our competitors may take advantage of our ideas and compete directly against us.***

Our success will depend to a significant degree on our ability to secure and protect intellectual property rights and to enforce patent and trademark protections relating to our technology. From time to time, litigation may be advisable to protect our intellectual property position. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any litigation in this regard could be costly, and it is possible that we will not have sufficient resources to fully pursue this litigation or to protect our other intellectual property rights. It could result in the rejection or invalidation of our existing and future patents. Any adverse outcome in litigation relating to the validity of our patents, or any failure to pursue litigation or otherwise to protect our patent position, could have a material adverse effect on our business, financial condition, results of operations and cash flows. Also, even if we prevail in litigation, the litigation would be costly in terms of management distraction as well as in money. In addition, confidentiality agreements with our employees, consultants, customers, and key vendors may not prevent the unauthorized disclosure or use of our technology. It is possible that these agreements will be breached or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Enforcement of these agreements may be costly and time consuming. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States.

***Because the medical device industry is litigious, we may be sued for allegedly violating the intellectual property rights of others.***

The medical technology industry has in the past been characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. In addition, major

**Table of Contents**

medical device companies have used litigation against emerging growth companies as a means of gaining or preserving a competitive advantage.

Should third parties file patent applications or be issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine the relative priorities of our inventions and the third parties' inventions. We could also be required to participate in interference proceedings involving our issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require us to cease using the technology or to license rights from prevailing third parties.

Third parties may claim we are using their patented inventions and may go to court to stop us from engaging in our normal operations and activities. These lawsuits are expensive to defend and conduct and would also consume and divert the time and attention of our management. A court may decide that we are infringing a third party's patents and may order us to cease the infringing activity. A court could also order us to pay damages for the infringement. These damages could be substantial and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If we are unable to obtain any necessary license following an adverse determination in litigation or in interference or other administrative proceedings, we would have to redesign our products to avoid infringing a third party's patent and could temporarily or permanently have to discontinue manufacturing and selling some of our products. If this were to occur, it would negatively impact future sales and, in turn, our business, financial condition, results of operations and cash flows.

***We have limited experience manufacturing our products and if we are unable to meet customer demand, we may not become profitable.***

We use internal manufacturing capacity and expertise to manufacture our products. We have limited experience in producing our products in commercial quantities. We may encounter difficulties in scaling up production of new products, including problems involving production yields, quality control and assurance, component supply and shortages of qualified personnel. Our failure to overcome these manufacturing problems could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our success will depend in part upon our ability to manufacture our products in compliance with the FDA's Quality System regulations and other regulatory requirements in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs.

***We are dependent upon a number of third-party suppliers to manufacture our products and the loss of any of these suppliers could harm our business.***

We depend upon a number of unaffiliated third-party suppliers for components and materials used in the manufacture of our products and, as such, our business would be seriously harmed if we were unable to develop and maintain relationships with suppliers that allow us to obtain sufficient quantities and quality materials and components on acceptable terms. If our principal suppliers cease to supply the materials and components we need to manufacture our products, the qualification of additional or replacement suppliers could be a lengthy process and there may not be adequate alternatives to meet our needs, which will have a material adverse effect on our business, financial condition, results of operations and cash flows. We may not be able to obtain the necessary components and materials used in our products in the future on a timely basis, if at all.

***If we fail to obtain or maintain necessary regulatory clearances or approvals for products, or if approvals are delayed or withdrawn, we will be unable to commercially distribute and market our products or any product modifications.***

Government regulation has a significant impact on our business. Government regulation in the United States and other countries is a significant factor affecting the research and development, manufacture and

**Table of Contents**

marketing of our products. In the United States, the FDA has broad authority under the federal Food, Drug and Cosmetic Act to regulate the distribution, manufacture and sale of medical devices. Foreign sales of drugs and medical devices are subject to foreign governmental regulation and restrictions, which vary from country to country. The process of obtaining FDA and other required regulatory clearances and approvals is lengthy and expensive. We may not be able to obtain or maintain necessary approvals for clinical testing or for the manufacturing or marketing of our products. Failure to comply with applicable regulatory approvals can, among other things, result in fines, suspension or withdrawal of regulatory approvals, product recalls, operating restrictions, and criminal prosecution. In addition, governmental regulations may be established which could prevent, delay, modify or rescind regulatory approval of our products. Any of these actions by the FDA, or change in FDA regulations, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Regulatory approvals, if granted, may include significant limitations on the indicated uses for which our products may be marketed. In addition, to obtain such approvals, the FDA and foreign regulatory authorities may impose numerous other requirements on us. FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory standards or unforeseen problems following initial marketing. We may not be able to obtain or maintain regulatory approvals for our products on a timely basis, or at all, and delays in receipt of or failure to receive such approvals, the loss of previously obtained approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition, results of operations and cash flows.

***Our products may be subject to product recalls even after receiving FDA clearance or approval, which would harm our reputation and our business.***

The FDA and similar governmental authorities in other countries have the authority to request and, in some cases, require the recall of our products in the event of material deficiencies or defects in design or manufacture. A governmental mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects. Any recall of product would divert managerial and financial resources and harm our reputation with customers and our business.

***We could be negatively impacted by future interpretation or implementation of the federal Stark law and other federal and state anti-referral laws.***

The federal Stark law prohibits a physician from referring medical patients for certain services to an entity with which the physician has a financial relationship. A financial relationship includes both investment interests in an entity and compensation arrangements with an entity. Many states have similar and often broader laws prohibiting referrals by any licensed health care provider to entities with which they have a financial relationship. These state laws generally apply to services reimbursed by both governmental and private payors. Violation of these federal and state laws may result in prohibition of payment for services rendered, loss of licenses, fines, criminal penalties and exclusion from governmental and private payor programs, among other things. We have financial relationships with physicians and physician-owned entities, which in turn have financial relationships with hospitals and other providers of designated health services. Although we believe that our financial relationships with physicians and physician-owned entities, as well as the relationships between physician-owned entities that purchase or lease our products and hospitals, are not in violation of applicable laws and regulations, governmental authorities might take a contrary position. If our financial relationships with physicians or physician-owned entities or the relationships between those entities and hospitals were found to be illegal, we and/or the affected physicians and hospitals could be subject to civil and criminal penalties, including fines, exclusion from participation in government and private payor programs and requirements to refund amounts previously received from government and private payors. In addition, expansion of our operations to new jurisdictions, or new interpretations of laws in our existing jurisdictions, could require structural and organizational modifications of our relationships with physicians, physician-owned entities and others to comply with that jurisdiction's laws.

**Table of Contents**

***If we become subject to claims, we may be required to pay damages that exceed our insurance coverage.***

Our business exposes us to potential product liability claims that are inherent in the testing, production, marketing and sale of medical devices. We are also subject to various other claims as described below in Part II, Item 1 Legal Proceedings. While we believe that we are reasonably insured against these risks, we may not be able to maintain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. A claim in excess of our insurance coverage would have to be paid out of cash reserves, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, any product liability claim likely would harm our reputation in the industry and our business.

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. A claim in excess of our insurance coverage would have to be paid out of cash reserves, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

***We are faced with intense competition and rapid technological and industry change, which may make it more difficult for us to achieve significant market penetration.***

The medical device industry generally, and the urological disease treatment market in particular, are characterized by rapid technological change, changing customer needs, and frequent new product introductions. If our competitors existing products or new products are more effective than or considered superior to our products, the commercial opportunity for our products will be reduced or eliminated. We face intense competition from companies in the cryosurgical marketplace as well as companies offering other treatment options, including radical surgery, radiation therapy and hormone therapy. If we are successful in penetrating the market for treatment of prostate cancer with our cryosurgical treatment, other medical device companies may be attracted to the marketplace. Many of our potential competitors are significantly larger than we are and have greater financial, technical, research, marketing, sales, distribution and other resources than we do. We believe there will be intense price competition for products developed in our markets. Our competitors may develop or market technologies and products, including drug-based treatments, that are more effective or commercially attractive than any that we are developing or marketing. Our competitors may obtain regulatory approval, and introduce and commercialize products before we do. These developments could have a material adverse effect on our business, financial condition, results of operations and cash flows. Even if we are able to compete successfully, we may not be able to do so in a profitable manner.

***Fluctuations in our future operating results may negatively impact the market price of our common stock.***

Our operating results have fluctuated in the past and can be expected to fluctuate from time to time in the future. Some of the factors that may cause these fluctuations include the following:

impact of legal proceedings;

costs of expanding our infrastructure to support more robust internal controls, including more effective policies and procedures;

costs to strengthen our accounting practices, disclosure controls and corporate governance;

market acceptance of our existing products, as well as products in development;

timing of payments received and the recognition of such payments as revenue under collaborative arrangements and strategic alliances;

ability to manufacture products efficiently;

**Table of Contents**

timing of our research and development expenditures;

timing of customer orders;

changes in reimbursement rates for our products and procedures by Medicare and other third-party payors;

potential impact of acquisitions;

timing of regulatory approvals for new products;

outcomes of clinical studies by us or our competitors;

competition from other treatment modalities; and

physician and patient acceptance of cryosurgery.

If our operating results are below the expectations of securities analysts or investors, the market price of our common stock may fall abruptly and significantly.

***Our stock price may be volatile and your investment could decline in value.***

Our stock price has fluctuated significantly in the past and is likely to continue to fluctuate significantly, making it difficult to resell shares when investors want to at prices they find attractive. The market prices for securities of emerging companies have historically been highly volatile. Future events concerning us or our competitors could cause such volatility including:

actual or anticipated variations in our operating results;

developments regarding government and third-party reimbursement;

changes in government regulation of our products and business practices;

developments concerning government investigation of us;

developments concerning proprietary rights;

developments concerning litigation or public concern as to the safety of our products or our competitors' products;

technological innovations or introduction of new products by us or our competitors;

investor and analyst perception of us and our industry;

general economic and market conditions; and

physician and patient acceptance of cryosurgery.

In addition, the stock market is subject to price and volume fluctuations that affect the market prices for companies in general, and small-capitalization, high technology companies in particular, which are often unrelated to the operating performance of these companies.

***Future sales of shares of our common stock may negatively affect our stock price.***

Future sales of our common stock, including shares issued upon the exercise of outstanding options and warrants or hedging or other derivative transactions with respect to our stock, could have a significant negative effect on the market price of our common stock. These sales



also might make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that we would deem appropriate.

***Our intangible assets and goodwill could become impaired.***

Intangible assets acquired in a purchase, such as intellectual property or developed technology, are generally amortized over various periods depending on their anticipated economic benefits or useful lives. Long-lived assets, including amortizable intangibles, are reviewed for impairment whenever events or changes

**Table of Contents**

in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. Following a review, if such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying value of the assets exceeds the fair value of the assets.

We had no reported goodwill prior to January 1, 2002. With the adoption of Statement of Financial Accounting Standards No. 142 Goodwill and Intangible Assets, goodwill can no longer be amortized against earnings. Goodwill balances are subject to an impairment review on an annual basis or sooner if indicators of potential impairment exist. The test for impairment requires us to first compare the fair value of the net assets of each reporting unit to their carrying value, including goodwill. If the fair value of the reporting unit is less than the carrying value, goodwill of the reporting unit is potentially impaired and we next calculate the implied fair value of goodwill by deducting the fair value of all tangible and intangible net assets of the reporting unit from the fair value of the reporting unit. If the implied fair value of goodwill is less than the carrying amount of goodwill, an impairment loss is recognized equal to the difference. In the past, we have recorded goodwill impairment related to our Timm Medical acquisition and an impairment of our investment in U.S. Medical Development, Inc. Significant estimates, including assumptions regarding future events and circumstances that cannot be easily predicted are required to perform an analysis of the value of goodwill. These estimates and assumptions may differ materially from actual outcomes and occurrences. Furthermore, no assurance can be given that we will not have further impairment charges related to Timm Medical or other acquisitions.

***Negative economic conditions in the United States may negatively impact our ability to achieve profitability.***

During the past several years, the United States and other international markets experienced a significant economic downturn. In addition, the United States and other countries suffered significant acts of hostility, terror and war. Such acts may increase or prolong such negative economic conditions. The economic downturn may impact our ability to maintain or increase profitability by negatively affecting growth in demand for our products. There can be no certainty as to the degree or severity of the duration of this downturn. We also cannot predict the extent and timing of the impact of the economic downturn in the United States and in other countries and geographic regions in which we conduct our business.

***Our facilities and systems are vulnerable to natural disasters or other catastrophic events.***

Our headquarters, cryosurgical products manufacturing facilities, research facilities and much of our infrastructure, including computer servers, are located in California, an area that is susceptible to earthquakes and other natural disasters. Our erectile dysfunction products are assembled, packaged and shipped in our Minneapolis facility. A natural disaster or other catastrophic event, such as an earthquake, fire, flood, severe storm, break-in, terrorist attack or other comparable problems could cause interruptions or delays in our business and loss of data or render us unable to accept and fulfill customer orders in a timely manner, or at all. In addition, as our Minneapolis facility is located in an area that is susceptible to harsh weather, a major storm, heavy snowfall or other similar event could prevent us from delivering products in a timely manner. We have no formal disaster recovery plan and our business interruption insurance may not adequately compensate us for losses that may occur. In the event that an earthquake, natural disaster or other catastrophic event were to destroy any part of our facilities or interrupt our operations for any extended period of time, or if harsh weather conditions prevent us from delivering products in a timely manner, our business, financial condition and operating results would be seriously harmed.

**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, short-term investments, accounts receivable, investments, accounts payable and accrued liabilities. 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

**Table of Contents**

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.* As required by Securities and Exchange Commission Rule 13a-15(b), our Chief Executive Officer and our Senior Vice President, Chief Financial Officer have evaluated the effectiveness of our disclosure controls and procedures within 90 days prior to the filing date of this report. Based on their evaluation, our Chief Executive Officer and our Senior Vice President, Chief Financial Officer have concluded that our disclosure controls and procedures are not yet effective because, until the filing of this report and the other past due reports on Form 10-Q that we are filing concurrently with this report, we have not been current in our reporting under Section 15(d) of the Securities Exchange Act of 1934. Our inability to timely file the required reports is due to, among other things, the fact that management's time and attention have been consumed by the auditing and re-auditing of our financial statements for the years ended December 31, 2000, 2001, 2002 and 2003, and the resulting restatements, by the development and implementation of improvements to our internal controls and financial reporting processes, and by the internal and external investigations into the accounting and other matters described in our consolidated financial statements and the related Notes contained in this report in Part I, Item 1 and in our Annual Reports on Form 10-K for the years ended December 31, 2002 and 2003 and in Part I, Item 2 of this report, Management's Discussion and Analysis of Financial Condition and Results of Operations.

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. These include, among other measures: new restrictions and guidelines governing sales personnel, terms and conditions of sale and revenue recognition; new and more stringent credit approval policies; new policies governing approval, review and recording of expenditures and other legal and financial transactions; new procedures governing documentation and approval of options and warrants issued in connection with legal and financial transactions; and new internal reporting procedures. 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. 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 date of the filing of 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, 2002 and 2001.

(b) *Changes in Internal Controls.* Except as described above in subsection (a) of this Item 4, there have been no significant changes in our internal controls or in other factors which could significantly affect internal controls subsequent to the date of our most recent evaluation of our internal controls.

**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 Note 7 to our condensed consolidated financial

**Table of Contents**

statements included herein and 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 intend to defend the case vigorously, but cannot assure you that it will be resolved in our favor.

On November 26, 2002, BioLife filed an action against us in the Delaware Court of Chancery seeking damages for alleged breaches of contract stemming from our acquisition, pursuant to an asset purchase agreement dated May 28, 2002, of the tangible and intangible assets related to BioLife's cryosurgical business. In the action, styled as BioLife Solutions, Inc. v. Endocare, Inc., Del. Ch., C.A. No. 20057-NC, BioLife alleged that we failed to timely register 120,022 shares of our common stock that were provided to BioLife in connection with the asset purchase agreement, in violation of a registration rights agreement relating to the shares that was executed in conjunction with the asset purchase agreement. BioLife sought damages of approximately \$1.6 million. We defended the action on the grounds that our obligation to register the shares was excused for various reasons, including as a consequence of BioLife's failure to transfer assets in accordance with the asset purchase agreement. Trial on all but one of the claims in the action was held during the week of March 31, 2003. On October 1, 2003, the Delaware Court ruled in favor of BioLife, awarding BioLife \$1,648,000, plus pre-judgment interest and costs (including legal fees), and requiring BioLife to surrender the 120,022 shares of our common stock to us. That ruling became an appealable final order and judgment on October 10, 2003. On February 20, 2004, we agreed with BioLife to settle all claims. As part of the settlement: we paid to BioLife \$1,887,000, which represented a discount of \$150,000 from the total judgment amount (including accrued interest and costs); BioLife returned to us the 120,022 shares of our common stock referred to above; and we agreed to abandon our appeal.

On December 6, 2002, Frederick Venables filed a purported derivative action against us and certain former officers and certain current and former board members 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. On April 23, 2004, the parties filed a stipulation agreeing to a conditional stay of the action for 270 days, continuing the deadline to respond to the complaint until after expiration of the stay. 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 intend to defend the case vigorously, but cannot assure you that it will be resolved in our favor.

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. 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.

**Table of Contents**

In December 2002, we filed a demand for arbitration before the American Arbitration Association in Minnesota against a former employee. The complaint included various claims in response to which the employee made several counterclaims. In March 2003, we were notified by the United States Department of Labor that counsel for the employee had presented a letter of complaint alleging that we and our former CEO and former CFO violated 18 U.S.C. § 1514A by improperly retaliating against the employee. In December 2003, we and the employee agreed to settle all claims on mutually acceptable terms without the admission of liability by any party for an amount that is not significant. Pursuant to the settlement, the employee withdrew his letter of complaint, and the Department of Labor has indicated that it considers the matter closed.

In June 2003, we were awarded a favorable judgment for \$351,000 in a litigation matter previously initiated by Timm Medical against a third party. Since collection is not assured, any amount recovered in connection with this judgment will be recorded in the period when it is actually paid to us.

**Item 2. Changes in Securities**

In June 2002, we issued 120,022 shares of our common stock to BioLife, an accredited investor, as partial consideration for our acquisition of its cryosurgical assets. 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. BioLife represented to us its intention to acquire the shares for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the certificate evidencing the shares.

**Item 3. Defaults Upon Senior Securities**

None.

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

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits and Reports on Form 8-K.****(a) 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, LLC, 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.

**Table of Contents**

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. (the Purchase Agreement ). Certain schedules and exhibits referenced in the Purchase Agreement have been omitted. We agree to furnish supplementally a copy of any omitted schedules or exhibits to the Commission upon request.
2.6(5)	Amendment No. 1 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of September 30, 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.
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(6)	Amended and Restated Bylaws of the Company.
10.1 (7)	Executive Separation Benefits Plan, approved by the Compensation Committee of the Board of Directors on July 17, 2002.
10.2(8)	Promissory Note, dated July 15, 2002, issued by U.S. Medical Development, Inc. to the Company.
10.3(9)	First Amended and Restated Promissory Note, dated September 30, 2002, issued by U.S. Medical Development, Inc. to the Company.
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 Katherine Greenberg.
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 Katherine Greenberg.

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

Management contract or compensatory plan or arrangement

- (1) Previously filed as an exhibit with our Form 8-K filed on March 5, 2002.
- (2) Previously filed as exhibits with our Registration Statement on Form S-3 filed on September 20, 2001 and October 31, 2001.
- (3) Previously filed as exhibits with our Form 10-Q filed on August 14, 2002.
- (4) Previously filed as an exhibit with our Form 8-K filed on August 16, 2002.
- (5) Previously filed as an exhibit with our Form 8-K filed on October 15, 2002.
- (6) Previously filed as an exhibit with our Form 10-K filed on March 15, 2004.
- (7) Previously filed as an exhibit with our Form 10-K filed on December 3, 2003.
- (8) Previously filed as an exhibit with our Form 8-K filed on August 16, 2002.
- (9) Previously filed as an exhibit with our Form 8-K filed on October 15, 2002.

**(b) Reports on Form 8-K**

On August 16, 2002, we filed a Form 8-K regarding our execution of a definitive Partnership and Limited Liability Company Membership Interest Purchase Agreement (the Purchase Agreement ), to purchase the mobile prostrate treatment businesses of U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C. for aggregate consideration of approximately \$11,210,000.



**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.

ENDOCARE, INC.

By: */s/ CRAIG T. DAVENPORT*

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

By: */s/ KATHERINE GREENBERG*

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Katherine Greenberg  
*Senior Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)*

Date: June 28, 2004



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**Table of Contents**

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44