ENDOCARE INC
Form 10-Q
May 15, 2001

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

FORM 10-Q

(Mark One)
[X] Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 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 incorporation or organization)	(I.R.S. Employer 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 [X] NO [ ]

The number of shares of the Registrant's Common Stock, par value $.001 per share, outstanding on May 8, 2001 was 15,334,515.

ENDOCARE, INC.
FORM 10-Q, QUARTER ENDED MARCH 31, 2001
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ITEM 1. FINANCIAL STATEMENTS

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

	THREE MONTHS ENDED MARCH 31,	
	2001	2000
Revenues:		
Net product sales	$ 2,413,115	$ 1,137,910
Mobile cryosurgical procedures	342,472	173,120

Total revenues.	2,755,587	1,311,030
Costs and expenses:		
Cost of product sales.	948,734	518,107
Cost of mobile cryosurgical procedures.	225,156	97,223
Research and development.	902,819	723,708
Selling, general and administrative . .	3,024,120	2,660,430
Total costs and expenses.	5,100,829	3,999,468
Loss from operations.	(2,345,242)	(2,688,438)
Interest income (expense), net.	3,074	(325,230)
Net loss.	$ (2,342,168)	$ (3,013,668)
Net loss per share of common stock - basic and diluted	$ (0.15)	$ (0.27)
Weighted average shares of common stock outstanding	15,153,761	11,299,878

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

ENDOCARE, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS

	MARCH 31, 2001 (UNAUDITED)	DECEMBER 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents.	$ 18,303,420	$ 22,016,448
Accounts receivable, net	2,884,743	2,113,766
Inventories.	1,861,106	1,543,733
Prepaid expenses and other current assets.	161,032	178,972
Total current assets	23,210,301	25,852,919
Property and equipment, net.	1,455,328	1,496,153
Deferred financing costs and other assets, net . .	1,481,677	1,495,718
Total assets	$ 26,147,306	$ 28,844,790
LIABILITIES AND SHAREHOLDERS' EQUITY		

Current Liabilities:		
Accounts payable	$ 1,589,236	$ 2,231,344
Accrued compensation	1,386,343	1,646,079
Other accrued liabilities.	1,757,011	1,523,602
Credit facility.	1,000,000	1,000,000
Total current liabilities.	5,732,590	6,401,025
Convertible debentures	6,500,000	7,500,000
Note payable and other liabilities	61,103	74,268
Total liabilities.	12,293,693	13,975,293
Shareholders' equity:		
Preferred stock, $.001 par value; 1,000,000 shares authorized; none issued and outstanding.	--	--
Common Stock, $.001 par value; 15,273,176 and 15,018,649 issued and outstanding at March 31, 2001 and December 31, 2000, respectively	15,273	15,019
Additional paid-in capital	49,381,884	48,163,186
Note receivable from stock sale.	(1,028,125)	(1,135,457)
Accumulated deficit.	(34,515,419)	(32,173,251)
Total shareholders' equity	13,853,613	14,869,497
Contingencies		
Total liabilities and shareholders' equity	$ 26,147,306	$ 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)

	THREE MONTHS ENDED MARCH 31,	
	2001	2000
Cash flows from operating activities:		
Net loss	$ (2,342,168)	$(3,013,668)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization.	96,162	96,217
Amortization of warrant value.	49,062	96,761
Amortization of deferred financing costs	60,000	188,335
Changes in operating assets and liabilities:		
Accounts receivable.	(770,975)	47,206
Inventories.	(280,303)	(270,038)
Prepaid expenses and other current assets.	4,524	(7,892)

Other assets	(149,800)	(4,998)
Accounts payable	(642,108)	474,482
Accrued compensation	(177,989)	(235,743)
Other accrued liabilities	220,611	267,798
Deferred revenue and other	--	(12,280)
Net cash used in operating activities	(3,932,984)	(2,373,820)
Cash flows from investing activities:		
Purchases of property and equipment	(56,902)	(55,188)
Net cash used in investing activities	(56,902)	(55,188)
Cash flows from financing activities:		
Issuance of common stock	276,858	186,993
Net cash provided by financing activities	276,858	186,993
Net decrease in cash and cash equivalents	(3,713,028)	(2,242,015)
Cash and cash equivalents, beginning of period	22,016,448	7,364,951
Cash and cash equivalents, end of period	$ 18,303,420	$ 5,122,936
Non-cash activities:		
Convertible debentures converted to common stock	$ 1,000,000	$ --
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	186,100
Total non-cash activities	$ 1,042,930	$ 621,100

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

ENDOCARE, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 and stent technologies for applications in oncology and urology. 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 and liver.

2. Financial Information

Basis of Presentation

In the opinion of management, 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 generally accepted accounting principles 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. Financial results for this interim period are not necessarily indicative of results to be expected for the full year 2001.

Accounting Principles

In June 1998, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities." The provisions of the statement require the recognition of all derivatives as either assets or liabilities in the consolidated balance sheet and the measurement of those instruments at fair value. The accounting for changes in the fair value of a derivative depends on the intended use of the derivative and the resulting designation. This statement, as amended, was effective in the first quarter of 2001. The adoption of SFAS 133 did not have a material effect on our financial position or results of operations.

In September 2000, the FASB issued Statement of Financial Accounting Standards No. 140. "Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities". The statement replaces Statement of Financial Accounting Standards No. 125 and is effective in the second quarter of 2001. SFAS 140 revises the accounting for securitizations and other transfers of financial assets. The adoption of SFAS 140 is not expected to have a material effect on our financial position or results of operations.

3. Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles 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

	MARCH 31, 2001	DECEMBER 31, 2000
Inventories:		
Raw materials . .	$ 846,862	$ 763,389
Work in process .	479,937	288,480
Finished goods. .	534,307	491,864
Total inventories	$1,861,106	$ 1,543,733

5. Net Loss Per Share

The Company has adopted SFAS No. 128, "Earnings Per Share." Under SFAS 128,

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 loss (numerator), shares (denominator) and per-share amounts for the three months ended March 31, 2000 and March 31, 2001 are $(3,014,000), 11,300,000 $(0.27), and $(2,342,000), 15,154,000 and $(0.15), respectively. As the Company has been in a net loss position for the periods presented, the potential dilution from the conversion of options, warrants and convertible debentures to common stock of approximately 5,038,000 and 4,021,000 for the three months ended March 31, 2000 and 2001, respectively, were not used to compute diluted loss per share as the effect was antidilutive. Consequently, diluted EPS equals basic EPS.

6. Merger

On June 30, 1999, Endocare acquired all the outstanding units of Advanced Medical Procedures, LLC, a Florida limited liability company ("AMP"). AMP operates a mobile cryosurgery business, which provides cryosurgical equipment for the treatment of prostate and liver cancer on a procedural basis. The acquisition was consummated pursuant to a Plan of Merger (the "AMP Merger Agreement") by and among AMP, Endocare, and Advanced Medical Procedures, Inc. ("AMPI"), a Delaware corporation and wholly-owned subsidiary of Endocare. Pursuant to the Merger Agreement, AMP was merged with and into AMPI, with AMPI surviving as a wholly-owned subsidiary of Endocare. The AMP unitholders received an aggregate of 260,000 shares of Endocare Common Stock in exchange for all of their AMP units. The acquisition was accounted for as a pooling-of-interests for financial reporting purposes. The pooling-of-interests method of accounting is intended to present as a single interest two or more common stockholders' interests which were previously independent; accordingly, the historical financial statements for the periods prior to the acquisition have been restated as though the companies had been combined. Fees and expenses related to the acquisition were expensed as incurred and amounted to approximately $50,000.

7. Debt

Convertible Debentures

On June 7, 1999 and July 30, 1999, the Company received $5,000,000 and $3,000,000, respectively, from the sale of its 7% convertible debentures due in three years (the "Debentures"). Interest was payable annually in cash or, at the Company's option, in common stock at a price per share based on recent bid prices prior to the date interest is paid. Under the financing arrangements, the purchasers had options to purchase additional debentures for the aggregate principal amounts of $5,000,000 and $3,000,000. Under the circumstances described below, the Company could require the purchasers to exercise these purchase options. The $5,000,000 principal amount of the Debentures was originally due on June 7, 2002, and was eligible for conversion into the Company's common stock in whole or in part at the purchasers' option at any time on or prior to June 7, 2002 at a conversion price of $5.125 per share. The $3,000,000 principal amount of the Debentures was originally due on July 29, 2002, and was eligible for conversion into the Company's common stock in whole or in part at the purchasers' option at any time, subject to certain restrictions, on or prior to July 29, 2002 at a conversion price of $6.00 per share. The conversion prices were subject to certain anti-dilution adjustments. In addition to the purchasers' option to convert the $5,000,000 principal amount of the Debentures, the Company could have required the purchaser to convert the Debentures into common stock at a conversion price of $5.125 per share (subject to certain anti-dilution adjustments) if the bid price for the common stock as

listed for quotation was above $8.00 per share for twenty (20) trading days during a consecutive (30) trading day period, and certain other conditions were met. Subject to certain restrictions, the Company could have required that the purchasers convert the $3,000,000 principal amount of the debentures into common stock at a conversion price of $6.00 per share (subject to certain anti-dilution adjustments) if the bid price for the common stock as listed for quotation was above $9.00 per share for twenty (20) trading days during a consecutive thirty (30) trading day period, and certain other conditions were met. During the second quarter of 2000, the original $8,000,000 in convertible debentures sold to the investors in 1999 was converted into 1,475,610 shares of common stock under the terms of the original agreements.

Under a securities purchase agreement, the purchasers had a call option exercisable at any time prior to June 7, 2002 to require that the Company sell to the purchasers an additional $5,000,000 principal amount of debentures. The additional debentures mature three years from the date they are issued, bear interest at 7% per annum and are convertible in whole or in part at a conversion price of $6.75 per share (subject to certain anti-dilution adjustments). The Company had a put option to require the purchasers to buy the $5,000,000 principal amount of additional debentures if the closing bid price for the common stock as listed for quotation was more that $10.00 per share for the twenty (20) trading days in a consecutive (30) trading day period and on the date the Company elected to exercise the put option, and if certain other conditions were met. The purchasers also had a call option exercisable at any time prior to July 29, 2002 to require the Company to sell to the purchasers an additional $3,000,000 principal amount of debentures. The additional debentures mature three years from the date they are issued, bear interest at 7% per annum and are convertible in whole or in part at the option of the purchasers at any time prior to maturity into common stock at a conversion price of $6.75 per share (subject to certain anti-dilution adjustments). The Company had a put option to require the purchasers to buy the $3,000,000 principal amount of additional debentures if the closing bid price for the common stock as listed for quotation was more than $9.00 per share for twenty (20) trading days in a consecutive thirty (30) trading day period and on the date the Company elected to exercise the put option, and certain other conditions were met. On May 5, 2000, the Company 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 and $1,000,000 was converted into 148,148 shares of common stock during the first quarter of 2001. Financing costs totaling $585,000 associated with the transaction are being amortized to interest expense over three years. The same investors originally purchased the $8,000,000 of convertible debentures in 1999.

The fair value of the purchasers' two call options described above totaling $1,600,000, was originally estimated using the Black-Scholes pricing model and was being amortized to interest expense over the lives of the call options. The net unamortized balance totaling $1,156,863 was reclassified to additional paid in capital upon conversion of the original $8,000,000 of convertible debentures into common stock in 2000.

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 March 31, 2001 $1,000,000 of the loan was outstanding. The Loan matures and all amounts must be repaid on July 31, 2001. The Loan bears interest at the highest prime or equivalent rate announced by certain designated banks, plus 2%

for the option 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 AMP, and contains certain restrictive covenants. The Company was in compliance with the restrictive covenants of the agreement as of March 31, 2001.

8. Stockholders' Rights Plan

In April 1999, the Company adopted a stockholder rights plan in which preferred stock purchase rights will be 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 patent infringement lawsuits against Israeli-based Galil Medical, Ltd., and its U.S. affiliate, Galil Medical USA, Inc. (collectively, "Galil"). The suit against Galil filed in the U.S. District Court for the Central District of California, alleges that Galil has marketed and sold cryosurgical systems that infringe Endocare's patented combination of cryo-cooling, ultrasound and temperature monitoring technology. Endocare's suit seeks damages and injunctive relief with respect to products and procedures, which are found to infringe Endocare's proprietary technology. In August 2000, Galil submitted counterclaims alleging that Endocare's cryosurgical probes infringe Galil's probe patents. Galil seeks unspecified damages and injunctive relief with respect to Endocare's cryosurgical system. The Company believes it has adequate defenses to these claims and intends to defend the litigation vigorously if necessary. All proceedings in the action were stayed by the District Court on December 13, 2000 pending the outcome of settlement discussions by the parties. The parties are currently engaged in settlement discussions.

In March 2000, the Company filed in the U.S. District Court for the Central District of California, a similar suit to the one discussed above against Cryomedical Sciences, Inc. "CMSI". In December 2000, the parties reached a settlement in this action. In the settlement agreement, CMSI stipulated for purposes of the agreement that the Company's patent combining cryo-cooling, ultrasound and temperature monitoring technology is valid and enforceable. On December 20, 2000, as part of the settlement, the District Court signed a Consent Judgment validating the settlement agreement in which CMSI stipulated for purposes of the agreement that Endocare's patent combining cryo-cooling, ultrasound and temperature monitoring technology is valid and enforceable. The settlement resulted in certain cross-licensing agreements.

In the normal course of business, Endocare 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

From time to time, the Company has received other correspondence alleging

infringement of proprietary rights of third parties. No assurance can be given that any relevant claims of third parties would not be upheld as valid and enforceable, and therefore that the Company could be prevented from practicing the subject matter claimed or would be required to obtain licenses from the owners of any such proprietary rights to avoid infringement. The Company does not expect any material adverse effect on its consolidated financial condition or the results of operations because of such actions.

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 be deemed to 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 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 and 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 and liver.

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. Under our cryosurgical system placement program, a system is placed at a customer site for use with our disposable Cryoprobes. The cost of the system is depreciated into product cost of sales over an estimated useful life of three years.

On June 30, 1999, we acquired all of the outstanding membership interests of

AMP. AMP operates a mobile cryosurgery business that provides cryosurgical equipment for the treatment of prostate and liver cancer on a procedural basis. The merger was accounted for as a pooling-of-interests for financial reporting purposes. The historical financial statements for the periods prior to the merger are restated as though our business had been combined during such periods.

Results of Operations

Three months ended March 31, 2001 and 2000

Net product sales for the three months ended March 31, 2001 increased 112% to $2,413,000 compared to $1,138,000 for the three months ended March 31, 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.

Revenues from mobile cryosurgical procedures for the three months ended March 31, 2001 increased 98% to $342,000 compared to $173,000 for the three months ended March 31, 2000. The increase corresponds to an increase in the number of mobile cryosurgical procedures performed.

Gross margin on net product sales was 61% for the three months ended March 31, 2001 compared to 54% for the three months ended March 31, 2000. The increase is due to a mix of higher margin cryosurgical probe and system sales coupled with a reduction in product costs due to increased manufacturing efficiencies.

Gross margin on mobile cryosurgical procedures was 34% for the three months ended March 31, 2001 compared to 44% for the three months ended March 31, 2000. The decrease is due to a change in procedure mix which included a greater number of lower margin procedures performed in 2001.

Research and development expense for the three months ended March 31, 2001 increased 25% to $903,000 compared to $724,000 for the three months ended March 31, 2000. The increase 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.

Selling, general and administrative expense for the three months ended March 31, 2001 increased 14% to $3,024,000 compared to $2,660,000 for the three months ended March 31, 2000. The increase reflects increased sales and marketing costs, including increased sales commissions, associated with increased commercialization of our cryosurgical product for prostate cancer.

Interest income (expense), net for the three months ended March 31, 2001 was $3,000 compared to $(325,000) for the three months ended March 31, 2000. The increase was 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 March 31, 2001 was $2,342,000, or 15 cents per share on 15,154,000 weighted average shares outstanding, compared to a net loss of $3,014,000 or 27 cents per share on 11,300,000 weighted average shares outstanding for the same period in 2000. The decrease in net loss 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.

Liquidity and Capital Resources

At March 31, 2001, our cash and cash equivalent balance was $18,303,000 compared to $22,016,000 at December 31, 2000. The decrease was due primarily to cash

used by operating activities. At March 31, 2001, our net working capital was $17,478,000 and the ratio of current assets to current liabilities was 4 to 1.

For the three months ended March 31, 2001, net cash used by operating activities was approximately $3,933,000 compared to $2,374,000 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 $1,861,000 at March 31, 2001, compared to $1,544,000 at the beginning of the year whereas, net accounts receivable increased to $2,885,000 at March 31, 2001, compared to $2,114,000 at December 31, 2000. Additions to property and equipment during the first three months of 2001 were approximately $57,000. Additionally, $43,000 of inventory was transferred to property and equipment in 2001 under our cryosurgical placement program. Working capital was used as current liabilities decreased to $5,733,000 from $6,401,000 at December 31, 2000.

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. Under the agreements, the purchasers of the convertible debentures had options to purchase additional debentures for the aggregate principal amounts of $5,000,000 and $3,000,000 prior to June 7, 2002 and July 29, 2002, respectively. The additional debentures mature three years from the date they are issued, bear interest at 7% per annum and are convertible in whole or in part at a conversion price of $6.75 per share (subject to certain anti-dilution adjustments). We had a put option to require the purchasers to buy the $5,000,000 principal amount of additional debentures if the closing bid price for the common stock as listed for quotation is more that $10.00 per share for the twenty (20) trading days in a consecutive thirty (30) trading day period and on the date we elect to exercise the put option, and if certain other conditions are met. We also had a put option to require the purchasers to buy the $3,000,000 principal amount of additional debentures if the closing bid price for the common stock as listed for quotation is more that $9.00 per share for twenty (20) trading days in a consecutive thirty (30) trading day period and on the date we elect to exercise the put option, and if certain other conditions are met. 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 and $1,000,000 was converted into 148,148 shares of common stock during the first quarter of 2001.

In addition, in July 1999, we 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. In April 2000, we increased the revolving portion of the credit facility from $2,000,000 to $4,000,000, in addition to the $1,000,000 based on eligible accounts receivable. As of March 31, 2001, $1,000,000 of the loan was outstanding. The loan matures and all amounts must be repaid on July 31, 2001. The loan bears interest at the highest prime or equivalent rate announced by certain designated banks, plus 2% for the option of the loan based on eligible account receivables or 3.5%. The loan is secured by a first priority lien on all of the assets of our business, except for intellectual property, is fully guaranteed by our subsidiary, AMP, and contains certain restrictive covenants. We expect to renew or replace the loan upon maturity.

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 and credit facility will provide sufficient resources to meet present and reasonably foreseeable working capital

requirements and other cash needs through at least the end of the first quarter of 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 prior to such time. There can be no assurance that financing will be available on terms acceptable 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. We also expect to renew or replace our credit line, which expires in July 2001.

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 three month period ended March 31, 2001, we had net losses of approximately $4.9 million, $9.3 million, $12.4 million and $2.3 million, respectively. As of March 31, 2001, our accumulated deficit was approximately $34.5 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, 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 accepted due to concerns regarding safety and efficacy and widespread use of alternative therapies. Our ability to successfully market our Cryocare System is dependent upon acceptance of cryosurgical procedures in the United States and certain international markets. Any 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 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 REIMBURSMENT 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 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 or third party medical expense reimbursement, which may arise from healthcare reform, would likely have a material adverse effect on the price for 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 have limited sales and marketing experience and if we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products. We have limited experience marketing and selling our products, and do not have experience marketing and selling our products in commercial quantities.

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. In March 1999, we exercised our right to terminate our exclusive worldwide distribution agreement with Boston Scientific Corporation

pursuant to which Boston Scientific had agreed to market and distribute the Cryocare System. As a result, future sales of the Cryocare System will be dependent on our marketing efforts. We may not be able to successfully expand our sales and marketing capabilities in order to effectively commercialize the Cryocare System product.

We believe that, to become and remain competitive, we will need to develop additional 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. We cannot ensure that (1) we were the first to invent the technologies covered by our patents or pending patent applications, (2) we were the first to file patent applications for these inventions, (3) any of our pending patent applications will result in issued patents, (4) others will not independently develop similar or alternative technologies or duplicate any of our technologies, (5) our patents will provide a basis for commercially viable products or will provide us with any competitive advantages, and (6) our processes or products do not or will not infringe patents or proprietary rights of others. In December 2000, we settled one patent infringement lawsuit that was initiated by us, We are currently involved in another patent infringement lawsuit initiated by us in the U.S. District Court for the Central District of California against a competitor. The complaint seeks damages and injunctive relief to prevent this competitor from marketing cryosurgical systems and components incorporating our patented combination of cryo-cooling, ultrasound and temperature monitoring technology. Counterclaims have been made against us by the competitor in this litigation alleging that our cryosurgical system infringes on the competitor's proprietary rights. All proceedings in the action were stayed by the District Court on December 13, 2000 pending the outcome of settlement discussions by the parties. The parties are currently engaged in

settlement discussions. This litigation and any other litigation necessary to protect our patent position could be costly, and it is possible that we will not have sufficient resources to fully pursue this litigation or to protect our other patent rights and could result in the rejection or invalidation of our existing and future patents, if any. If we are unsuccessful in this lawsuit our competitors may be able to use certain of our cryosurgical systems technology. This outcome, or 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, from time to time, we have received correspondence alleging infringement of proprietary rights of third parties. We may have to pay substantial damages, possibly including treble damages, for past infringement if it is ultimately determined that our products infringe a third party's patents. Further, we may be prohibited from selling our products before we obtain a license, which, if available at all, may require us to pay substantial royalties. 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 our products, the commercial opportunity for our products will be reduced or eliminated. The commercial opportunity for our products will be reduced or eliminated if our competitors develop and market products that are superior to our products. 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, will 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 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.

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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 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, our distributors and healthcare providers who purchase our products and services are subject to state and federal laws prohibiting kickbacks or other forms of bribery in the healthcare industry. We may be subject to civil and criminal prosecution and penalties if we or our agents violate any of these laws.

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 or product recalls. Our existing insurance coverage 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 for 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. 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 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) 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 March 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. 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 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 debentures. At March 31, 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.

We maintain a $5,000,000 credit facility bearing interest at the highest prime rate or equivalent rate announced by certain designated banks, plus 2% or 3.5%. The current rate of interest on the credit facility is approximately 12.5%. This is our only debt, which does not have a fixed rate of interest. A significant change in interest rates would not materially impact our consolidated financial statements. The credit facility expires in July 2001.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In March 2000, we filed patent infringement lawsuits against Israeli-based Galil Medical, Ltd., and its U.S. affiliate, Galil Medical USA, Inc. (collectively, "Galil"). The suit against Galil filed in the U.S. District Court for the Central District of California, alleges that Galil has marketed and sold cryosurgical systems that infringe our patented combination of cryo-cooling, ultrasound and temperature monitoring technology. Our suit seeks damages and injunctive relief with respect to products and procedures, which are found to infringe our proprietary technology. In August 2000, Galil submitted counterclaims alleging that our cryosurgical probes infringe Galil's probe patents. Galil seeks unspecified damages and injunctive relief with respect to our cryosurgical system. We believe we have adequate defenses to these claims and intend to defend the litigation vigorously if necessary. All proceedings in the action were stayed by the District Court on December 13, 2000 pending the outcome of the settlement discussions by the parties. The parties are currently engaged in settlement discussions. We do not expect any material adverse effect on our consolidated financial condition or the results of operations because of such actions.

In March 2000, we filed in the U.S. District Court for the Central District of California, a similar suit to the one discussed above against Cryomedical Sciences, Inc. In December 2000, the parties reached a settlement in this action. In the settlement agreement, CMSI stipulated for purposes of the agreement that our patent combining cryocooling, ultrasound and temperature monitoring technology is valid and enforceable. On December 20, 2000, as part of the settlement, the District Court signed a Consent Judgment validating the settlement agreement in which CMSI stipulated for purposes of the agreement that our patent combining cryo-cooling, ultrasound and temperature monitoring technology is valid and enforceable. The settlement resulted in certain cross-licensing agreements.

In the normal course of business, we are subject to various other legal matters. While the results of litigation and claims cannot be predicted with certainty, we believe that the final outcome of these matters will not have a material

adverse effect on our consolidated results of operations or financial condition.

From time to time, we have received other correspondence alleging infringement of proprietary rights of third parties. No assurance can be given that any relevant claims of third parties would not be upheld as valid and enforceable, and therefore that we could be prevented from practicing the subject matter claimed or would be required to obtain licenses from the owners of any such proprietary rights to avoid infringement. We do not expect any material adverse effect on our consolidated financial condition or the results of operations because of such actions.

Item 2. Changes in Securities
None.

Item 3. Defaults Upon Senior Securities
None.

Item 4. Submission of Matters to a Vote of Security Holders
None.

Item 5. Other Information
None

Item 6. Exhibits and Reports on Form 8-K
(a) 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: May 11, 2001

ENDOCARE, INC.

By: /s/ Paul W. Mikus
Paul W. Mikus
Chief Executive Officer and President
(Duly Authorized Officer)

By: /s/ William R. Hughes
William R. Hughes
Senior Vice President and
Chief Financial Officer
(Principal Financial and Accounting Officer)