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ENDOCARE INC
Form 10-Q
August 15, 2001

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

FORM 10-Q

(Mark One)

☒ Quarterly report pursuant to Section 13 or 15(d) of the Securities
Exchange Act of 1934

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2001

or

☐ Transition report pursuant to Section 13 or 15(d) of the Securities
Exchange Act of 1934

For the transition period from _____ to _____

COMMISSION FILE NUMBER 0-27212

ENDOCARE, INC.

(Exact name of registrant as specified in its charter)

Delaware 33-0618093
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)

7 STUDEBAKER, IRVINE, CALIFORNIA 92618
(Address of principal executive office) (Zip Code)

(949) 595-4770
(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. YES ☒ NO ☐

The number of shares of the Registrant's Common Stock, par value \$.001 per share, outstanding on August 6, 2001 was 16,820,868.

ENDOCARE, INC.
FORM 10-Q, QUARTER ENDED JUNE 30, 2001
INDEX

PAGE

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Part I. Financial Information

Item 1. Financial Statements (unaudited)

Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2001 and 2000 . . .	3
Condensed Consolidated Balance Sheets at June 30, 2001 and December 31, 2000	4
Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2001 and 2000	5
Notes to Condensed Consolidated Financial Statements	6

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	9
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Item 3. Quantitative and Qualitative Disclosures About Market Risk	18
--	----

Part II. Other Information

Item 1. Legal Proceedings	19
Item 2. Changes in Securities	19
Item 3. Defaults Upon Senior Securities	19
Item 4. Submission of Matters to a Vote of Security Holders	19
Item 5. Other Information	20
Item 6. Exhibits and Reports on Form 8-K	20
Signature Page	21

ITEM 1. FINANCIAL STATEMENTS

ENDOCARE, INC. AND SUBSIDIARY CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS JUNE	
	2001	2000	2001	
Revenues:				
Net sales.	\$ 3,537,849	\$ 1,565,213	\$ 6,293,436	\$
Costs and expenses:				
Cost of sales.	1,272,403	754,687	2,446,293	
Research and development	923,445	820,944	1,826,264	
Selling, general and administrative. . . .	3,440,374	3,194,905	6,464,494	
	-----	-----	-----	-----

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Total costs and expenses	5,636,222	4,770,536	10,737,051	
Loss from operations.	(2,098,373)	(3,205,323)	(4,443,615)	
Interest income (expense), net.	34,467	(146,070)	37,541	
Net loss.	\$ (2,063,906)	\$ (3,351,393)	\$ (4,406,074)	\$
Net loss per share of common stock - basic and diluted	\$ (.13)	\$ (.27)	\$ (.29)	\$
Weighted average shares of common stock outstanding	15,601,688	12,535,000	15,379,381	

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

ENDOCARE, INC. AND SUBSIDIARY CONDENSED CONSOLIDATED BALANCE SHEETS

	JUNE 30, 2001 (UNAUDITED)	DECEMBER 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents.	\$ 15,927,694	\$ 22,016,448
Accounts receivable, net	3,670,629	2,113,766
Inventories.	2,197,975	1,543,733
Prepaid expenses and other current assets. .	116,152	178,972
Total current assets	21,912,450	25,852,919
Property and equipment, net	1,448,376	1,496,153
Investments, intangible and other assets, net .	4,557,689	1,495,718
Total assets	\$ 27,918,515	\$ 28,844,790
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,997,483	\$ 2,231,344
Accrued compensation.	1,822,198	1,646,079
Other accrued liabilities.	1,350,468	1,523,602
Credit facility	1,558,011	1,000,000

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Total current liabilities	6,728,160	6,401,025
Convertible debentures.	2,300,000	7,500,000
Note payable and other liabilities.	54,971	74,268
	-----	-----
Total liabilities	9,083,131	13,975,293
Shareholders' equity:		
Preferred stock, \$.001 par value; 1,000,000		
shares authorized; none issued and outstanding	--	--
Common stock, \$.001 par value; 16,177,495 and		
15,018,649 issued and outstanding at June 30,		
2001 and December 31, 2000, respectively	16,178	15,019
Additional paid-in capital.	56,426,656	48,163,186
Note receivable from stock sale	(1,028,125)	(1,135,457)
Accumulated deficit	(36,579,325)	(32,173,251)
	-----	-----
Total shareholders' equity.	18,835,384	14,869,497
Total liabilities and shareholders' equity.	\$ 27,918,515	\$ 28,844,790
	=====	=====

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

ENDOCARE, INC. AND SUBSIDIARY CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	SIX MONTHS ENDED JUNE 30,	
	2001	2000
Cash flows from operating activities:		
Net loss.	\$ (4,406,074)	\$ (6,365,061)
Adjustments to reconcile net loss to net		
cash used in operating activities:		
Depreciation and amortization	196,460	274,501
Amortization of warrant value	98,124	191,674
Amortization of deferred financing costs.	89,937	284,114
Changes in operating assets and liabilities:		
Accounts receivable	(1,556,863)	(51,017)
Inventories	(617,172)	(527,334)
Prepaid expenses and other current assets	38,656	37,460
Other assets.	(118,053)	386,612
Accounts payable.	(233,861)	630,027
Accrued compensation.	176,119	98,278
Other accrued liabilities	(92,939)	238,081
Net cash used in operating activities	(6,425,665)	(4,802,665)
	-----	-----
Cash flows from investing activities:		
Purchases of property and equipment	(117,054)	(99,655)
Investment in alliances and patent.	(458,850)	(435,000)
	-----	-----
Net cash used in investing activities	(575,904)	(534,655)
	-----	-----

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Cash flows from financing activities:		
Borrowings under the credit facility . . .	558,011	258,040
Issuance of common stock	354,806	754,559
Issuance of convertible debentures	--	8,000,000
Financing costs	--	(585,000)
Net cash provided by financing activities . . .	912,814	8,427,599
<hr/>		
Net decrease in cash and cash equivalents . . .	(6,088,754)	3,090,279
Cash and cash equivalents, beginning of period.	22,016,448	7,364,951
<hr/>		
Cash and cash equivalents, end of period. . . .	\$ 15,927,694	\$ 10,455,230
<hr/>		
Non-cash activities:		
Convertible debentures and accrued interest converted to common stock, net of unamortized deferred financing costs of \$1,573,585 and \$217,750 in 2001 and 2000, respectively		
Issuance of common stock as investment	2,837,293	--
Acquisition of trademark and domain name through issuance of 20,000 shares of common stock	--	435,000
Transfer of inventory to property and equipment for placement at customer sites	42,930	483,154
Forgiveness of recourse loan and compensation to employees	81,747	--
<hr/>		
Total non-cash activities	\$ 8,416,746	\$ 7,524,318
<hr/>		

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

ENDOCARE, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Organization and Operations of the Company

Endocare, Inc. ("Endocare" or the "Company") is a vertically-integrated medical device company that develops, manufactures and markets cryosurgical applications in oncology and urology. Cryoablation is the use of sub-zero temperatures to destroy abnormal tissue. The Company also operates a mobile cryosurgery business. The Company has concentrated on developing devices for the treatment of the two most common diseases of the prostate, prostate cancer and benign prostate hyperplasia. The Company is also developing cryosurgical technologies for treating tumors in other organs, including the kidney, breast, liver and lung. Additionally, the Company is developing stent technologies for urological disorders.

2. Financial Information

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements contain all adjustments necessary (consisting only of normal recurring accruals) to present fairly the financial information contained therein. These statements do not include all disclosures required by accounting principles generally accepted in the United States of America and should be read in conjunction with the audited consolidated financial statements and other information included in the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

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Financial results for this interim period are not necessarily indicative of results to be expected for the full year 2001.

Accounting Principles

In July 2001, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations" and No. 142, "Goodwill and Other Intangible Assets." Statement 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001 as well as all purchase method business combinations completed after June 30, 2001. Statement 141 also specifies criteria for intangible assets acquired in a purchase method business combination must meet to be recognized and reported apart from goodwill, noting that any purchase price allocable to an assembled workforce may not be accounted for separately. Statement 142 will require that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead tested for impairment at least annually in accordance with the provisions of Statement 142. Statement 142 will also require that intangible assets with definite useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of."

The Company is required to adopt the provisions of Statement 141 immediately, except with regard to business combinations initiated prior to July 1, 2001, and Statement 142 effective January 1, 2002. Furthermore, any goodwill and any intangible asset determined to have an indefinite useful life that are acquired in a purchase business combination completed after June 30, 2001 will not be amortized, but will continue to be evaluated for impairment in accordance with the appropriate pre-Statement 142 accounting literature. Goodwill and intangible assets acquired in business combinations completed before July 1, 2001 will continue to be amortized prior to the adoption of Statement 142.

Because of the extensive effort needed to comply with adopting Statements 141 and 142, it is not practicable to reasonably estimate the impact of adopting these Statements on the Company's financial statements, including whether any transitional impairment losses will be required to be recognized as the cumulative effect of a change in accounting principle.

3. Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

4. Supplemental Financial Statement Data

	JUNE 30, 2001	DECEMBER 31, 2000
Inventories:		
Raw materials . .	\$1,078,188	\$ 763,389
Work in process .	660,274	288,480
Finished goods. .	459,513	491,864
	-----	-----
Total inventories	\$2,197,975	\$ 1,543,733

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5. Net Loss Per Share

Under SFAS No. 128, "Earnings Per Share", basic EPS is calculated by dividing net earnings (loss) by the weighted-average common shares outstanding during the period. Diluted EPS reflects the potential dilution to basic EPS that could occur upon conversion or exercise of securities, options, convertible debentures, or other such items, to common shares using the treasury stock method based upon the weighted-average fair value of the Company's common shares during the period. In accordance with SFAS 128, the consolidated net loss (numerator), shares (denominator) and per-share amounts for the three months ended June 30, 2000 and June 30, 2001 are \$(3,351,393), 12,535,000 \$(0.27), and \$(2,063,906), 15,601,688 and \$(0.13), respectively. The consolidated net loss (numerator), shares (denominator) and per share amount for the six months ended June 30, 2000 and 2001 are \$(6,365,061), 11,917,000 and \$(0.53), and \$(4,406,074), 15,379,381 and \$(0.29), respectively. As the Company has been in a consolidated net loss position for the periods presented, the potential dilution from the conversion of options, warrants and convertible debentures to common stock of approximately 4,310,000 and 3,435,000 for the three months ended June 30, 2000 and 2001, respectively, and 4,674,000 and 3,435,000 for the six months ended June 30, 2000 and 2001, respectively, were not used to compute diluted loss per share as the effect was antidilutive. Consequently, diluted EPS equals basic EPS.

The Company's revenues are derived from cryosurgical product sales and cryosurgery procedures. The Company's revenues from cryosurgical procedures for the three and six month period ended June 30, 2001 and 2000 were \$412,000, \$754,000, \$172,000 and \$345,000, respectively.

6. Collaborative Agreements

On June 30, 2001, the Company issued 213,010 shares of Common Stock valued at their fair value of \$2,837,293 in consideration for a membership interest, in the form of Class A Units of U.S. Therapies, L.L.C. ("UST"), equal to approximately five percent (5%) of the total issued and outstanding Class A units of UST on a fully-diluted basis. In a related "Distributor Agreement", U.S. Medical Devices Ltd. ("USMD"), a subsidiary of UST, was appointed a distributor and given exclusive distribution rights to the Company's Cryocare Probe Surgical System and associated disposable products in certain territories and for certain customers. The investment in UST is included in investments, intangible and other assets in the accompanying consolidated balance sheet for June 30, 2001. The Company has recorded sales of \$1,310,000 and \$1,955,000 to USMD for the three months and six months ended June 30, 2001, respectively.

In October 1999, the Company entered into a strategic alliance with Sanarus Medical, Inc. ("Sanarus") to commercialize the Company's proprietary cryosurgical technology in the treatment of breast cancer, benign breast tumors and gynecological diseases. The terms of the related agreements included an equity investment by the Company in Sanarus totaling \$300,000 and a warrant received by the Company to acquire at that time approximately 57% of Sanarus common stock in consideration for entering into a manufacturing supply and license agreement. In the event the Company were to exercise the warrant at that time, the Company would then own a majority equity position in Sanarus. The investment is included in other assets in the accompanying consolidated balance sheets as of December 31, 2000 and June 30, 2001 and is reflected at cost, which approximates fair market value, as the Company does not have significant influence over the operations of Sanarus. In June 2001, the Company provided a bridge loan to Sanarus in the amount of \$250,000. This amount was subsequently repaid in July 2001 upon Sanarus' receipt of a secondary equity financing round from outside investors. Sanarus' second round of financing effectively reduced

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the Company's ownership percentage to approximately 21% on a fully-diluted basis at July 2001.

7. Debt

Convertible Debentures

On May 5, 2000, the Company received \$8,000,000 from the sale of additional debentures to the same institutional investors pursuant to certain call options referenced above, of which \$500,000 was converted into 74,074 shares of common stock during the fourth quarter of 2000, \$1,000,000 was converted into 148,148 shares of common stock during the first quarter of 2001 and \$4,200,000 was converted into 622,222 shares of common stock during the second quarter of 2001. Financing costs totaling \$585,000 associated with the transaction are being amortized to interest expense over three years. In July 2001, the final \$2,300,000 was converted into 340,741 shares of common stock.

Credit Facility

On July 29, 1999, the Company entered into a Loan and Security Agreement with a lender which originally provided for a revolving credit line in the amount of \$2,000,000 plus up to an additional \$1,000,000 based on eligible accounts receivable of the Company (the "Loan"). In April 2000, the Company increased the revolving portion of its credit facility from \$2,000,000 to \$4,000,000 in addition to the \$1,000,000 based on eligible accounts receivable of the Company. As of June 30, 2001, \$1,558,000 of the loan was outstanding. The Loan accrued interest at the highest prime or equivalent rate announced by certain designated banks, plus 2% for the portion of the loan based on eligible accounts receivable or 3.5%. The Loan was secured by a first priority lien on all of the assets of the Company, except for intellectual property, was fully guaranteed by AMP, and contained certain restrictive covenants. The Company was in compliance with the restrictive covenants of the agreement as of June 30, 2001. The loan matured on July 31, 2001 and was paid in full on that date.

8. Stockholders' Rights Plan

In April 1999, the Company adopted a stockholder rights plan in which preferred stock purchase rights were distributed as a dividend at the rate of one right for each share of common stock held as of the close of business on April 15, 1999. The rights are designed to guard against partial tender offers and other abusive and coercive tactics that might be used in an attempt to gain control of the Company or to deprive the Company's stockholders of their interest in the long-term value of the Company. The rights will be exercisable only if a person or group acquires 15% or more of the Company's common stock (subject to certain exceptions stated in the Plan) or announces a tender offer the consummation of which would result in ownership by a person or group of 15% or more of the Company's common stock. At any time on or prior to the close of business on the first date of a public announcement that a person or group has acquired beneficial ownership of 15% or more of the Company's common stock (subject to certain exceptions stated in the Plan), the rights are redeemable for one cent per right at the option of the Board of Directors.

9. Legal Proceedings

In March 2000, the Company filed in the U.S. District Court for the Central District of California, two separate patent infringement lawsuits, one against Israeli-based Galil Medical, Ltd, and its U.S. affiliate, Galil Medical USA, Inc. (collectively, "Galil") and the other against Cryomedical Sciences, Inc. ("CMSI"). In March 2001 and December 2000, the parties reached a settlement in these actions. Each of Galil and CMSI stipulated for purposes of their respective settlement agreements that the Company's patent combining cryo-cooling, ultrasound and temperature monitoring technology is valid and

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enforceable. The settlements resulted in certain cross-licensing agreements between Galil and Endocare and between CMSI and Endocare.

In the normal course of business, the Company is subject to various other legal matters. While the results of litigation and claims cannot be predicted with certainty, the Company believes that the final outcome of these matters will not have a material adverse effect on its consolidated results of operations or financial condition.

ITEM 2.

ENDOCARE, INC. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following 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, 2000.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations may contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended and are subject to the Safe Harbor provisions created by that statute. Our business and results of operations are subject to various risks and uncertainties including, but not limited to, those discussed under the caption "Factors That May Affect Our Future Results and The Trading Price of Our Common Stock" included elsewhere in this report, and in risk factors contained in our other periodic reports filed with the Securities and Exchange Commission. Such risk factors include, but are not limited to, limited operating history of our business with a history of losses; fluctuations in our order levels; uncertainty regarding market acceptance of our current and new products; uncertainty of product development and the associated risks related to clinical trials; the rapid pace of technological change in our industry; our limited sales, marketing and manufacturing experience, and the ability to convince health care professionals and third party payers of the medical and economic benefits of our Cryocare System. The actual results that we achieve may differ materially from any forward-looking statements due to such risks and uncertainties and we undertake no obligation to update any such forward-looking statements.

General

We are a fully-integrated medical device company that develops, manufactures and markets cryosurgical technologies and are developing stent technologies for applications in oncology and urology. We have concentrated on developing devices for the treatment of the two most common diseases of the prostate, prostate cancer and benign prostate hyperplasia. We are also developing cryosurgical technologies for treating tumors in other organs, including the kidney, breast, liver and lung.

We derive revenues primarily from the sale of our Cryocare Systems, related disposable Cryoprobes and revenue from mobile cryosurgical procedures. Revenues are recognized upon the shipment of products, or in the case of our mobile cryosurgical procedures, upon the completion of procedures.

Results of Operations

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Three and six months ended June 30, 2001 and 2000

Net sales for the three months ended June 30, 2001 increased 126% to \$3,538,000 compared to \$1,565,000 for the three months ended June 30, 2000. The increase was attributable primarily to the increased sales of our Cryocare System and related disposable Cryoprobes following Medicare's July 1, 1999 implementation of national coverage for localized prostate cancer due to the expanded commercialization of the product and collaborative sales alliances. Our business plan is focused primarily on the sale and placement of Cryocare Systems and related disposables.

Net sales for the six months ended June 30, 2001 increased 119% to \$6,293,000 compared to \$2,876,000 in 2000. The increase is attributed to the reasons stated above.

Gross margin on net sales was 64% for the three months ended June 30, 2001 compared to 52% for the three months ended June 30, 2000. The increase is due primarily to a mix of higher margin cryosurgical system and probe sales coupled with a reduction in product costs due primarily to increased manufacturing efficiencies.

Gross margin on net products sales for the six months ended June 30, 2001 was 61% compared to 52% for the same period in 2000. The increase is due to the reasons described above.

Research and development expense for the three months ended June 30, 2001 increased 12% to \$923,000, compared to \$821,000 for the three months ended June 30, 2000. The increase primarily reflects the investment we have made in the form of additional personnel and related infrastructure to support general product improvement in our Cryocare System, new product development efforts and clinical costs associated with the Horizon Prostatic Stent .

Research and development expense for the six months ended June 30, 2001 increased 18% to \$1,826,000, compared to \$1,545,000 for the same period in 2000. The increase is primarily attributable to continued investment in new product development and the improvement of existing products.

Selling, general and administrative expense for the three months ended June 30, 2001 increased 8% to \$3,440,000, compared to \$3,195,000 for the three months ended June 30, 2000. The increase reflects increased sales and marketing costs, including increased sales commissions, associated with increased commercialization of our cryosurgical product for prostate cancer.

Selling, general and administrative expense for the six months ended June 30, 2001 increased 10% to \$6,464,000, compared to \$5,855,000 for the same period in 2000. The increase is primarily attributable to increased sales, marketing and infrastructure costs.

Interest income (expense), net for the three months ended June 30, 2001 was \$34,000, compared to \$(146,000) for the three months ended June 30, 2001. The increase was primarily due to increased interest income associated with a higher balance of cash and cash equivalents in 2001, partially offset by interest expense.

Interest income (expense), net for the six months ended June 30, 2001 was \$38,000 compared to \$(471,000) for the six months ended June 30, 2000. The increase is primarily due to increased interest income associated with a higher balance of cash and cash equivalents in 2001, partially offset by interest expense.

Our net loss for the three months ended June 30, 2001 was \$2,064,000 or 13 cents per share on 15,602,000 weighted average shares outstanding, compared to a net

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loss of \$3,351,000, or 27 cents per share on 12,535,000 weighted average shares outstanding for the same period in 2000. The decrease in net loss primarily resulted from increased revenues and lower cost of sales as a percentage of sales and increased interest income, partially offset by higher research and development and selling, general and administrative expenses.

Our net loss for the six months ended June 30, 2001 was \$4,406,000 or 29 cents per share on 15,379,000 weighted average shares outstanding compared to a net loss of \$6,365,000 or 53 cents per share on 11,917,000 weighted average shares outstanding for the same period in 2000. The decrease in net loss is primarily attributable to increased revenues and lower cost of sales as a percentage of sales and increased interest income, partially offset by higher research and development and selling, general and administrative expenses.

Liquidity and Capital Resources

At June 30, 2001, our cash and cash equivalent balance was \$15,928,000 compared to \$22,016,000 at December 31, 2000. The decrease was due primarily to cash used by operating activities. At June 30, 2001, our net working capital was \$15,184,000 and the ratio of current assets to current liabilities was 3 to 1.

For the six months ended June 30, 2001, net cash used in operating activities was \$6,426,000 compared to \$4,803,000 for the same period in 2000. In conjunction with the increased sales of our Cryocare System and related disposable Cryoprobes for prostate cancer, inventory increased to \$2,198,000 at June 30, 2001, compared to \$1,544,000 at the beginning of the year and net accounts receivable increased to \$3,671,000 at June 30, 2001, compared to \$2,114,000 at December 31, 2000. Additions to property and equipment during the first six months of 2001 were approximately \$117,000. Current liabilities increased to \$6,728,000 at June 30, 2001 from \$6,401,000 at December 31, 2000.

On June 30, 2001, the Company issued 213,010 shares of Common Stock valued at their fair value of \$2,837,293 in consideration for a membership interest, in the form of Class A Units of U.S. Therapies, L.L.C. ("UST"), equal to approximately five percent (5%) of the total issued and outstanding Class A units of UST on a fully-diluted basis. In a related "Distributor Agreement", U.S. Medical Devices Ltd. ("USMD"), a subsidiary of UST, was appointed a distributor and given exclusive distribution rights to the Company's Cryocare Probe Surgical System and associated disposable products in certain territories and for certain customers. The investment in UST is included in investments, intangible and other assets in the accompanying consolidated balance sheet for June 30, 2001. The Company has recorded sales of \$1,310,000 and \$1,955,000 to USMD for the three months and six months ended June 30, 2001, respectively.

In June and July 1999, we received a total of \$8,000,000 from the sale to institutional investors of 7% convertible debentures due in three years from the date of issuance. During the second quarter of 2000, the \$8,000,000 in convertible debentures was converted into 1,475,610 shares of common stock under the terms of the agreements. On May 5, 2000, we received \$8,000,000 from the sale of the additional 7% convertible debentures to institutional investors pursuant to the purchase options discussed above, of which \$500,000 was converted into 74,074 shares of common stock during the fourth quarter of 2000, \$1,000,000 was converted into 148,148 shares of common stock during the first quarter of 2001 and \$4,200,000 was converted into 622,222 shares of common stock during the second quarter of 2001. In July 2001, the final \$2,300,000 was converted into 340,741 shares of common stock.

On July 29, 1999, the Company entered into a Loan and Security Agreement with a lender which originally provided for a revolving credit line in the amount of \$2,000,000 plus up to an additional \$1,000,000 based on eligible accounts receivable of the Company (the "Loan"). In April 2000, the Company increased

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the revolving portion of its credit facility from \$2,000,000 to \$4,000,000 in addition to the \$1,000,000 based on eligible accounts receivable of the Company. As of June 30, 2001, \$1,558,000 of the loan was outstanding. The Loan bears interest at the highest prime or equivalent rate announced by certain designated banks, plus 2% for the portion of the loan based on eligible accounts receivable or 3.5%. The Loan is secured by a first priority lien on all of the assets of the Company, except for intellectual property, is fully guaranteed by our subsidiary, AMP, and contains certain restrictive covenants. The Company was in compliance with the restrictive covenants of the agreement as of June 30, 2001. The loan matured on July 31, 2001. The credit facility was paid in full on that date.

In November 2000, we sold 1,509,440 shares of our common stock at a price of \$13.25 per share in a private placement. After transaction fees, legal, accounting, filing fees and other associated expenses of approximately \$1,648,000, the net contribution to our capital was approximately \$18,352,000.

We believe that our existing cash resources will provide sufficient resources to meet present and reasonably foreseeable working capital requirements and other cash needs into 2002. If we elect to undertake or accelerate significant research and development projects for new products or pursue corporate acquisitions, we may require additional outside financing sooner than anticipated. There can be no assurance that financing will be available on acceptable terms or at all. We expect that to meet our long-term needs we may need to raise substantial additional funds through the sale of our equity securities, the incurrence of indebtedness or through funds derived through entering into collaborative agreements with third parties.

FACTORS THAT MAY AFFECT OUR FUTURE RESULTS AND THE TRADING PRICE OF OUR COMMON STOCK

WE HAVE A LIMITED OPERATING HISTORY AND WE EXPECT TO CONTINUE TO GENERATE LOSSES

Since our inception, we have engaged primarily in research and development and have minimal experience in manufacturing, marketing and selling our products in commercial quantities.

We have incurred annual operating losses since inception. For the fiscal years ended December 31, 1998, 1999, 2000 and the six month period ended June 30, 2001, we had net losses of approximately \$4.9 million, \$9.3 million, \$12.4 million and \$4.4 million, respectively. As of June 30, 2001, our accumulated deficit was approximately \$36.6 million. We may not be able to successfully develop or commercialize our current or future products, achieve significant revenues from sales or procedures or achieve or sustain profitability. We expect to continue to incur operating losses because our products will require substantial expenditures relating to, among other matters, development, clinical testing, regulatory compliance, manufacturing and marketing. 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 thereafter.

OUR PRODUCTS MAY NOT ACHIEVE MARKET ACCEPTANCE, WHICH COULD LIMIT OUR FUTURE REVENUE

Our products, including our Cryocare System and related accessories and disposable products, are in the early stages of market introduction. Our products may not be accepted by potential customers. We believe that recommendations and endorsements of physicians and patients and sufficient reimbursement by health care payers will be essential for market acceptance of our Cryocare System and other products, and these recommendations and endorsements may not be obtained and sufficient reimbursement may not be forthcoming. Cryosurgery has existed for many years, but has not been widely

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accepted primarily due to concerns regarding safety and efficacy and widespread use of alternative therapies. Use of our Cryocare System requires significant physician education and training. Our ability to successfully market our Cryocare System is dependent, among other things, upon acceptance of cryosurgical procedures in the United States and certain international markets. Any adverse side effects 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. Emerging new technologies and procedures to treat cancer, prostate enlargement and other prostate disorders also may negatively affect the market acceptance of cryosurgery. Our Cryocare System and our other products may not gain any significant degree of market acceptance among physicians, patients and health care payers. If our products do not achieve market acceptance, our future revenue will be limited.

WE MAY NOT BE SUCCESSFUL IN DEVELOPING OR MARKETING OUR PRODUCTS

Our growth depends in large part on continued ability to successfully develop and commercialize our current products under development or any new products. Several of our products are in varying stages of development. Our Horizon Prostatic Stent is in clinical trials and has not been approved for marketing in the United States. We also are developing enhancements to our Cryocare System. We may experience difficulties that could delay or prevent the successful development and commercialization of our current products under development or any new 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 prior to obtaining necessary regulatory or reimbursement approvals. Our failure to successfully develop and commercialize new products or to achieve significant market acceptance would have a significant negative effect on our financial condition.

THERE IS UNCERTAINTY RELATING TO THIRD PARTY REIMBURSEMENT WHICH IS CRITICAL TO MARKET ACCEPTANCE OF OUR PRODUCTS

In the United States, health care providers, such as hospitals and physicians, that purchase our products generally rely on third party payers, principally federal Medicare, state Medicaid and private health insurance plans, to reimburse all or part of the cost of medical procedures involving our products and on reimbursement for our products and procedures. While certain private health insurance companies pay for the procedures in which our products are used in certain areas of the United States, private insurance reimbursement may not be adopted nationally or by additional insurers and may be terminated by those private insurance companies currently paying for procedures in which our products are used. Reimbursement levels from Medicare, Medicaid or private insurers may not be sufficient to induce physicians to perform, and patients to elect, procedures utilizing our products. Further, we anticipate that, under the prospective payment system used by private health care payers, the cost of our products will be incorporated into the overall cost of the procedures in which they are used and that there will be no separate, additional reimbursement for our products. This also may discourage the use of our products. Furthermore, we could be negatively affected by changes in reimbursement policies of government or private health care payers, particularly to the extent any such changes affect reimbursement for procedures in which our products are used. Failure by physicians, hospitals and other users of our products to obtain sufficient reimbursement from health care payers for procedures involving our products could have a significant negative effect on our financial condition.

Furthermore, significant attention is placed on reforming the healthcare system in the United States and other countries. Any changes in Medicare, Medicaid or third party medical expense reimbursement, which may arise from healthcare reform, would likely have a material adverse effect on the price for

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our products. In addition, changes to the healthcare system may also affect the commercial acceptance of products we are currently developing and products we may develop in the future. Several proposals have been made in the United States Congress and various state legislatures recently that, if adopted, would reform the healthcare system in the United States and potentially reduce healthcare spending which may result in a material adverse effect on our business.

WE HAVE LIMITED SALES AND MARKETING EXPERIENCE

We currently handle most of our own marketing, distribution and sales of our Cryocare Systems. We have limited experience marketing and selling our products, and do not have experience marketing and selling our products in commercial quantities. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our Cryocare System product or other products.

We derive the majority of our revenues from the sales of Cryocare Systems and expect that sales of Cryocare Systems will continue to constitute the majority of our sales for the foreseeable future. Any factor negatively impacting the sales or usage of Cryocare Systems would have a significant effect on our business.

We believe that, to become and remain competitive, we will need to develop third party international distribution channels and a direct sales force for our products. If we enter into third party marketing arrangements, our percentage share of product revenues is likely to be lower than if we directly marketed and sold our products through our own sales force. Establishing marketing and sales capabilities sufficient to support sales in commercial quantities will require significant resources. We may not be able to recruit and retain direct sales personnel, succeed in establishing and maintaining any third party distribution channels or succeed in our future sales and marketing efforts.

WE ARE DEPENDENT UPON A LIMITED NUMBER OF THIRD PARTY SUPPLIERS TO MANUFACTURE OUR PRODUCTS

We depend upon a limited number of unaffiliated third-party suppliers for components and materials used in the manufacture of our products and, as such, our business would be seriously harmed if we were unable to develop and maintain relationships with suppliers that allow us to obtain sufficient quantities and quality materials and components on acceptable terms. If our principal suppliers cease to supply the materials and components we need to manufacture our products, there may not be adequate alternatives to meet our needs, which will have a material adverse effect on our business. To date, we have been able to obtain the necessary components and materials used in the manufacture of our products without material delays, however, there can be no assurance that we will be able to obtain the necessary components and materials used in our products in the future on a timely basis, if at all.

WE ARE DEPENDENT ON ADEQUATE PROTECTION OF OUR PATENT AND PROPRIETARY RIGHTS

We may not be able to obtain effective patents to protect our technologies from use by other companies with competitive products, and patents of other companies could prevent us from developing or marketing our products. Our success will depend, to a significant degree, on our ability to secure and protect intellectual proprietary rights and enforce patent and trademark protections relating to our technology. While we believe that the protection of patents or licenses is important to our business, we also rely on trade secrets, know-how and continuing technological innovation to maintain our competitive position. From time to time, litigation may be advisable to protect our patent position. 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

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protect our other patent rights and could result in the rejection or invalidation of our existing and future patents, if any. Any adverse outcome in litigation relating to the validity of our patents, or any other failure to pursue litigation or otherwise to protect our patent position, could materially harm our business and financial condition. In addition, in the future, we may receive correspondence alleging infringement of proprietary rights of third parties. Even if infringement claims against us are without merit, defending a lawsuit takes significant time, may be expensive and may divert management attention from other business concerns. We try to preserve the confidentiality of our technology by entering into confidentiality agreements with our employees, consultants, customers, and key vendors and by other means. These measures may not, however, prevent the unauthorized disclosure or use of such 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. In addition, enforcement of these agreements may be costly and time consuming.

WE ARE FACED WITH INTENSE COMPETITION AND RAPID TECHNOLOGICAL AND INDUSTRY CHANGE

We are faced with intense competition and rapid technological and industry change and, 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 other surgical device manufacturers, as well as, in some cases, from pharmaceutical companies. Many of our competitors are significantly larger than us and have greater financial, technical, research, marketing, sales, distribution and other resources than us. 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 succeed in obtaining regulatory approval, and introducing or commercializing products before we do. Such developments could have a significant negative effect on our financial condition. Even if we are able to compete successfully, we may not be able to do so in a profitable manner. 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. Our products may be rendered obsolete as a result of future innovations.

WE MAY NEED ADDITIONAL LONG-TERM FINANCING

If we undertake or accelerate significant research and development projects for new products or pursue corporate acquisitions, we may require additional outside financing. Such additional funds may be raised through the sale of our equity securities or the incurrence of additional debt or through collaborative arrangements. Any additional equity financing may be dilutive to shareholders, 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 certain of our technologies, products or marketing territories. Our failure to raise capital when needed could have a significant negative effect on our business, operating results, financial condition and prospects.

WE HAVE LIMITED MANUFACTURING EXPERIENCE

We have limited experience in producing our products in commercial quantities. Manufacturers often 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 negatively impact our business and financial condition. We use internal manufacturing capacity in our

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manufacturing efforts. Certain of our purchased components and processes are currently available from or performed by a single vendor. Any supply interruption from a single source vendor would have a significant negative effect on our ability to manufacture our products until a new source of supply is qualified and, as a result, could have a significant negative effect on our business and financial condition. Our success will depend in part upon our ability to manufacture our products in compliance with the FDA's Good Manufacturing Practices regulations and other regulatory requirements in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. Failure to increase production volumes in a timely or cost-effective manner or to maintain compliance with the FDA's Good Manufacturing Practices or other regulatory requirements could have a significant negative effect on our financial condition.

WE ARE DEPENDENT ON KEY PERSONNEL

Failure to attract and retain skilled personnel could hinder our research and development and sales and marketing efforts. Our future success depends to a significant degree upon the continued services of key technical and senior management personnel, including Paul W. Mikus, our Chief Executive Officer. None of these individuals is bound by an employment agreement or covered by an insurance policy of which we are the beneficiary. Our future success also depends on our continuing ability to attract, retain and motivate highly qualified managerial, technical and sales personnel. Competition for such personnel is intense, particularly in southern California where we are located. The inability to retain or attract qualified personnel could have a significant negative effect upon our research and development and sales and marketing efforts and thereby materially harm our business and financial condition.

GOVERNMENT REGULATION CAN HAVE 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 and the Public Health Service 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 approvals is lengthy and expensive. We may not be able to obtain 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 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 such position by the FDA, or change of position by the FDA, may adversely impact our business and financial condition. 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 strictly 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 the occurrence of unforeseen problems following initial marketing. We may not be able to obtain 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 would have a significant negative effect on our financial condition. In addition, the health care industry in the United States is generally subject to fundamental change due to regulatory, as well as political, influences. We anticipate that Congress and state legislatures will continue to review and

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assess alternative health care delivery and payment systems. Potential approaches that have been considered include controls on health care spending through limitations on the growth of private purchasing groups and price controls. We cannot predict what impact the adoption of any federal or state health care reform measures may have on our business.

WE COULD BE NEGATIVELY IMPACTED BY FUTURE INTERPRETATION OR IMPLEMENTATION OF FEDERAL AND STATE FRAUD AND ABUSE LAWS, INCLUDING ANTI-KICKBACK LAWS.

Federal anti-kickback laws and regulations prohibit the offer, payment, solicitation and receipt of any form of remuneration in exchange for referrals of products or services for which payment may be made by Medicare, Medicaid or other federal healthcare programs. Violations of federal anti-kickback laws are punishable by monetary fines, civil and criminal penalties and exclusion from participation in Medicare, Medicaid and other federal healthcare programs. Several states have similar laws. While we believe our operations are in material compliance with the applicable Medicare and Medicaid fraud and abuse laws, including the anti-kickback laws, there is a risk that the federal government might investigate our arrangements with physicians and other third parties. Such investigations, regardless of their outcome, could damage our reputation and adversely affect important business relationships that we have with third parties, including physicians, hospitals and others. If our arrangements with physicians and other third parties were found to be illegal, we could be subject to civil and criminal penalties, including fines and possible exclusion from participation in governmental payor programs. Significant fines could cause liquidity problems and adversely affect our results of operations. Exclusion from participation from government payor programs would eliminate an important source of revenue and adversely affect our business.

WE COULD BE NEGATIVELY IMPACTED BY FUTURE INTERPRETATION OR IMPLEMENTATION OF THE FEDERAL STARK LAW AND OTHER STATE AND FEDERAL ANTI-REFERRAL LAWS

We are also subject to federal and state statutes and regulations banning payments for referrals of patients and referrals by physicians to healthcare providers with whom the physicians have a financial relationship. The federal Stark Law applies to Medicare and Medicaid and prohibits a physician from referring 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 laws. 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. Although we believe that our financial relationships with physicians are not in violation of applicable laws and regulations, governmental authorities might take a contrary position. If our financial relationships with physicians were found to be illegal, we 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 and others to comply with that jurisdiction's laws. Such structural and organizational modifications could result in lower profitability and failure to achieve our growth objectives.

WE MAY BE NEGATIVELY IMPACTED BY PRODUCT LIABILITY AND PRODUCT RECALL

The manufacture and sale of medical products entails significant risk of product liability claims and product recalls. Our existing insurance coverage

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limits may not be adequate to protect us from any liabilities we might incur in connection with the clinical trials or sales of our products. We may require increased product liability coverage as our products are commercialized. Insurance is expensive and may not be available on acceptable terms, or at all. A successful product liability claim or series of claims brought against us in excess of our insurance coverage, or a recall of our products, would have a significant negative effect on our business and financial condition. Even unsuccessful claims could result in the significant expenditure of funds and management time, could substantially harm our reputation and could harm our business.

WE MAY EXPERIENCE FLUCTUATIONS IN OUR FUTURE OPERATING RESULTS

If our revenue declines in a quarter from the revenue in the previous quarter our earnings will likely decline because many of our expenses are relatively fixed. In particular, research and development, sales and marketing and general and administrative expenses are not affected directly by variations in revenue. In some future quarter or quarters, due to a decrease in revenue or for some other reason, our operating results likely will be below the expectations of securities analysts or investors. In this event, the market price of our common stock may fall abruptly and significantly.

OUR BUSINESS IS EXPOSED TO RISKS RELATED TO ACQUISITIONS AND MERGERS

As part of our strategy to commercialize our products, we may acquire one or more businesses, such as a related company that would use our products in clinical applications. In June 1999, we consummated a business combination with Advanced Medical Procedures, LLC, a regional mobile cryosurgery service company that provides our cryosurgical equipment for the treatment of prostate and liver cancer on a procedural basis. We may not be able to effectively integrate our business with any other business we may acquire or merge with or effectively utilize the business acquired to develop and market our products. The failure to integrate an acquired company or acquired assets into our operations may cause a drain on our financial and managerial resources, and thereby have a significant negative effect on our business and financial results.

These difficulties could disrupt our ongoing business, distract our management and employees or increase our expenses. Furthermore, any physical expansion in facilities due to an acquisition may result in disruptions that seriously impair our business. We are not experienced in managing facilities or operations in geographically distant areas. In addition, our profitability may suffer because of acquisition-related costs or amortization costs or impairment of acquired goodwill and other intangible assets. Finally, in connection with any future acquisitions, we may incur debt or issue equity securities as part or all of the consideration for the acquired company's assets or capital stock. We may be unable to obtain sufficient additional acquisition financing on favorable terms or at all. In addition, equity issuances would be dilutive to our existing stockholders.

OUR COMMON STOCK HAS A LIMITED MARKET AND TRADING HISTORY

If we fail to satisfy the continued listing requirements of the Nasdaq National Market or Nasdaq SmallCap Market, our stock could become subject to the SEC's Penny Stock Rules, making the stock difficult to sell. Our common stock began trading on the Nasdaq SmallCap Market on February 28, 1997 and in May 2000 was listed and is currently traded on the Nasdaq National Market. If we are unable to maintain the standards for quotation on the Nasdaq National Market or the Nasdaq SmallCap Market, the ability of our investors to resell their shares may be limited. In addition, our securities may be subjected to "penny stock" rules that impose additional sales practice and market making requirements on broker-dealers who sell or make a market in such securities. This could affect the ability or willingness of broker-dealers to sell or make a market in our

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securities and the ability of holders of our securities to sell their securities in the secondary market.

OUR STOCK PRICE MAY FLUCTUATE SIGNIFICANTLY

Our stock price has in the past fluctuated and is likely to continue to fluctuate significantly, making it difficult to resell shares when an investor wants to at prices they find attractive. The market prices for securities of emerging companies have historically been highly volatile. Future announcements concerning us or our competitors could cause such volatility including announcements regarding: our operating results, technological innovations or new commercial products, corporate collaborations, government and third party reimbursement, government regulation, developments concerning proprietary rights, litigation or public concern as to the safety of our products, investor perception of us and our industry, and general economic and market conditions. 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. In addition, any failure by us to meet or exceed estimates of financial analysts is likely to cause a decline in our common stock price.

THE 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 and the conversion of convertible debentures 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. Such 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.

ANTI-TAKEOVER PROVISIONS IN OUR CHARTER MAY HAVE A POSSIBLE NEGATIVE EFFECT ON OUR STOCK PRICE

Certain provisions of our Certificate of Incorporation and Bylaws 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 certain corporation actions and may have the effect of delaying or preventing a change in control. In addition, 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 shall 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 Endocare. The foregoing factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock.

CALIFORNIA ENERGY CRISIS

Our headquarters and principal operations are located in Orange County, California. California has recently found itself in a utility crisis caused, in part, by a lack of affordable power sources and the financial instability of several of its primary power suppliers. Orange County has undergone several periods of "rolling blackouts," a technique used by our power provider to conserve its resources. Although our operations have not been halted as a

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result of these conservation measures, potential suspensions of our operations due to power disruptions could result in materially higher costs and lost revenues, either of which would materially adversely impact our business, financial condition and results of operations.

ITEM 3.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our financial instruments include cash, cash equivalents, notes receivable and credit facility debentures. At June 30, 2001, the carrying values of our financial instruments approximated their fair values.

Our policy is not to enter into derivative financial instruments. We do not have any significant foreign currency exposure since we do not transact business in foreign currencies. Therefore, we do not have significant overall currency exposure. 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.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

As previously reported, in March 2000, the Company filed two patent infringement lawsuits against Israeli-based Galil Medical, Ltd, and its U.S. affiliate, Galil Medical USA, Inc. (collectively, "Galil") in the U.S. District Court for the Central District of California. Additional developments were also reported in our first quarterly report for this fiscal year. In March 2001, the Company and Galil reached a settlement. In the settlement, Galil stipulated for purposes of the agreement that the Company's patent combining cryo-cooling, ultrasound and temperature monitoring technology is valid and enforceable. The settlement resulted in certain cross-licensing agreements between Galil and Endocare.

In the normal course of business, the Company is subject to various other legal matters. While the results of litigation and claims cannot be predicted with certainty, the Company believes that the final outcome of these matters will not have a material adverse effect on its consolidated results of operations or financial condition.

Item 2. Changes in Securities

In June 2001, in connection with the hiring of John V. Cracchiolo as our Chief Operating Officer and Chief Financial Officer, Mr. Cracchiolo was granted options to purchase an aggregate of 350,000 shares of the Company's common stock. 50,000 of such options were granted pursuant to the Company's 1995 Stock Plan, and 300,000 of such options were granted outside of the Company's existing stock option plans. The exercise price for the approximately 322,332 non-qualified stock options issued to Mr. Cracchiolo is \$13.75, and the exercise price of the approximately 27,688 incentive stock options is \$14.00 per share. The 300,000 option shares granted outside of the Company's existing stock option plans were issued in a private transaction exempt from the registration requirements of the Securities Act in accordance with Section 4(2) of the Securities Act. Of the 350,000 option shares granted, 300,000 of the option shares will become exercisable in annual and monthly installments during Mr. Cracchiolo's continued service as an officer of the Company and the remaining

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50,000 option shares will vest upon the earlier of June 2006 or the attainment of performance based objectives

In June 2001, the Company issued 213,010 shares of its common stock valued at \$2,837,293 in consideration for a membership equal to approximately 5% of the total issued and outstanding Class A Units of U.S. Therapies, L.L.C. on a fully-diluted basis. The Company issued the shares in a private transaction exempt from the registration requirements of the Securities Act pursuant to Regulation D promulgated under the Securities Act and/or Section 4(2) of the Securities Act.

Item 3. Defaults Upon Senior Securities

Not applicable.

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

The Company's Annual Meeting of Stockholders was held on May 22, 2001. Proposal 1, submitted to a vote of security holders at the meeting was the election of Directors. The following Directors, being all the Directors of the Company, were elected at the meeting, with the total number of votes cast as follows:

NAME	BROKER VOTES FOR	VOTES AGAINST OR WITHHELD	ABSTENTIONS	BROKER NON-VOTES
Paul W. Mikus.	10,678,290	1,633,073	0	0
Peter F. Bernardoni. . .	12,293,991	17,372	0	0
Robert F. Byrnes	12,293,943	17,420	0	0
Benjamin Gerson, M.D.. .	12,294,143	17,220	0	0
Alan L. Kaganov, Sc.D. .	12,294,143	17,220	0	0
Michael J. Strauss, M.D.	12,294,143	17,220	0	0

Proposal 2, submitted to a vote of security holders at the meeting, was to ratify the appointment of KPMG LLP as the Company's independent auditors for fiscal year 2001. Votes cast were as follows:

VOTES FOR	VOTES AGAINST	ABSTENTIONS	BROKER NON-VOTES
12,222,786	83,979	4,558	0

The proposal was approved.

Item 5. Other Information

Not applicable.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit	Description
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- 3.1(1) Certificate of Incorporation
- 3.2(2) Amended and Restated Bylaws
- 10.1 Offer letter to John V. Cracchiolo, dated June 11, 2001
- 10.2 Compensation Agreement issued to John V. Cracchiolo dated June 25, 2001
- 10.3* Distribution agreement with USMD, ltd., dated as of June 27, 2001
 - (1) Previously filed with amendment number 1 to the Company's application for registration on Form 10-SB filed with the SEC on
 - (2) Previously filed with
 - (*) Confidential portions of this exhibit were omitted by means of marking such portins with an asterisk (the "Mark").

(b) Reports on Form 8-K -- None

SIGNATURES

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

Date: August 13, 2001

ENDOCARE, INC.

By: /s/ Paul W. Mikus

Paul W. Mikus
Chief Executive Officer and President
(Duly Authorized Officer)

By: /s/ John V. Cracchiolo

John V. Cracchiolo
Chief Operating Officer and
Chief Financial Officer
(Principal Financial and
Accounting Officer)