ENDOCARE INC
Form 10-Q
August 09, 2004

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2004

OR

o **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	**33-0618093**
(State of Incorporation)	*(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 þ No o; (2) Yes þ No o.

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

Yes þ No o

The number of shares of the Registrant s common stock, par value $.001 per share, outstanding at June 30, 2004 was 24,007,482.

Form 10-Q, Quarter Ended June 30, 2004

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PART I FINANCIAL INFORMATION

Item 1. *Condensed Consolidated Financial Statements*

ENDOCARE, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(Unaudited)			
Total revenues	$ 8,312,359	$ 7,490,367	$ 15,693,983	$ 15,152,151
Costs and expenses:				
Cost of revenues	4,313,299	3,469,503	8,547,381	7,465,548
Research and development	451,674	365,437	988,055	698,250
Selling, general and administrative	9,089,147	11,979,009	20,268,637	21,526,866
Total costs and expenses	13,854,120	15,813,949	29,804,073	29,690,664
Loss from operations	(5,541,761)	(8,323,582)	(14,110,090)	(14,538,513)
Gain on divestitures, net	50,523	9,944,424	50,523	9,944,424
Interest income	26,973	218,096	71,863	439,325
Interest expense		(22,521)		(27,298)
Income (loss) before minority interests	(5,464,265)	1,816,417	(13,987,704)	(4,182,062)
Minority interests	(155,392)	(154,965)	(255,428)	(244,384)
Net income (loss)	$ (5,619,657)	$ 1,661,452	$ (14,243,132)	$ (4,426,446)
Net income (loss) per share of common stock basic and diluted				
Basic	$ (0.23)	$ 0.07	$ (0.59)	$ (0.18)
Diluted	(0.23)	0.07	(0.59)	(0.18)
Weighted average shares of common stock outstanding:				
Basic	23,999,882	24,155,740	24,095,318	24,153,862
Diluted	23,999,882	25,287,911	24,095,318	24,153,862

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

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ENDOCARE, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2004	December 31, 2003
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and equivalents	$ 11,369,837	$ 23,976,539
Accounts receivable, net	3,712,392	3,822,570
Inventories	4,325,914	2,609,046
Prepaid expenses and other current assets	3,484,434	4,432,578
Total current assets	22,892,577	34,840,733
Property and equipment, net	4,670,781	5,638,579
Goodwill	17,538,224	17,538,224
Intangibles, net	11,143,742	11,745,778
Investments and other assets	1,619,156	2,233,601
Total assets	$ 57,864,480	$ 71,996,915
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 3,585,996	$ 3,035,242
Accrued compensation	3,374,973	3,858,527
Other accrued liabilities	9,572,339	8,942,830
Total current liabilities	16,533,308	15,836,599
Minority interests	711,909	839,029
Total liabilities	17,245,217	16,675,628
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: 24,007,482 and 24,183,254 issued and outstanding at June 30, 2004 and December 31, 2003, respectively	24,007	24,390
Additional paid-in capital	169,217,273	171,875,434
Accumulated deficit	(128,622,017)	(114,378,885)
Deferred compensation		(107,271)
Treasury stock at cost, 206,200 shares at December 31, 2003		(2,092,381)
Total stockholders equity	40,619,263	55,321,287
Total liabilities and stockholders equity	$ 57,864,480	$ 71,996,915

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

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ENDOCARE, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2004	**2003**
Net cash used in operating activities	$(14,344,198)	$ (7,856,753)
Cash flows from investing activities:		
Sales of property and equipment	219,835	
Purchases of property and equipment	(398,107)	(440,165)
Proceeds from divestitures	2,500,000	6,980,000
Intangibles		(61,000)
Sale of available for sale securities		22,183,160
Other assets	270,445	(1,259,867)
Net cash provided by investing activities	2,592,173	27,402,128
Cash flows from financing activities:		
Stock options and warrants exercised	31,600	20,312
Partnership distributions to minority interests	(382,548)	(222,202)
Treasury stock received in settlement	(503,729)	
Net cash used in financing activities	(854,677)	(201,890)
Net increase (decrease) in cash and cash equivalents	(12,606,702)	19,343,485
Cash and cash equivalents, beginning of period	23,976,539	18,177,825
Cash and cash equivalents, end of period	$ 11,369,837	$37,521,310
Non-cash activities:		
Transfer of inventory to property and equipment	$ 235,936	$ 594,387
Retirement of treasury shares held	2,596,110	
Deferred compensation on options forfeited	93,905	
Unrealized loss on available for sale securities		12,466

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

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Operations of the Company

Endocare, Inc. (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, 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. Following its incorporation under the laws of the state of Delaware in 1994, the Company became an independent, publicly-owned corporation upon Medstone s distribution of the Company s stock to the existing stockholders on January 1, 1996.

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

The accompanying condensed consolidated financial statements reflect all adjustments, consisting solely of normal recurring accruals, needed to present fairly the financial results for these interim periods. The condensed consolidated results of operations presented for the interim periods are not necessarily indicative of the results for a full year.

All intercompany transactions and accounts have been eliminated in the consolidation.

2. Recent Operating Results and Liquidity

The Company s operating results for the second quarter and for the first six months of 2004 reflect the impact of divestitures in 2003 of certain non-core lines of business. While these divestitures provided non-recurring infusions of cash and 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. In addition, while the Company has continued to make progress in lowering its recurring selling, general and administrative costs throughout 2003 and 2004, the Company expects to record another loss for fiscal 2004 and has continued to experience significant non-recurring costs associated with ongoing investigations and other matters related to its historical accounting and financial reporting. These non-recurring costs were approximately $14.3 million during the fiscal year 2003 (including executive severance charges of $3.6 million) and $3.5 million and $5.3 million net of insurance reimbursement for defense-related costs in the first six months of 2003 and 2004, respectively. The costs in the six months ended June 30, 2003 and 2004 are primarily legal, audit and accounting support fees. For the six months ended June 30, 2004 a portion of these costs also related to the Company s efforts to achieve compliance with section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes 404) by the December 31, 2004 deadline.

Since inception, the Company has incurred losses from operations and has reported negative cash flows. As of June 30, 2004, the Company had an accumulated deficit of $128.6 million and cash and cash equivalents of $11.4 million. In addition to the cash needed to fund the Company s ongoing operations, there will continue to be substantial demands on cash related to ongoing investigations of the Company s historical accounting and financial reporting. There may also be material cash payments required in connection with resolving a class action and a derivative law suit (see Note 8). 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.

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company also faces potentially large cash expenditures in the future related to directors and officers liability insurance and indemnification obligations, delinquent state and local tax obligations, as well as additional investment needed to bring the Company into compliance with SEC rules and regulations, including with Sarbanes 404. The Company may also incur costs related to its efforts to regain listing on a national exchange or market.

While the Company has continued to experience growth in cryosurgical probe and procedure revenues through the first six months of 2004 and has significantly reduced its selling, general and administrative costs before non-recurring expenses and insurance recoveries, through this period compared to the same period in 2003, it is not expected to reach break-even or cash flow positive in 2004. The Company will use cash reserves to finance its cash flow deficit throughout the remainder of 2004. In order to continue as a going concern, the Company will need to raise additional capital to fund operations through the sale of debt or equity securities to public or private investors, the sale or licensing of its assets or incurring debt secured by the Company s assets. Additional capital may 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.

3. Restructuring and Cost Reductions

In June 2004, the Company initiated a cost-reduction program, which includes consolidation of certain sales functions and territories, streamlining of its corporate organizational structure, reduction in staffing, and elimination of less promising research and development, clinical and marketing activities. In addition, management is reviewing product design and manufacturing processes in an effort to identify potential cost efficiencies and is renegotiating the Company s contracts with third party cryo-service providers in order to improve gross margins.

As part of this cost-reduction program, the Company incurred total severance and related costs in June 2004 of $319,000 in connection with the elimination of 19 positions. This reduction in work force is expected to generate $2.3 million in annualized savings. This action follows the December 2002 divestiture of a Winter Park, Florida billing subsidiary and the 2003 downsizing of its Timm Medical Technologies, Inc. (Timm Medical) operations in Eden Prairie, Minnesota. These earlier restructurings have contributed to a $3 million overall improvement in selling, general and administrative expenses in the first six months of 2004, compared to the same period last year. Combined, cuts in workforce have resulted in a net headcount reduction from 194 employees at the end of 2002 to 150 employees as of June 30, 2004.

4. Stock-Based Compensation

At June 30, 2004, Endocare had four stock-based compensation plans. The Company accounts for the plans under the recognition and measurement principles (the intrinsic-value method) prescribed in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees,* and related interpretations. Compensation cost for stock options granted to employees is reflected in net income (loss) and is measured as the excess of the market price of the Company s stock at the date of grant over the amount an employee must pay to acquire the stock, or the exercise price. Compensation costs for fixed awards that are subject to vesting are recognized pro-rata over the vesting period. In practice, the Company has only awarded stock options to its employees with exercise prices equal to the fair market value of the stock at the date of grant.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income (loss), as reported(a)	$(5,619,657)	$ 1,661,452	$(14,243,132)	$(4,426,446)
Reconciling items (net of related tax effects):				
Add: Stock-based employee compensation expense determined under the intrinsic-value-based method for all awards(b)	4,383	6,194	13,103	12,388
Less: Stock-based compensation expense determined under the fair-value-based method for all awards	(983,866)	(2,183,808)	(1,804,178)	(3,658,666)
Net adjustment	(979,483)	(2,177,614)	(1,791,075)	(3,646,278)
Net loss, as adjusted	$(6,599,140)	$ (516,162)	$(16,034,207)	$(8,072,724)
Basic and diluted loss per share:				
As reported	$ (0.23)	$ 0.07	$ (0.67)	$ (0.18)
As adjusted	$ (0.27)	$ (0.02)	$ (0.59)	$ (0.33)

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

(b) Since the Company issues options with exercise prices equal to or exceeding the fair values of the underlying common stock, no compensation expense is recorded for options issued to employees, except for compensation expense equal to the intrinsic value of unvested options assumed in the Company s acquisition of Timm Medical and amortized over the remaining vesting period.

5. 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 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. No goodwill impairment indicators existed for the six months ended June 30, 2004 and, as a result, interim impairment testing was not required.

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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 2003 and the first six months of 2004.

6. Amendment to Purchase Agreement of the Mobile Prostate Treatment Business

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 Businesses) from a group of affiliated companies collectively known as USMD. Under the original agreement, the Company agreed to forgive $7.7 million in loans and an earnest deposit if the Mobile Businesses achieve $12 million in gross revenues during the period October 1, 2002 to December 31, 2005 (the Forgiveness Period). The purchase agreement was amended February 2004 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 market rate. As a result, the reduction in service fee does not require a reallocation of goodwill.

7. Dispositions

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, 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

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

of the sale, the Company terminated its pre-existing distribution agreement with CryoCath. CryoCath was the exclusive distributor for cryoprobes and consoles in connection with the SurgiFrost system, a cryoablation system designed to treat cardiac arrhythmias. The sale resulted in a gain of $10 million in the second quarter of 2003. 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. Royalty income from sales of CryoCath products was $162,000 and $293,000 for the three-month and six-month periods ended June 30, 2004, respectively.

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 after the sale of the Dura II and urinary incontinence product lines. With the exception of certain marketing and financial functions, all 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 communication of the separation terms to the affected employees. Since that time, in order to improve service levels related to its Timm Medical products, the Company has returned packaging and shipping operations for its ErecAid products back to the Eden Prairie location.

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. 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 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 $298,000 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, are 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. On May 14, 2004 the Company received the first payment from SRS under the note in the amount of $51,000, which was reported as a gain on divestitures.

Mobile Prostate Treatment Businesses

In late 2003 and early 2004, the Company initiated the dissolution of five of the 13 partnerships acquired from U.S. Medical Development, Inc., and its affiliates, U.S.M.D., Ltd. and U.S.M.D. I L.L.C. (collectively 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

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

8. 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 under the Separation Agreement to the former CFO were released from the escrow account.

Legal Matters

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

In November 2002, the Company was named as a defendant, together with certain former officers, one of whom is also a former board member, in a class-action lawsuit filed in the United States District Court for the Central District of California. On February 2, 2003, the court issued an order consolidating this action with various other similar complaints and ordering plaintiffs to file a consolidated complaint, which was filed on October 31, 2003. The consolidated complaint asserts two claims for relief, alleging that the defendants violated sections of the Securities Exchange Act of 1934 by purportedly issuing false and misleading statements regarding the Company s revenues and expenses in press releases and SEC filings. Plaintiffs seek class certification and unspecified damages from the Company, as well as forfeiture and reimbursement of bonus compensation received by two of the individual defendants. On April 26, 2004, the court issued an order

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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. Pursuant to a stipulation filed on or about April 23, 2004 and approved by the court, the deadline to respond to the complaint has been stayed until 2005. The complaint seeks unspecified monetary damages, equitable relief and injunctive relief based upon allegations that the defendants issued false and misleading statements regarding the Company s revenues and expenses in press releases and SEC filings. The Company intends to defend the case vigorously, but cannot assure you that it will be resolved in the Company s favor.

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

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. On February 20, 2004, the Company agreed with BioLife to settle all claims for $1,887,000, plus return by BioLife to the Company of the 120,022 shares of the Company s common stock referred to above.

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

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

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Related Party Transactions

Loans to Officers

In November 1999, the Company received a full recourse promissory note for $1,028,000 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 Company forgave $64,000 and $129,000 for the three months and six months ended June 30, 2003, respectively, which was recorded as compensation expense (included in selling, general and administrative expense). At December 31, 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 for 100,000 shares of the Company s common stock valued at $1,410,000. The Company extended the loan to the shareholder to assist with the payment of related federal income taxes arising from the 2002 purchase transaction. The loan is secured by the shares issued, bears interest at 1.8% and is due at the earlier of January 2005 or 30 days after the borrower ceases to be a consultant to the Company.

10. Capital Stock and Earnings Per Share

During the first quarter of 2004, the Company retired 326,222 of its common shares held in treasury, including 120,022 shares purchased from BioLife for $504,000 in February 2004, in connection with settlement of its litigation with this company (see Note 8).

Basic earnings (loss) per share are computed by dividing net income (loss) by the weighted average number of common shares outstanding for the respective periods. Diluted earnings (loss) per share, calculated using the treasury stock method, gives effect to the potential dilution that could occur upon the exercise of certain stock options that were outstanding during the respective periods presented. For periods when the

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ENDOCARE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company reported a net loss, these potentially dilutive common shares were excluded from the diluted loss per share calculation because they were anti-dilutive.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss, as reported	$ (5,619,657)	$ 1,661,452	$ (14,243,132)	$ (4,426,446)
Basic and diluted loss per common share	$ (0.23)	$ 0.07	$ (0.59)	$ (0.18)
Basic weighted average shares	23,999,882	24,155,740	24,095,318	24,153,862
Dilutive effect of outstanding stock options and warrants		1,132,171		
Diluted weighted average shares	23,999,882	25,287,911	24,095,318	24,153,862

11. Income Taxes

The Company reported no income tax expense for each of the six months ended June 30, 2004 and 2003 due to its operating losses. The continuing operating losses resulted in an increase in the valuation allowance of $5.7 million and $1.8 million during the six months ended June 30, 2004 and 2003, respectively. Due to the Company s history of operating losses, management has determined that it is more likely than not that the Company s deferred tax assets will not be realized through future earnings. Accordingly, valuation allowances were recorded to fully reserve the Company s deferred tax assets as of June 30, 2004 and 2003.

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

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

This discussion contains forward-looking statements based on our current expectations. There are various factors many beyond our control that could cause our actual results or the occurrence or timing of expected events to differ materially from those anticipated in these forward-looking statements. Some of these factors are described below and other factors are described elsewhere in this Quarterly Report on Form 10-Q. 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 $14.2 million for the six months ended June 30, 2004 and a loss of $25.4 million for the year ended December 31, 2003. As of June 30, 2004, we had an accumulated deficit of $128.6 million. We expect to incur additional losses as we continue our sales and marketing efforts, upgrade our infrastructure, strengthen our financial reporting processes and controls, and improve our 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 into our historical accounting and financial reporting and matters stemming from these investigations, including expenses related to shareholder litigation. (See Notes 2 and 8 to the condensed consolidated financial statements included in this report.)

In June 2004, we adopted a cost-reduction program, which includes consolidation of certain sales functions and territories, streamlining of our corporate organizational structure, reduction in staffing, and elimination of less promising research and development, clinical and marketing activities. In addition, we are reviewing our product design and manufacturing processes in an effort to identify potential cost efficiencies and are renegotiating our contracts with third party cryo-service providers in order to improve our gross margins.

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As part of this cost-reduction program, we incurred total severance and related costs in June 2004 of $319,000 in connection with the elimination of 19 positions. This reduction in work force is expected to generate $2.3 million in annualized savings. This action follows the December 2002 divestiture of our Winter Park, Florida billing subsidiary and the 2003 downsizing of our Timm Medical operations in Eden Prairie, Minnesota. These earlier restructurings have contributed to a $3 million overall improvement in selling, general and administrative expenses in the first six months of 2004, compared to the same period last year. Combined, these reductions in workforce have resulted in a net headcount reduction from 194 employees at the end of 2002 to 150 employees as of June 30, 2004.

Results of Operations

Three and Six Months Ended June 30, 2004 Compared to Three and Six Months Ended June 30, 2003

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 payors for the use of our Cryocare Surgical Systems in cryoablation treatments for which we charge a per-procedure fee. Beginning with the first quarter of 2003, we shifted our sales emphasis for cryosurgical products in the urology market from equipment sales to procedure growth. Through our placement program, we provide equipment to hospitals with high-volume potential for cryosurgery procedures and charge them a per-procedure fee for use of the equipment.

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.

In addition to our cryosurgery products, we sell other products acquired when we purchased Timm Medical, a urological device manufacturer, in the first quarter of 2002. We continue to sell our ErecAid vacuum therapy systems and RigiScan monitors, although in 2003 we either divested or discontinued the remaining urological product lines acquired in the Timm Medical purchase. The reduction in year-over-year sales of our Timm Medical products is largely attributable to these divestitures. Sales of divested or discontinued product lines acquired in the Timm Medical purchase totaled $1,300,000 for the first six months of 2003.

Revenues for the three months ended June 30, 2004 increased 11.0% to approximately $8,312,000 compared to $7,490,000 for the three months ended June 30, 2003. The increase in revenues was primarily attributable to growth in sales of disposables and procedure fees related to our cryosurgical business, partially offset by the impact of divestitures of non-core product lines in 2003.

The number of cryosurgical procedures performed, and related sales of disposable products used in these procedures, grew significantly in the three months ended June 30, 2004 compared to the same period in 2003. Procedures increased 55.1%, from an estimated 833 in the second quarter of 2003 to an estimated 1,292 in the second quarter of 2004, while the related revenues increased 44.2%, from $4,042,000 in the earlier quarter to $5,830,000 in the second quarter of 2004. Contributing to growth in sales of cryosurgical products was an increase in sales of these products into the interventional radiology market. Our average revenue per cryosurgical procedure declined slightly during the first six months of 2004 compared to the same period in 2003. This is partly due to an increase in sales of our cryosurgical disposables, without the service component, directly to hospitals or other service providers, and partly due to pricing pressure from certain of our large hospital customers.

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Sales of our Timm Medical product lines decreased 21.8% from $2,643,000 in the three months ended June 30, 2003 to $2,068,000 in the three months ended June 30, 2004. This was primarily due to the divestiture of the Dura II line of implantable penile prostheses and the divestiture of the urinary incontinence product lines in 2003. Divestitures of these non-core products acquired in the Timm Medical purchase accounted for a reduction of $411,000 in sales.

Revenues from the sale of our Cryocare Surgical Systems were down from $392,000 in the second quarter of 2003 to $116,000 in the second quarter of 2004. This is primarily due to our strategy of promoting adoption of our technology through an emphasis on growth in cryosurgical procedures, rather than through sales of capital equipment.

Revenues for the six months ended June 30, 2004 increased 3.6% to $15,694,000 compared to $15,152,000 in 2003. The increase in revenue is primarily due to growth in sales of cryosurgical disposables and procedure fees, partially offset by divestitures of the urinary incontinence products and the Dura II line. Sales of cryosurgical probes and procedures grew 38.8% from $7,594,000 for the six months ended June 30, 2003 to $10,538,000 for the same period in 2004. Sales of Cryocare Surgical Systems decreased from $508,000 in the first six months of 2003 to $232,000 for the first six months of 2004, due to a reduction in the number of units sold.

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 June 30, 2004 increased 24.3% to $4,313,000 compared to $3,470,000 for the three months ended June 30, 2003. The increase in cost of revenues resulted primarily from growth in sales of cryosurgical probes and procedures, offset by elimination of costs related to the Dura II and urinary incontinence product lines that were divested in the second and fourth quarters of 2003, respectively. Cost of revenues related to our cryosurgical probes and procedures rose $1,280,000, from $1,949,000 to $3,229,000 for the second quarter of 2004 compared to the same period in the prior year. This increase was partly driven by higher probe and procedure revenues and partly by an increase in cryosurgical procedure fees paid to third party service providers.

Cost of revenues for the six months ended June 30, 2004 increased 14.5% to $8,547,000 compared to $7,466,000 in the prior-year period. Reasons for the increase are consistent with the explanations above for the quarter-over-quarter increase. Cost of revenues for cryosurgical probes and procedures for the first six months of 2004 was $6,054,000 compared to $4,182,000 for the first six months of 2003. Cost of revenues related to our Timm Medical product lines fell $597,000 from the six months ended June 30, 2003 to the six months ended June 30, 2004 due to product line divestures.

Gross Margins. Gross margins on revenues declined to 48.1% for the three months ended June 30, 2004 compared to 53.7% for the three months ended June 30, 2003 due primarily to a reduction in gross margins on disposable cryosurgical probes and procedures and to divestiture in 2003 of higher margin product lines acquired in our Purchase of Timm Medical. Margins on cryosurgical disposables and procedures dropped from 51.8% in the second quarter of 2003 to 44.6% in the second quarter of 2004 due to a shift in the composition of our cryosurgical business away from sales of procedures where we earn a service fee towards sales of procedures where we pay a third party to provide the service component or where we sell disposables without a service component.

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Gross margins on revenues for the six months ended June 30, 2004 decreased to 45.5% compared to 50.7% for the same period in 2003 for reasons consistent with those described above.

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. 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 June 30, 2004 increased 23.8% to $452,000 compared to $365,000 for the three months ended June 30, 2003. The increase was primarily attributable to one-time costs incurred in June 2004 in connection with our reduction in staff as well as a higher allocation of costs to R&D for regulatory and quality testing activities. As a percentage of revenues, research and development expenses increased to 5.4% in the second quarter of 2004 from 4.9% during the three months ended June 30, 2003.

Research and development expense for the six months ended June 30, 2004 increased 41.5% to $988,000 compared to $698,000 for the same period in 2003. As a percentage of revenues, research and development expenses increased to 6.3% from 4.6%. The variances are attributable to the reasons stated above, as well as to higher contract engineering costs in 2004 related to product improvements.

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, legal affairs, 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. This category also includes reserves for litigation losses less amounts recoverable under our insurance policies. Litigation reserves and insurance recoveries are recorded when such amounts are probable and can be reasonably estimated. 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 June 30, 2004 decreased 24.1% to $9,089,000 compared to $11,979,000 for the three months ended June 30, 2003 as a result of our efforts to streamline operations beginning with the closure of our Florida billing and contracting subsidiary in December 2002, consolidation of certain Timm Medical operations in our California headquarters in June 2003, divestiture of non-core product lines and elimination of related support costs throughout 2003. Additionally, non-recurring legal and accounting costs incurred in connection with investigations into the Company s historical accounting and financial reporting, as well as for Sarbanes 404 compliance, declined from approximately $2.5 million in the quarter ended June 30, 2003 to approximately $2.0 million in the same period in 2004. As a percentage of revenues, selling, general and administrative expenses declined from 159.9% to 109.3% for the second quarters of 2003 and 2004, respectively.

Selling, general and administrative expenses for the six months ended June 30, 2004 decreased 5.8% to $20,269,000 compared to $21,527,000 for the same period in 2003. Reasons for the decrease in these costs are consistent with those described above. Legal, audit and accounting support fees related to regulatory investigations of the Company s historical accounting and financial reporting and related litigation, were approximately $5.3 million for the six months ended June 30, 2004 compared to $3.5 million for the same period in 2003. Compared to the first six months of 2003, selling, general and administrative costs, before the impact of these non-recurring charges, declined $3.1 million, or 17.2% in the six months ended June 30, 2004.

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Interest Income, Net. Interest income, net, for the three months ended June 30, 2004 was $27,000 compared to $196,000 for the three months ended June 30, 2003. The decrease in net interest income in 2004 compared to 2003 resulted from continued decline in our cash balances.

Interest income, net for the six months ended June 30, 2004 was $72,000 compared to $412,000 for the six months ended June 30, 2003. As for the three month period, the decrease was due to declining cash balances.

Minority Interest. Minority interests represent earnings attributable to minority investors in the mobile prostate treatment businesses we acquired from USMD on September 30, 2002. The amounts recorded for minority interests were $155,000 and $255,000 for the three months and six months ended June 30, 2004, respectively, compared to $155,000 and $244,000 for the three months and six months ended June 30, 2003, respectively. Revenues and earnings from these businesses remained consistent with our overall operations.

Gain on Divestitures, Net. During the three months ended June 20, 3003 we recorded a net gain of approximately $9.9 million related to divestiture of the SurgiFrost and Dura II product lines. Also, in April 2003, we sold the intangibles and inventory related to our Dura II products to American Medical Systems for $2.2 million resulting in a net loss of approximately $35,000.

Net income (Loss). Net loss for the three months ended June 30, 2004 was $5,620,000 or $0.23 per diluted share on 24,000,000 weighted average shares outstanding, compared to net income of $1,661,000, or $0.07 per diluted share on 25,288,000 weighted average shares outstanding for the same period in 2003. The net income in the 2003 period is primarily a result of the gain on divestitures, as discussed above.

Our net loss for the six months ended June 30, 2004 was $14,243,000, or $0.59 per diluted share, on 24,095,000 weighted average shares outstanding, compared to a net loss of $4,426,000, or $0.18 per share, on 24,154,000 weighted average shares outstanding for the same period in 2003.

Liquidity and Capital Resources

Since inception, we have incurred losses from operations and have reported negative cash flows. As of June 30, 2004, we had an accumulated deficit of $128.6 million and cash and cash equivalents of $11.4 million. We currently have no long-term debt, and no long-term financial obligations other than under operating leases and purchase commitments for raw material used in manufacturing our products. Although we believe that our existing cash and cash equivalents will be sufficient to fund our working capital requirements, capital expenditures and other obligations through 2004, there are certain risks and uncertainties that could, in the future, change our opinion regarding the adequacy of our capital resources. During the six months ended June 30, 2004, $14.2 million of our cash was used to fund operating losses. These losses were partially offset by our efforts to reduce net uses of working capital through aggressive collections of accounts receivable, management of vendor payables, and deferral of non-essential capital expenditures.

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, as described above in Note 8 to our condensed consolidated financial statements. In addition, during the first six months of 2004 we incurred approximately $5.3 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 and with our efforts to gain compliance with Sarbanes 404.

We face the possibility that there will be additional material cash payments required in connection with resolving matters related to the investigations into our historical accounting and financial reporting. We and certain former officers and certain current and former board members have been named defendants in a class action and a derivative lawsuit. In addition, we, current and former members of our Board of Directors, former members of our senior management, former sales personnel, and our current head of sales and marketing have

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received Wells Notices from the SEC (See Note 8 to our condensed consolidated financial statements contained in this report). We are generally obliged, to the extent permitted by law, to indemnify our directors and officers who are named defendants in litigation related to their service. At this point in time we are unable to provide a reasonable estimate of our potential liability in these cases.

We may be required to pay judgments or settlements and to incur expenses in defending against these claims that could be material. Further, while we carry $20 million of director s and officers liability insurance coverage, this coverage may not be adequate to cover all costs related to these lawsuits, including any resulting judgments or settlements. As described below under Risks Related to Our Business, for claims asserted during the period from June 10, 2002 through June 10, 2003, our three excess carriers have filed arbitration complaints, contending our former management made misstatements or omissions in the applications for insurance coverage and seeking rescission of the policies. 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, maintaining compliance with the SEC rules and regulations required of publicly traded companies, including Sarbanes 404, and fulfilling requirements prerequisite to becoming re-listed on a national stock exchange or market. We are currently projecting an operating loss for fiscal 2004, as well as a net use of cash.

While we have continued to experience growth in cryosurgical probe and procedure revenues through the first six months of 2004 and have reduced our selling, general and administrative costs through this period compared to the same period in 2003, we are not expected to reach break-even or cash flow positive in 2004. We will use cash reserves to finance our cash flow deficit in 2004. In order to continue as a going concern, we will need to raise additional capital to fund operations through the sale of equity securities to public or private investors, incurring debt, or the sale or licensing of our assets. Additional capital may not be available on terms acceptable us, or at all. If additional capital were raised through the issuance of equity securities, the percentage of our stock owned by our then-current stockholders would be reduced.

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

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governance policies and procedures. The significant time and effort spent has adversely affected our operations and may continue to do so in the future.

We face risks relating to our liquidity.

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

In addition we are making significant investments in the development and implementation of sound internal controls and corporate governance policies and procedures designed to enhance the accuracy, quality and consistency of our financial information and reporting. 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, 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.

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We have incurred annual operating losses each year since our inception. For the six months ended June 30, 2004, and 2003, we had losses from operations of approximately $14.1 million and $14.5 million, respectively. As of June 30, 2004, our accumulated deficit was approximately $128.6 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 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

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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 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, 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.

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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 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.

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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.

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

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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 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

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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 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

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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 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.

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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.

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, our three excess carriers have filed arbitration complaints, contending our former management made misstatements or omissions in the applications for insurance coverage and seeking rescission of the policies. 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.

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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;

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;

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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 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 then 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

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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. At June 30, 2004, the carrying values of our financial instruments approximated their fair values. Our policy is not to enter into derivative financial instruments. In addition, we do not enter into any futures or forward contracts and therefore, we do not have significant market risk exposure with respect to commodity prices.

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

Item 4. ***Controls and Procedures***

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

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

Since March 2003, management has implemented and continues to implement significant changes in organization, policies and procedures designed to enhance our disclosure controls and procedures and the related internal controls. Nevertheless, during much of 2003, many of these enhancements to our disclosure controls and procedures and the related internal controls were not yet in place, or were only partially in place. In addition, until the recent filing of our past due reports on Form 10-Q, we have not been current in our reporting under Section 15(d) of the Securities Exchange Act of 1934. For this reason, management has undertaken an extensive and substantive review and evaluation of all financial transactions that, individually or collectively, could have a material impact on the information contained in this Form 10-Q. These review

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procedures, in combination with the changes in internal control that have been implemented as of the end of the period covered by this report, form the basis for our determination that the financial statements and other information contained in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the six months ended June 30, 2003 and 2004.

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

PART II OTHER INFORMATION

Item 1. *Legal Proceedings*

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

In November 2002, we were named as a defendant, together with certain former officers, one of whom is also a former board member, in a class-action lawsuit filed in the United States District Court for the Central District of California. On February 2, 2003, the court issued an order consolidating this action with various other similar complaints and ordering plaintiffs to file a consolidated complaint, which was filed on October 31, 2003. The consolidated complaint asserts two claims for relief, alleging that the defendants violated sections of the Securities Exchange Act of 1934 by purportedly issuing false and misleading statements regarding our revenues and expenses in press releases and SEC filings. Plaintiffs seek class certification and unspecified damages from us, as well as forfeiture and reimbursement of bonus compensation received by two of the individual defendants. On April 26, 2004, the court issued an order denying our motion to dismiss the consolidated complaint. We intend to defend the case vigorously, but cannot assure you that it will be resolved in our favor.

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. Pursuant to a stipulation filed on or about April 23, 2004 and approved by the court, the deadline to respond to the complaint has been stayed until 2005. The complaint seeks unspecified monetary damages, equitable relief and injunctive relief based upon allegations that the defendants issued false and misleading statements regarding our revenues and expenses in press releases and SEC filings. We 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. On June 30, 2004, we reported our receipt of a Wells Notice from the SEC and the issuance of Wells Notices to our former senior management, former sales personnel, and our current head of sales and marketing. On July 23, 2004, we reported the receipt of Wells Notices from the SEC by two former members and one current member of our board of directors, all of whom are former members of our audit committee. We are cooperating fully with this investigation. We cannot assure you that this matter will be resolved in our favor.

The DOJ is currently conducting an investigation into allegations that we and certain of our current and former officers and directors intentionally issued or caused to be issued false and misleading statements

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regarding our revenues and expenses in SEC filings. We are cooperating fully with this investigation. We cannot assure you that this matter will be resolved in our favor.

Item 2. ***Changes in Securities and Use of Proceeds***

In May 2004 we issued 15,000 shares to a former director upon his exercise of stock options granted to him while he was a director. The exercise price of these options ranged from $2.06 to $2.13 per share, for an aggregate exercise price of $31,612. We issued these shares in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, in that the issuance did not involve a public offering. The issuee represented to us his 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***

Not applicable.

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.
2.4(3)	Asset Purchase Agreement dated May 28, 2002, by and among the Company and Cryomedical Sciences, Inc. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.5(4)	Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of August 12, 2002, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C. Certain schedules and exhibits referenced in this exhibit have been omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.6(5)	Amendment No. 1 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of August 12, 2002, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C.

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Exhibit No.	Description
2.7(6)	Agreement of Purchase and Sale, dated as of April 7, 2003, by and among American Medical Systems, Inc., the Company and Timm Medical Technologies, Inc.
2.8(7)	Asset Purchase and Technology License Agreement, dated as of April 29, 2003, by and between the Company and CryoCathTechnologies Inc.
2.9(8)	Agreement of Purchase and Sale, dated as of October 15, 2003, by and between SRS Medical Corp. and Timm Medical Technologies, Inc.
2.10(9)	Amendment No. 2 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of February 27, 2004, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C.
2.11(9)	Service Fee Agreement, dated as of February 26, 2004, by and among Endocare, Inc. and the Limited Partners of Mid-America Cryotherapy, L.P.
2.12(9)	First Amendment to Agreement of Purchase and Sale, dated as of March 25, 2004, by and between SRS Medical Corp. and Timm Medical Technologies, Inc.
3.1(2)	Certificate of Amendment of Restated Certificate of Incorporation of the Company.
3.2(2)	Certificate of Designation of Series A Junior Participating Preferred Stock of the Company.
3.3(2)	Restated Certificate of Incorporation.
3.4(10)	Amended and Restated Bylaws of the Company.
10.1	Letter Agreement, dated as of June 9, 2004, by and between the Company and Katherine Greenberg.
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 exhibits to our Form 8-K filed on March 5, 2002.

(2) Previously filed as exhibits to our Registration Statement on Form S-3 filed on September 20, 2001 and October 31, 2001.

(3) Previously filed as exhibits to our Form 10-Q filed on August 14, 2002.

(4) Previously filed as exhibits to our Form 8-K filed on August 16, 2002.

(5) Previously filed as an exhibit to our Form 8-K filed on October 15, 2002.

(6) Previously filed as an exhibit to our Form 8-K filed on April 22, 2003.

(7) Previously filed as an exhibit to our Form 8-K filed on April 29, 2003.

(8) Previously filed as an exhibit to our Form 8-K filed on October 20, 2003.

(9) Previously filed as an exhibit to our Form 10-Q filed on May 10, 2004.

(10) Previously filed as an exhibit to our Form 10-K filed on March 15, 2004.

(b) *Reports on Form 8-K*

We furnished a Form 8-K under Item 12 on May 11, 2004 to report the release of our unaudited financial results for the quarter ended March 31, 2004.

We filed a Form 8-K under Item 5 on June 30, 2004 to report our receipt of a Wells Notice from the SEC and the issuance of Wells Notices to our former senior management, former sales personnel and our current head of sales and marketing.

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SIGNATURES

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

ENDOCARE, INC.

By: /s/ CRAIG T. DAVENPORT

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

By: /s/ KATHERINE GREENBERG

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

Date: August 9, 2004

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2.4(3)	Asset Purchase Agreement dated May 28, 2002, by and among the Company and Cryomedical Sciences, Inc. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.5(4)	Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of August 12, 2002, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C. Certain schedules and exhibits referenced in this exhibit have been omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.6(5)	Amendment No. 1 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of August 12, 2002, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C.
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2.9(8)	Agreement of Purchase and Sale, dated as of October 15, 2003, by and between SRS Medical Corp. and Timm Medical Technologies, Inc.
2.10(9)	Amendment No. 2 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of February 27, 2004, by and among Endocare, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C.
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Exhibit No.	Description
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