ENDOCARE INC
Form 10-Q
November 09, 2001

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

FORM 10-Q

(Mark One)

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 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 I.D. 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 at October 31, 2001 was 17,224,243.

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ENDOCARE, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2001

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

ENDOCARE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Revenues	4,214,766	1,759,878	10,508,202	4,636,120
Costs and expenses				
Cost of revenues	1,289,414	853,375	3,735,707	2,223,391
Research and development	766,417	831,514	2,592,681	2,376,167
Selling, general and administrative	3,527,527	2,821,454	9,992,021	8,676,788
Total costs and expenses	5,583,358	4,506,343	16,320,409	13,276,346
Loss from operations	(1,368,592)	(2,746,465)	(5,812,207)	(8,640,226)
Interest income (expense), net	110,546	(106,189)	148,087	(577,488)

Net loss	$(1,258,046)	$(2,852,654)	$(5,664,120)	$(9,217,714)
Net loss per share of common stock basic and diluted	$(.07)	$(.22)	$(.36)	$(.75)
Weighted average shares of common stock outstanding	16,920,505	13,228,000	15,899,541	12,358,000

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

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ENDOCARE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
AT SEPTEMBER 30, 2001 AND DECEMBER 31, 2000
(UNAUDITED)

	September 30, 2001	December 31, 2000
ASSETS		
Current assets		
Cash and cash equivalents	$13,482,114	$22,016,448
Accounts receivable, net	4,483,472	2,113,766
Inventories	2,507,451	1,543,733
Prepaid expenses and other current assets	219,249	178,972
Total current assets	20,692,286	25,852,919
Property and equipment, net	1,514,273	1,496,153
Investments, intangible and other assets, net	4,091,971	1,495,718
Total assets	$26,298,530	$28,844,790
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	$1,738,465	$2,231,344
Accrued compensation	2,090,533	1,646,079

Other accrued liabilities	1,046,094	1,523,602
Credit facility		1,000,000
Total current liabilities	4,875,092	6,401,025
Convertible debentures		7,500,000
Note payable and other liabilities	41,665	74,268
Total liabilities	4,916,757	13,975,293
Stockholders equity		
Preferred Stock, $.001 par value; 1,000,000 shares authorized; none issued and outstanding		
Common stock, $.001 par value; 50,000,000 shares authorized; 17,182,847 and 15,018,649 issued and outstanding at September 30, 2001 and December 31, 2000, respectively	17,183	15,019
Additional paid-in capital	60,230,086	48,163,186
Note receivable from stock sale	(1,028,125)	(1,135,457)
Accumulated deficit	(37,837,371)	(32,173,251)
Total stockholders equity	21,381,773	14,869,497
Total liabilities and stockholders equity	$26,298,530	$28,844,790

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

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ENDOCARE, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000
(UNAUDITED)

	Nine Months Ended September 30,	
	2001	2000
Cash flows from operating activities:		
Net loss	$(5,664,120)	$(9,217,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	330,549	455,081
Amortization of warrant value	147,186	242,911
Amortization of deferred financing costs	833	336,614
Changes in operating assets and liabilities:		
Accounts receivable	(2,369,706)	(326,764)
Inventories	(998,998)	(955,994)
Prepaid expenses and other assets	(64,441)	(303,363)
Accounts payable	(492,879)	1,004,848
Accrued liabilities	155,107	1,289,274
Net cashed used in operating activities	(8,956,469)	(7,475,107)
Cash flows for investing activities		
Purchases of property and equipment	(270,778)	(188,125)
Investment in alliances		

(158,850)		
Advance to affiliate		
(250,000)		
Repayment of advance to affiliate		
250,000		
Net cash used in investing activities		
(429,628)	(188,125)	
Cash flows from financing activities		
Issuance of common stock		
1,894,366	908,175	
Issuance of convertible debentures		
	8,000,000	
Proceeds from credit facility		
	2,000,000	
Payments on credit facility and note payable		
(1,032,603)		
Financing costs		
(10,000)	(585,000)	
Net cash provided by financing activities		
851,763	10,323,175	
Net increase (decrease) in cash and cash equivalents		
(8,534,334)	2,659,943	
Cash and cash equivalents, beginning of period		
22,016,448	7,364,951	

Cash and cash equivalents, end of period	$13,482,114	$10,024,895
Non-cash activities		
Convertible debentures and accrued interest converted to common stock, net of unamortized deferred financing costs	$7,309,726	$6,606,164
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	35,280	702,254
Issuance of Common Stock as investment		2,837,293
Forgiveness of recourse loan and compensation to employees		81,747

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

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

1. Organization and Operations of the Company

Endocare, Inc. (Endocare or the Company) is a medical device company focused on the development of urological healthcare technologies with the potential to dramatically improve men s health and quality of life. The Company currently focuses on the diagnosis, monitoring and treatment of prostate disease. Its first product, the Cryocare Surgical System, is a minimally invasive cryosurgical system for the targeted treatment of prostate cancer. The Company plans to partner with third parties to develop cryosurgical technologies for treating tumors in other organs, including the kidney, lung, breast, liver and bones as well as the treatment of cardiac arrhythmia, including atrial fibrillation. Additionally, the Company is developing stent technologies for urological disorders.

2. Financial Information

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

Accounting Principles

Effective January 1, 2001, we adopted SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. SFAS No. 133 establishes accounting and reporting standards for derivative instruments and hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. The adoption of SFAS No. 133 did not have a material effect on our financial position or results of operations.

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 which 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 regards 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. These statements are not expected to have material impact on the Company s financial reporting and related disclosure.

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In August 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. This statement requires an enterprise to record the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of tangible long-lived assets. Since the requirement is to recognize the obligation when incurred, approaches that have been used in the past to accrue the asset retirement obligation over the life of the asset are no longer acceptable. SFAS No. 143 also requires the enterprise to record the contra to the initial obligation as an increase to the carrying amount of the related long-lived asset, i.e., the associated asset retirement costs, and to depreciate that cost over the life of the asset. The liability is increased at the end of each period to reflect the passage of time, i.e., accretion expense, and changes in the estimated future cash flows underlying the initial fair value measurement. We will adopt SFAS No. 143 in 2003. This statement is not expected to have a material impact on the Company s financial reporting and related disclosures.

In October 2001, the FASB issued Statement No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS 144 supersedes Statement No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, and the accounting and reporting provisions of APB Opinion No. 30, *Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*, for the disposal of a segment of a business. SFAS 144 retains the requirement in Opinion No. 30 to report separately discontinued operations and extends that reporting to a component of an entity that either has been disposed of or is classified as held for sale.

The Company is required and plans to adopt the provisions of SFAS 144 for the quarter ending March 31, 2002. The Company has not determined the impact that SFAS 144 will have on its financial statements.

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

	SEPTEMBER 30, 2001	DECEMBER 31, 2000
Inventories:		
Raw materials	$1,221,396	$763,389
Work in progress	765,391	288,480
Finished goods	520,664	491,864
Total inventories	$2,507,451	$1,543,733

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 Statement 128, the consolidated net loss (numerator), shares (denominator) and per-share amounts for the three months ended September 30, 2001 and September 30, 2000 are $(1,258,046), 16,920,505 and $(0.07), and $(2,852,654), 13,228,000 and (0.22), respectively. The consolidated net loss (numerator), shares (denominator) and per share amount for the nine months ended September 30, 2001 and 2000 are $(5,664,120), 15,899,541 and $(0.36), and $(9,217,714), 12,358,000 and $(0.75), respectively. As the Company has been in a consolidated net loss position for the periods presented, the potential dilution from the conversion of

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options, warrants and convertible debentures to common stock of approximately 3,883,000 and 4,306,000 for the three months ended September 30, 2001 and 2000, respectively, and 3,883,000 and 4,551,000 for the nine months ended September 30, 2001 and 2000, 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 nine month periods ended September 30, 2001 were $436,989 and $1,191,396, as compared to $237,160 and $582,440 for the same period in 2000, respectively.

6. Collaborative Agreements

On June 30, 2001, we issued 213,010 shares of our common stock with a fair value of $2,837,293 as consideration for a membership interest in the form of Class A Units of U.S. Therapies, LLC, equal to approximately 9% of the total issued and outstanding Class A Units of U.S. Therapies and approximately 5% of the Class A Units on a fully-diluted basis. U.S. Therapies is a national urology group representing more than 150 urologists across the nation. In a related Distributor Agreement, U.S. Medical Devices, Ltd., a subsidiary of U.S. Therapies, was appointed a distributor and given exclusive distribution rights to our Cryocare Surgical System and associated disposable products in 16 states. U.S. Medical Devices also has the exclusive right to distribute the Cryocare Surgical System to HealthTronics Surgical Services, Inc. (Nasdaq: HTRN) and its affiliates, a company that provides urologic and orthopedic services to patients in 35 states through physician partnerships. The investment in UST is included in investments, intangible and other assets in the accompanying consolidated balance sheet for September 30, 2001 and is carried using the cost method of accounting. The Company has recognized sales of $1,465,000 and $3,420,000 to USMD for the three months and nine months ended September 30, 2001, respectively.

In October 1999, we entered into a strategic alliance with Sanarus Medical, Inc., a privately held medical device company. The terms of the related agreements included a 5% equity investment by our company in Sanarus totaling $300,000. We also received a warrant to acquire at that time approximately 79% of Sanarus common stock in consideration for entering into a manufacturing, supply and license agreement. The investment is included in other assets in our consolidated balance sheets as of December 31, 2000 and September 30, 2001 and is reflected at cost as we do not have significant influence over the operations of Sanarus. In June 2001, we provided a bridge loan to Sanarus in the amount of $250,000. This amount was subsequently repaid in July 2001 upon Sanarus receipt of additional equity financing, which financing along with other financings by Sanarus reduced our potential ownership percentage to approximately 22% on a fully-diluted basis.

In September 2001, we entered into a strategic alliance with CryoCath Technologies, Inc. pursuant to an exclusive global market access and supply agreement, whereby CryoCath Technologies, Inc. and Endocare will co-develop a new, advanced line of surgical probe systems to surgically treat cardiac arrhythmias. CryoCath will purchase the newly developed systems from Endocare and market them on a global basis under the CryoCath trademark, Surgifrost . The Company recognized $125,000 in license revenue from CryoCath Technologies, Inc. during the three-month period ending September 30, 2001.

Also, in September 2001, we entered into a new expanded distribution agreement with Qualigen, Inc. Under this new agreement, we will sell Qualigen s FDA-cleared 15-minute total prostate specific antigen test as a stand alone product, non-exclusively directly to urology practices.

7. Debt

Convertible Debentures

In June and July 1999, we received a total of $8 million 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, these debentures were converted into 1,475,610 shares of common stock pursuant to the terms of the

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debentures. On May 5, 2000, we received a total of $8 million from the sale of additional 7% convertible debentures, of which $0.5 million of these debentures were converted into 74,074 shares of common stock during the fourth quarter of 2000, $1 million of these debentures were converted into 148,148 shares of common stock during the first quarter of 2001, $4.2 million of these debentures were converted into 622,222 shares of common stock during the second quarter of 2001, and the final $2.3 million of these debentures were converted into 340,741 shares of common stock in July 2001.

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. 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 Advanced Medical Procedures, LLC, a Florida limited liability company, or AMP, a wholly-owned subsidiary of the Company, contained certain restrictive covenants. 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 (the 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 the normal course of business, the Company is subject to various legal matters. While the result of litigation and claims cannot be predicted with certainty, the Company believes that the final outcome of these matters will not have a material effect on the Company s 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. Management does not expect any material adverse effect on the consolidated financial condition or the results of operations because of such actions.

ITEM 2. ENDOCARE, INC. S 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

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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 Trading Price of 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 payors 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 medical device company focused on the development of urological healthcare technologies with the potential to dramatically improve men s health and quality of life. We are currently concentrating on the diagnosis, monitoring and treatment of prostate disease. Our goal is to develop or acquire a full suite of diagnostic and therapeutic products and services addressing the urology market.

Our first product, the Cryocare Surgical System, is a minimally invasive cryosurgical system for the targeted treatment of prostate cancer. We commenced commercial sales of our FDA cleared Cryocare Surgical System in the United States in July 1999. We obtained the CE Mark for the Cryocare Surgical System, and have registered the Cryocare Surgical System for distribution in Canada, Australia and New Zealand. We sell the Cryocare Surgical System to urology groups and urologists through our sales force and through distribution arrangements.

We were formed in 1990 as a research and development division of Medstone International, Inc. (Nasdaq: MEDS), a manufacturer of shockwave lythotripsy equipment for the treatment of kidney stones. On January 1, 1996, we became an independent, publicly-owned corporation upon Medstone s distribution of our stock to their existing stockholders. We have incurred significant operating losses and negative cash flows from operations in each full fiscal year since January 1, 1996. We incurred net losses of approximately $4.9 million in 1998, $9.3 million in 1999, $12.4 million in 2000 and $5.7 million for the nine months ended September 30, 2001. As of September 30, 2001, we had an accumulated deficit of $37.8 million. We expect to incur additional losses as we expand our sales and marketing efforts and continue to develop new products.

We generate revenues primarily from sales of our Cryocare Surgical System units and from the recurring sales of our disposable cryoprobes. We recognize revenues upon shipment for sales of system units and disposable cryoprobes. In the past, we placed our Cryocare Surgical System units with urology groups on a per-use basis to expand our installed base, and thus increase the market for our disposable cryoprobes. Under this placement program, we receive revenue from each use of the Cryocare Surgical System unit, which we recognize upon completion of the procedure. The cost of the Cryocare Surgical System unit is depreciated into cost of revenues over an estimated useful life of three years. Prior to Medicare s initiation of national reimbursement coverage for our Cryocare Surgical System in July 1999, we focused on generating revenues from a mobile cryosurgery business in which we provided cryosurgical equipment for the treatment of prostate and liver cancer on a procedural basis. Revenues from mobile cryosurgical procedures, as a percentage of total revenues have declined over the nine month period ended September 30, 2001 and are expected to continue to decline due to our increased strategic focus on system, probe and procedural sales.

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The initial product mix of Cryocare Surgical System units when compared to disposable cryoprobes will negatively impact our gross margins until we have established a sufficiently large installed base of users. In the event we establish an installed base of Cryocare Surgical System units, we expect to generate an increasing portion of our revenues through recurring sales of our disposable cryoprobes.

Cost of revenues consists primarily of:

- costs relating to the manufacture of our Cryocare Surgical System units and disposable cryoprobes,
- depreciation of Cryocare Surgical System units placed with urology groups,
- costs relating to our internal operations, and
- royalties on product sales.

Research and development expenses include expenses associated with the design, development, testing and enhancement of our products. These expenses consist primarily of:

- Salaries and related personnel expenses,
- fees paid to outside service providers,
- expenditures for clinical trials,
- expenditures for purchases of laboratory supplies, and
- utilities and other facility expenses related to product development.

We expense research and development expenses when incurred. Our research and development efforts are periodically subject to significant non-recurring expenses and fees that can cause significant variability in our quarterly research and development expenses.

Selling, general and administrative expenses primarily consist of:

- salaries, commissions and related expenses for personnel engaged in sales, marketing, customer service and administrative functions,
- expenses associated with advertising, trade shows, promotional and other marketing activities,
- legal and regulatory expenses, and
- general corporate expenses.

Results of Operations

Three and Nine Months ended September 20, 2001 and 2000

Revenues. Revenue for the three months ended September 30, 2001 increased 139% to $4,215,000 compared to $1,760,000 for the same period in 2000. The increase was attributable primarily to continued commercialization of the Company s cryosurgical technology and related cryoprobes. On June 30, 2001, we entered into a distribution agreement with U.S. Medical Devices, a subsidiary of U.S. Therapies, LLC, in which we hold an approximate 5% membership interest in the form of Class A Units. Sales to U.S. Medical Dev., Ltd., accounted for approximately 35% and 33% of our revenue for the three-month and

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nine-month periods ending September 30, 2001, respectively. Revenues for the nine months ended September 30, 2001 increased 127% to $10,508,000 compared to $4,636,000 for the same period in 2000. The increase is due to the reasons described above.

Cost of Revenues. Cost of Revenues for the nine months ended September 30, 2001 increased 68% to $3,735,600 compared to $ 2,223,000 for the same period in 2000. The increase resulted primarily from increased system and probe sales. Cost of Revenues for the three months ended September 30, 2001 increased 51% to $1,289,000 compared to $854,000 for the same period in 2000. The increase was due primarily to the increased system and probe sales.

Gross Margin. Gross margin on revenues increased to 69% for the three months ended September 30, 2001, compared to 52% for the same period in 2000. The increase is due to a mix of higher margin cryosurgical system and probe sales in 2001 coupled with a reduction in product costs due to increased manufacturing efficiencies. Gross margin on revenues increased to 64% for the nine months ended September 30, 2001 compared to 52% for the same period in 2000. The increase is due to higher margin system and related probe sales as a percentage of total revenue.

Research and Development. Research and development expense for the three months ended September 30, 2001 decreased 8% to $766,000 compared to $832,000 for the same period in 2000. The decrease can be attributed to the leveraging of previous research and development across current products. Research and development expense for the nine months ended September 30, 2001 increased 9% to $2,593,000 compared to $2,376,000 for the same period in 2000. The increase is attributable to the increase in product offerings.

Selling, General and Administrative Expenses. Selling, general and administrative expense for the three months ended September 30, 2001 increased 25% to $3,528,000 compared to $2,821,000 for the same period in 2000. The increase reflects increased sales and marketing costs associated with the commercialization of Endocare s cryosurgical product for prostate cancer, including increased sales commissions and an increase in Endocare s direct sales and marketing personnel between periods. Selling, general and administrative expense for the nine months ended September 30, 2001 increased 15% to $9,992,000 compared to $8,677,000 for the same period in 2000. The increase is attributable to the increase in sales and marketing expenditures along with increased sales commission expense associated with the greater revenues.

Interest Income (Expense), Net. Interest income (expense), net for the three months ended September 30, 2001 was $111,000 compared to ($106,000) for the same period in 2000. The change was due primarily to a reduction in interest expense as a result of the conversion of the remaining $2,300,000 in convertible debentures, net of related deferred financing cost, in July 2000 and the extinguishment of the $1 million credit facility on July 31, 2001. Interest income (expense), net for the nine months ended September 30, 2001 was $148,000 compared to ($577,000) in the same period in 2000. The change was due to the elimination of the interest expense associated with the credit facility that was paid in full upon Maturity and the conversion of all remaining debentures.

Net Loss. Endocare s net loss for the three months ended September 30, 2001 was $1,258,000, or 7 cents per share on 16,920,505 weighted average shares outstanding, compared to a net loss of $2,853,000, or 22 cents per share on 13,228,000 weighted average shares outstanding for the same period in 2000. The decrease in net loss resulted from increased revenues and related higher gross margins and lower interest expense. Endocare s net loss for the nine months ended September 30, 2001 was $5,664,000 or 36 cents per share on 15,900,000 weighted average shares outstanding, compared to a net loss of $9,218,000 or 75 cents per share on 12,358,000 weighted average shares outstanding for the same period in 2000. The decrease in net loss resulted from increased revenue, related higher gross margins and lower interest expense.

Liquidity and Capital Resources

Since our inception we have funded our operations primarily through private placements of equity securities, private placements of convertible debentures that were subsequently converted into equity

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securities, loans that were subsequently converted into equity securities, the use of short-term and long-term debt and sales to customers. At September 30, 2001, we had cash and cash equivalents of $13,482,000, compared to $22,016,000 at December 31, 2000.

In June and July 1999, we received a total of $8 million 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, these debentures were converted into 1,475,610 shares of common stock pursuant to the terms of the debentures. On May 5, 2000, we received a total of $8 million from the sale of additional 7% convertible debentures, of which $0.5 million of these debentures were converted into 74,074 shares of common stock during the fourth quarter of 2000, $1 million of these debentures were converted into 148,148 shares of common stock during the first quarter of 2001, $4.2 million of these debentures were converted into 622,222 shares of common stock during the second quarter of 2001, and the final $2.3 million of these debentures were converted into 340,741 shares of common stock in July 2001. As of September 30, 2001, the Company had no long term debt and no debentures.

Cash Used in Operations. Net cash used in operating activities was approximately $4.3 million, $8.4 million, $10.7 million and $9 million for the years ended December 31, 1998, 1999, 2000 and for nine months ended September 30, 2001, respectively. For these periods, net cash used in operating activities resulted primarily from net losses. In conjunction with the increased sales of our Cryocare Surgical System and related disposable cryoprobes, inventory increased to $2,507,000 at September 30, 2001 compared to $1,544,000 at December 31, 2000 and net accounts receivable increased to $4,483,000 at September 30, 2001 compared to $2,114,000 at December 31, 2000. Our current liabilities declined to $4,875,000 at September 30, 2001 compared to $6,401,000 at December 31,2000. The decrease in our current liabilities can be attributed primarily to the extinguishment of the credit facility and related interest.

Investing Activities. Net cash used in investing activities was approximately $0.35 million, $0.64 million, $0.48 million and $0.43 million for the years ended December 31, 1998, 1999, 2000 and for the nine months ended September 30, 2001, respectively. The net cash used in investing activities primarily included additions to property and equipment as well as investments in alliances and patents.

Cash Provided by Financing Activities. Net cash provided by financing activities was approximately $7.0 million, $10.1 million, $25.9 million and $0.85 million for the years ended December 31, 1998, 1999, 2000 and the nine months ended September 30, 2001, respectively. The net cash provided by financing activities was primarily attributable to the net proceeds from private placements of equity securities, exercise of outstanding convertible debentures, options and warrants and borrowings under our credit facility.

Working Capital. Our working capital decreased to $15.8 million at September 30, 2001 from $19.5 million at December 31, 2000. The decrease in working capital was due to our use of cash in operations, higher accounts receivable, increased inventory and an increase in current liabilities. At September 30, 2001, the ratio of current assets to current liabilities was 4.2 to 1.

On June 30, 1999, we acquired all of the outstanding membership interests of Advanced Medical Procedures, LLC, a Florida limited liability company, or AMP. The AMP unit holders received an aggregate of 260,000 shares of our common stock in exchange for all of their AMP units. AMP operated a mobile cryosurgery business which provided cryosurgical equipment for the treatment of prostate and liver cancer on a per procedure 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 businesses had been combined during such periods.

In October 1999, we entered into a strategic alliance with Sanarus Medical, Inc., a privately held medical device company. The terms of the related agreements included a 5% equity investment by our company in Sanarus totaling $300,000. We also received a warrant to acquire at that time approximately 79% of Sanarus common stock in consideration for entering into a manufacturing, supply and license agreement. The investment is included in other assets in our consolidated balance sheets as of December 31, 2000 and September 30, 2001 and is reflected at cost as we do not have significant influence over the operations of Sanarus. In June 2001, we provided a bridge loan to Sanarus in the amount of $250,000. This amount was

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subsequently repaid in July 2001 upon Sanarus receipt of additional equity financing, which financing along with other financings by Sanarus reduced our potential maximum ownership percentage to approximately 22% on a fully-diluted basis.

In June 2001, we entered into a five year distribution agreement with Qualigen, Inc. pursuant to which we will distribute Qualigen s 15-minute prostate cancer screening test as an integral part of our developmental diagnostic workstation. We have an exclusive distribution right in the United States for one-year, which exclusivity period may be extended for additional one-year periods over the term of the agreement if we satisfy minimum purchase commitments.

On June 30, 2001, we issued 213,010 shares of our common stock valued at its fair market value of $2,837,293 in consideration for a membership interest, in the form of Class A units of U.S. Therapies, LLC, equal to approximately 5% of the total issued and outstanding Class A units of U.S. Therapies on a fully-diluted basis. We simultaneously entered into a distribution agreement with U.S. Medical Devices Ltd., a subsidiary of U.S. Therapies, under which U.S. Medical Devices received exclusive sales rights to our Cryocare Surgical System and related disposable products in 16 states and the exclusive right to sell to HealthTronics Surgical Services, Inc. (Nasdaq: HTRN) and its affiliates. We recorded the investment in U.S. Therapies in investments, intangible and other assets in our balance sheet as of September 30, 2001 using the cost method of accounting. Sales to U.S. Medical Devices accounted for approximately 33% and 35% of our revenues for the nine-month and three-month periods ended September 30, 2001, respectively.

Although there can be no certainty, we believe that we can be cash flow positive in 2002. We also expect increased sales and marketing expenses related to the promotion of our Cryocare Surgical System, increased expenses related to our Horizon Prostatic Stent, increased research and development expenses, as well as expenses for additional personnel and product enhancement efforts. Our future capital requirements will depend on a number of factors, including market acceptance of our Cryocare Surgical System, the resources we devote to developing and supporting our products, continued progress of our research and development of potential products, the need to acquire licenses to technology and the availability of other financing. We believe that our current cash balances together with revenue to be derived from sales of our Cryocare Surgical System will be sufficient to fund our operations for at least the next 12 months. 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. 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 replace our credit line which matured in July 2001. Additional equity or debt financing may not be available on acceptable terms, or at all. If we are unable to obtain additional capital, we may be required to reduce our selling and marketing activities, reduce the scope of or eliminate our research and development programs, or relinquish rights to technologies or products that we might otherwise seek to develop or commercialize. In the event that we incur additional indebtedness to fund our operations, we may have to grant the lender a security interest in our assets.

We believe that holidays, major medical conventions and vacations taken by physicians, patients and patient families may have a seasonal impact on our sales. We are continuing to monitor and assess the impact seasonality may have on demand of our products.

Inflation

The impact of inflation on our business has not been material to date.

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

Before deciding to invest in our common stock, or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information in this quarterly report our quarterly report for the quarters ended March 31, 2001 and June 30, 2001, our annual report on Form 10-K

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for the year ended December 31, 2000, and our other filings with the SEC. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of any of the following risks could harm our business. In that case, the trading price of our common stock could decline and you may lose all or part of your investment.

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 nine-month period ended September 30, 2001, we had net losses of approximately $4.9 million, $9.3 million, $12.4 million and $5.7 million, respectively. As of September 30, 2001, our accumulated deficit was approximately $37.8 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.

WE RELY ON A SINGLE PRODUCT, THE CRYOCARE SURGICAL SYSTEM, WHICH COULD FAIL TO ACHIEVE MARKET ACCEPTANCE OR GENERATE SIGNIFICANT REVENUE.

We introduced our sole product, the Cryocare Surgical System, to the market in July 1999. We derive substantially all of our revenues from sales of Cryocare Surgical Systems and related disposable supplies and expect that sales of Cryocare Surgical Systems and related disposable supplies will continue to constitute the majority of our sales for the foreseeable future. Accordingly, our success is entirely reliant on our ability to market the Cryocare Surgical System commercially in the United States and other countries. However, the Cryocare Surgical System and any future products may not be accepted by potential customers. We believe that recommendations and endorsements of physicians and patients will be essential for market acceptance of our Cryocare Surgical System and other products, and these recommendations and endorsements may not be obtained.

Cryosurgery has existed for many years, but has not been widely accepted primarily due to concerns regarding safety and efficacy and widespread use of alternative therapies. Because of a lack of precise monitoring, cryosurgical procedures performed in the 1970s resulted in high cancer recurrence and negative side effects, such as rectal fistula and incontinence, and attached a stigma to cryosurgical treatment. Now that ultrasound guidance and temperature sensing are available for more precise monitoring, we will need to overcome this stigma to obtain market acceptance for our product. Use of our Cryocare Surgical System requires significant physician education and training.

Our ability to successfully market our Cryocare Surgical System is dependent, among other things, upon acceptance of cryosurgical procedures both in the United States and international markets. Any adverse side effects, including impotence or incontinence, recurrence of cancer or future reported adverse events or other unfavorable publicity involving patient outcomes from the use of cryosurgery, whether from our products or the products of our competitors, could adversely affect acceptance of cryosurgery. 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 Surgical System and our other products may not gain any significant degree of market acceptance among physicians, patients and health care payors. If our cryosurgical products do not achieve market acceptance, we will likely remain unprofitable.

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IF WE ARE UNABLE TO CONTINUE TO DEVELOP INNOVATIVE PRODUCTS IN THE PROSTATE AND OTHER UROLOGICAL MARKETS, OUR BUSINESS WILL SUFFER.

Our growth depends in large part on continued ability to successfully develop and commercialize our current products under development and any new products in the prostate and other urological markets. 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 Surgical 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. In addition, our competitors may succeed in developing commercially viable products that render our products obsolete or less attractive. Our failure to successfully develop and commercialize new products will likely have a significant negative effect on our financial prospects.

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 and use our mobile services generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to reimburse all or part of the cost of medical procedures involving our products and services and on reimbursement for our products and procedures. While some private health insurance companies pay for the procedures in which our products are used in some 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. If reimbursement levels from Medicare, Medicaid, other governmental health care programs or private insurers are not sufficient, physicians may choose not to recommend, and patients may not choose, procedures utilizing our products.

Currently, reimbursement under Medicare for our disposable products used in outpatient procedures is provided under a pass through system in which Medicare pays the cost we charge the hospital for our products. Pass through reimbursement status only remains for a period of two to three years, dependent upon the time period in which the Centers for Medicare and Medicaid Services, or CMS, formerly the Healthcare Financing Administration, or HCFA, obtains sufficient data to establish a cost. We obtained pass through status for disposable products related to the Cryocare Surgical System on April 1, 2001. Thus, pass through status for those products will terminate no later than April 1, 2004. After pass through status terminates, the cost of our disposable products will be incorporated into the hospital outpatient prospective payment system and there will be no separate reimbursement for our disposable products. Federal law limits the total cost for pass through payments to 2.5% of expenditures for all hospital outpatient services in a given year. On November 2, 2001, CMS published a final rule indicating that significant pro rata reductions will be required for 2002 in order to meet the statutory limit on the amount of the pass through payments, but did not provide the specific amount of the pro rata reduction. In a subsequent final rule to be published by December 1, 2001, CMS will include the tables necessary to calculate the 2002 pass through payment rates. The impact on our revenues of the pass through payment reduction is unclear at this time. In addition, if proposed regulations for hospital outpatient services are finalized as written, pass through status may be shortened to as little as one year if CMS develops sufficient data to establish a cost. Further, we anticipate that, under the prospective payment system used by private health care payors, 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 disposable products. This may discourage the use of our products.

International market acceptance of our products may depend, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government sponsored health care and private insurance. We may not obtain international reimbursement approvals in a timely

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manner, if at all. Our failure to receive international reimbursement approvals may negatively impact market acceptance of our products in the international markets in which those approvals are sought.

Furthermore, significant attention is focused 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, may have a material adverse effect on reimbursement for our products or procedures in which our products are used and may reduce the price we are able to charge for our products. In addition, changes to the healthcare system may also affect the commercial acceptance of products we are currently developing and products we may develop in the future. Potential approaches that have been considered include controls on healthcare spending through limitations on the growth of private purchasing groups and price controls. Several proposals have been made in the United States Congress and various state legislatures recently that, if adopted, would potentially reduce healthcare spending which may result in a material adverse effect on our business.

WE MAY HAVE DIFFICULTY MANAGING OUR GROWTH.

We expect to continue to experience significant growth in the scope of our operations and the number of our employees. This growth will likely continue to place a significant strain on our management and operations. Our ability to manage this growth will depend upon our ability to attract, hire and retain skilled employees. Our success will also depend on the ability of our officers and key employees to continue to implement and improve our operational and other systems, to manage multiple, concurrent development projects and to hire, train and manage our employees. Our future success is heavily dependent upon growth and acceptance of new products. If we cannot scale our business appropriately or otherwise adapt to anticipated growth and new product introduction, our business, financial condition and results of operations will be adversely affected.

WE HAVE LIMITED SALES AND MARKETING EXPERIENCE AND ANY FAILURE TO SIGNIFICANTLY EXPAND SALES OF OUR PRODUCTS WILL NEGATIVELY IMPACT FUTURE REVENUE.

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

IF OUR RELATIONSHIP WITH U.S. MEDICAL DEVICES IS DISRUPTED, OUR REVENUES COULD BE SIGNIFICANTLY REDUCED.

We have an exclusive distribution agreement with U.S. Medical Devices Ltd. For the nine months ended September 30, 2001, 33% of our revenues were derived from sales made to U.S. Medical Devices. As a result, our revenues are dependent in large part on continued sales to this distributor.

OUR SUCCESS WILL DEPEND ON OUR ABILITY TO ATTRACT AND RETAIN KEY PERSONNEL.

In order to execute our business plan, we need to attract, retain and motivate a significant number of highly qualified managerial, technical and sales personnel. If we fail to attract and retain skilled scientific and

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marketing personnel, our research and development and sales and marketing efforts will be hindered. Our future success depends to a significant degree upon the continued services of key management personnel, including 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. Competition for such personnel is intense, particularly in southern California where we are located. If we do not attract and retain qualified personnel we will not be able to achieve our growth objectives.

IF WE FAIL TO PROTECT OUR INTELLECTUAL PROPERTY RIGHTS, OUR COMPETITORS MAY TAKE ADVANTAGE OF OUR IDEAS AND COMPETE DIRECTLY AGAINST US.

Our success will depend to a significant degree on our ability to secure and protect intellectual proprietary rights and enforce patent and trademark protections relating to our technology. While we believe that the protection of patents and trademarks is important to our business, we also rely on a combination of copyright, trade secret, nondisclosure and confidentiality agreements, know-how and continuing technological innovation to maintain our competitive position. From time to time, litigation may be advisable to protect our intellectual property position. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any litigation in this regard could be costly, and it is possible that we will not have sufficient resources to fully pursue this litigation or to protect our other intellectual property rights. It could result in the rejection or invalidation of our existing and future patents. Any adverse outcome in litigation relating to the validity of our patents, or any failure to pursue litigation or otherwise to protect our patent position, could materially harm our business and financial condition. In addition, confidentiality agreements with our employees, consultants, customers, and key vendors may not prevent the unauthorized disclosure or use of our technology. It is possible that these agreements will be breached or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Enforcement of these agreements may be costly and time consuming. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States.

BECAUSE THE MEDICAL DEVICE INDUSTRY IS LITIGIOUS, WE MAY BE SUED FOR ALLEGEDLY VIOLATING THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS.

The medical technology industry has in the past been characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. In addition, major medical device companies have used litigation against emerging growth companies as a means of gaining a competitive advantage.

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

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

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

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IF WE REQUIRE FUTURE CAPITAL, WE MAY NOT BE ABLE TO SECURE ADDITIONAL FUNDING IN ORDER TO EXPAND OUR OPERATIONS AND DEVELOP NEW PRODUCTS.

If we fail to reach profitability, undertake or accelerate significant research and development projects for new products or pursue corporate acquisitions, we may need additional outside financing. We may raise these additional funds by selling our equity securities, incurring additional debt or entering into collaborative arrangements. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve interest expense and restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to some of our technologies, products or marketing territories. Our failure to raise capital when needed could harm our business.

WE HAVE LIMITED EXPERIENCE MANUFACTURING OUR PRODUCTS AND IF WE ARE UNABLE TO MEET CUSTOMER DEMAND, WE MAY NOT BECOME PROFITABLE.

We use solely internal manufacturing capacity to manufacture our products. We have limited experience in producing our products in commercial quantities. We may encounter difficulties in scaling up production of new products, including problems involving production yields, quality control and assurance, component supply and shortages of qualified personnel. Our failure to overcome these manufacturing problems could negatively impact our business and financial condition.

Our success will depend in part upon our ability to manufacture our products in compliance with the FDA s Quality System Regulation and other regulatory requirements in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. Our manufacturing facility is subject to periodic inspection by the FDA, state agencies and foreign regulatory agencies. If we fail to increase production volumes in a timely or cost-effective manner or to maintain compliance with the FDA s Quality System Regulation or other regulatory requirements, our business will suffer.

WE ARE DEPENDENT UPON A LIMITED NUMBER OF THIRD-PARTY SUPPLIERS TO MANUFACTURE OUR PRODUCTS AND THE LOSS OF ANY OF THESE SUPPLIERS COULD HARM OUR BUSINESS.

We depend upon a 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, the qualification of additional or replacement supplies could be a lengthy process and there may not be adequate alternatives to meet our needs, which will have a material adverse effect on our business. We may not be able to obtain the necessary components and materials used in our products in the future on a timely basis, if at all.

IF WE FAIL TO OBTAIN OR MAINTAIN NECESSARY REGULATORY CLEARANCES OR APPROVALS FOR PRODUCTS, OR IF APPROVALS ARE DELAYED OR WITHDRAWN, WE WILL BE UNABLE TO COMMERCIALLY DISTRIBUTE AND MARKET OUR PRODUCTS OR ANY PRODUCT MODIFICATIONS.

Government regulation has a significant impact on our business. Government regulation in the United States and other countries is a significant factor affecting the research and development, manufacture and marketing of our products. In the United States, the FDA has broad authority under the Federal Food, Drug and Cosmetic Act to regulate the distribution, manufacture and sale of medical devices. Foreign sales of drugs and medical devices are subject to foreign governmental regulation and restrictions, which vary from country to country. The process of obtaining FDA and other required regulatory clearances and approvals is lengthy and expensive. We may not be able to obtain or maintain necessary approvals for clinical testing or for the manufacturing or marketing of our products. Failure to comply with applicable regulatory approvals can, among other things, result in fines, suspension or withdrawal of regulatory approvals, product recalls, operating restrictions, and criminal prosecution. In addition, governmental regulations may be established which could prevent, delay, modify or rescind regulatory approval of our products. Any of

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these actions by the FDA, or change in FDA regulations, 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 prohibits the marketing of approved medical devices for unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory standards or unforeseen problems following initial marketing. We may not be able to obtain or maintain regulatory approvals for our products on a timely basis, or at all, and delays in receipt of or failure to receive such approvals, the loss of previously obtained approvals, or failure to comply with existing or future regulatory requirements would have a significant negative effect on our financial condition.

OUR PRODUCTS MAY BE SUBJECT TO PRODUCT RECALLS EVEN AFTER RECEIVING FDA CLEARANCE OR APPROVAL, WHICH WOULD HARM OUR REPUTATION AND OUR BUSINESS.

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

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

Federal anti-kickback laws and regulations prohibit the knowing and willful offer, payment, solicitation and receipt of any form of remuneration in exchange for the referral of an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made by Medicare, Medicaid and 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 a major 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 FEDERAL AND STATE 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 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, often broader laws prohibiting referrals by any licensed health care provider. 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

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have financial relationships with physicians and physician-owned entities. Although we believe that our financial relationships with physicians and physician-owned entities are not in violation of applicable laws and regulations, governmental authorities might take a contrary position. If our financial relationships with physicians or physician-owned entities 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, physician-owned entities 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.

IF WE BECOME SUBJECT TO PRODUCT LIABILITY CLAIMS, WE MAY BE REQUIRED TO PAY DAMAGES THAT EXCEED OUR INSURANCE COVERAGE.

Our business exposes us to potential product liability claims that are inherent in the testing, production, marketing and sale of medical devices. While we believe that we are reasonably insured against these risks, we may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Currently, we maintain product liability insurance in amounts we deem to be reasonable. A product liability claim in excess of our insurance coverage would have to be paid out of cash reserves and would harm our reputation in the industry and our business.

WE ARE FACED WITH INTENSE COMPETITION AND RAPID TECHNOLOGICAL AND INDUSTRY CHANGE, WHICH MAY MAKE IT MORE DIFFICULT FOR US TO ACHIEVE SIGNIFICANT MARKET PENETRATION.

The medical device industry generally, and the urological disease treatment market in particular, are characterized by rapid technological change, changing customer needs, and frequent new product introductions. If our competitors existing products or new products are more effective than or considered superior to our products, the commercial opportunity for our products will be reduced or eliminated. We face intense competition from companies in the cryosurgical marketplace as well as companies offering other treatment options, including radical surgery, radiation therapy and hormone therapy. If we are successful in penetrating the market for treatment of prostate cancer with our cryosurgical treatment, other medical device companies may be attracted to the marketplace. Many of our potential competitors are significantly larger than 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 obtain regulatory approval, and introduce and commercialize products before we do. These 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.

FLUCTUATIONS IN OUR FUTURE OPERATING RESULTS MAY NEGATIVELY IMPACT THE MARKET PRICE OF OUR COMMON STOCK.

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

- the impact of acquisitions,
- market acceptance of our existing products, as well as products in development,
- the timing of regulatory approvals,
- the timing of payments received and the recognition of such payments as revenue under collaborative arrangements and strategic alliances,

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our ability to manufacture products efficiently,

the timing of our research and development expenditures, and

the timing of customer orders.

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

IF WE ACQUIRE NEW AND COMPLEMENTARY BUSINESSES, PRODUCTS OR TECHNOLOGIES INSTEAD OF DEVELOPING THEM OURSELVES, WE MAY BE UNABLE TO COMPLETE THESE ACQUISITIONS OR TO SUCCESSFULLY INTEGRATE AN ACQUIRED BUSINESS OR TECHNOLOGY IN A COST-EFFECTIVE AND NON-DISRUPTIVE MANNER.

As part of our strategy to acquire complementary urological products and technologies, we may acquire one or more businesses or lines of business. 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 cannot assure you that we will be able to identify suitable acquisition opportunities. 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 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 acquiring businesses or managing facilities or operations in geographically distant areas. In addition, our profitability may suffer because of acquisition-related costs, amortization costs, restructuring or impairment of acquired goodwill and other intangible assets. There is also a risk of loss of key employees, customers and vendors of recently acquired businesses. 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, any equity issuances will be dilutive to our existing stockholders.

OUR STOCK PRICE MAY BE VOLATILE AND YOUR INVESTMENT COULD DECLINE IN VALUE.

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 events concerning us or our competitors could cause such volatility including:

actual or anticipated variations in our operating results,

developments regarding government and third-party reimbursement,

changes in government regulation,

government investigation of us or our products,

changes in reimbursement rates or methods affecting our products,

developments concerning proprietary rights,

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litigation or public concern as to the safety of our products or our competitor s products,

technological innovations or new commercial products by us or our competitors,

investor perception of us and our industry, and

general economic and market conditions including market uncertainty related to the September 11, 2001 terrorist attacks and any potential military action resulting from the attacks.

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. Any failure by us to meet or exceed estimates of financial analysts is likely to cause a decline in our common stock price.

OUR COMMON STOCK HAS A LIMITED MARKET AND TRADING HISTORY AND THERE MAY NOT BE AN ACTIVE, LIQUID TRADING MARKET FOR OUR COMMON STOCK.

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 in February 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.

FUTURE SALES OF SHARES OF OUR COMMON STOCK MAY NEGATIVELY AFFECT OUR STOCK PRICE.

Future sales of our common stock, including shares issued upon the exercise of outstanding options and warrants or hedging or other derivative transactions with respect to our stock, could have a significant negative effect on the market price of our common stock. These sales also might make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that we would deem appropriate.

WE COULD BE DIFFICULT TO ACQUIRE DUE TO ANTI-TAKEOVER PROVISIONS IN OUR CHARTER, OUR STOCKHOLDERS RIGHTS PLAN AND DELAWARE LAW.

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

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

Some of the information in this report and in the documents we have filed with the Securities and Exchange Commission, may contain forward-looking statements within the meaning of the federal securities laws. Forward-looking statements include, but are not limited to, statements about our plans, objectives, expectations and intentions and other statements contained in this prospectus and the accompanying prospectus supplement that are not historical facts. You may find these statements under Factors That May Affect Future Results and Trading Price of Common Stock, Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report and in the other documents filed with the SEC.

We typically use terms such as may, will, expect, anticipate, intend, plan, believe, seek and estimate and similar words t forward-looking statements, although we express some forward-looking statements differently. You should be aware that these statements are not guarantees of future performance and are subject to risks and uncertainties, some of which are beyond our control and are difficult to predict, and that our actual results could differ materially from those expressed or forecasted in the forward-looking statements due to a number of factors, including:

- failure to successfully commercialize our products,
- failure to develop new products,
- competitive factors,
- general economic conditions,
- failure to achieve positive results in clinical trials,
- uncertainty regarding our patents and patent rights and costs of patent litigation, including the material harm to us if there were an unfavorable outcome of any such litigation,
- government regulation,
- government investigation,
- changes in reimbursement rates or methods, or
- technological change.

You should also consider carefully the statements under Factors That May Affect Future Results and Trading Price of Common Stock and other sections of this report and in the other documents filed with the SEC, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements. You should not place undue reliance on any forward-looking statements, which reflect our management s view only as of the date of this report. We have no plans to update these forward-looking statements.

We use market data and industry forecasts throughout this report, which we have obtained from internal surveys, market research, publicly available information and industry publications. Industry publications generally state that the information they provide has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. Similarly, we believe that the surveys and market research we or others have performed are reliable, but we have not independently verified this information.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. Our financial instruments include cash, cash equivalents and notes receivable. At September 30, 2001, the carrying values of our financial instruments approximated their fair values. We do not believe that an increase in market rates would have any significant negative impact on our consolidated financial statements.

Our policy is not to enter into derivative financial instruments. In addition, we do not enter into any futures or forward contracts and therefore, we do not have significant market risk exposure with respect to commodity prices.

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

The Company maintained a $5,000,000 credit facility that accrued interest at the highest prime rate or equivalent rate announced by certain designated banks, plus 2% or 3.5%. This was the Company s only debt which did not have a fixed-rate of interest. The credit facility expired in July 2001.

PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

The Company, in the normal course of business, 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 the Company s 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. Management does not expect any material adverse effect on the consolidated financial condition or the results of operations because of such actions.

ITEM 2. Changes in Securities

During the period from July 1, 2001 through September 30, 2001, the Company granted stock options to 11 individuals covering an aggregate of 76,500 shares of its common stock, pursuant to the Company s 1995 Stock Plan. All such options were granted at exercise prices equaling fair market value on the date of grant, vest over a four-year period, and are exercisable over a ten-year period. No consideration was paid for any of such options. Such grants were exempt from the registration requirement of the Securities Act as not involving the sale of a security.

ITEM 3. Defaults Upon Senior Securities

Not applicable.

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

Not applicable.

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ITEM 5. Other Information

Most prostate procedures using our Cryocare Surgical System currently are performed in hospitals on an inpatient basis and are reimbursed under Medicare's hospital prospective payment system. We also have established reimbursement for outpatient procedures under the Medicare program. Currently, reimbursement under Medicare for our disposable products used in outpatient procedures is provided under a pass through system in which Medicare pays the costs we charge the hospital for our products. Federal law limits the total cost for pass through payments to 2.5% of expenditures for all hospital outpatient services in a given year. On August 24, 2001, the Centers for Medicare and Medicaid Services, or CMS, published a proposed rule indicating that significant pro rata reductions might be required for 2002 in order to meet the statutory limit on the amount of the pass through payments. On November 2, 2001, CMS published a final rule with information and estimates regarding a uniform reduction in the pass through payments for 2002, but did not provide the specific amount of the pro rata reduction. In a subsequent final rule to be published by December 1, 2001, CMS will include the tables necessary to calculate the 2002 pass through payment rates. The impact on our revenues of the pass through payment reduction is unclear at this time.

ITEM 6. Exhibits and Reports on Form 8-K.

(a) Exhibits

Exhibit No.	Title
2.1(1)	Agreement and Plan of Merger dated June 30, 1999 by and among the Company, Advanced Medical Procedures, Inc., a Delaware corporation, Advanced Medical Procedures, LLC, a Florida limited liability company, Gary M. Onik, M.D., Robert F. Byrnes and Jerry Anderson. Schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the SEC upon request.
3.3(2)	Restated Certificate of Incorporation
3.4(3)	Certificate of Designation of Series A Junior Participating Preferred Stock of the Company.
3.5(4)	Certificate of Amendment of Restated Certificate of Incorporation of the Company.
3.6(5)	Amended and Restated Bylaws of the Company
10.30(6)	Promissory Notes dated August 8, 2001 and July 24, 2001, as subsequently amended, by Paul Mikus in favor of the Company.
10.31(7)	Change in Employment

Status and Settlement Agreement and Release effective as of June 25, 2001 by and between the Company and William Hughes.10.32(8) Consulting and Confidentiality Agreement dated as of June 1, 2001 by and between the Company and Michael Strauss, M.D.10.33(9) Note and Warrant Purchase Agreement dated as of April 1, 2001 by and among the Company, Sanarus Medical, Inc. and specified purchasers and related Convertible Promissory Note and Warrant to Purchase Series B Preferred Stock dated April 1, 2001.10.34(10) Offer of Employment effective as of February 16, 2001 by and between the Company and Kevin Quilty.10.35(11) Offer of Employment effective as of September 22, 2000 by and between the Company and David Battles.10.36(12) Offer of Employment

effective as of August 14, 2000 by and between the Company and Holly Williams.10.37(13) Promissory Note dated November 2, 1999 by Jerry Anderson in favor of the Company.

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Exhibit No.	Title
10.38(14)	Promissory Note cancellations between the Company and each of Paul Mikus, Vincent Cutarelli, Jay Eum and William Hughes.10.39(15) Consulting Agreement dated as of January 6, 1999 by and between the Company and Robert Byrnes.10.40(16) Consulting Agreement dated as of January 6, 1999 by and between the Company and Alan Kaganov.10.41(17) Loan and Security Agreement dated as of October 1, 1998 between the Company and Advanced Medical Procedures, LLC, a Florida limited liability company and related Revolving Promissory Note dated October 1, 1998.10.42(18) Guarantor Security Agreement dated as of October 1,

1998 by and between the Company and Robert Byrnes.10.43(19) Scientific Advisory Board Agreement dated as of December 2, 1997 by and between the Company and Foundation Research, Inc.10.44(20) Consulting Agreement dated as of May 27, 1997 by and between the Company and Bob Byrnes.10.45(***) Global Supply and Market Access Agreement by and between Endocare, Inc. and CryoCath Technologies, Inc., dated September 21, 2001.10.46(***) Distribution Agreement by and between Endocare, Inc. and Qualigen, Inc., dated September 25, 2001.

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(1) Incorporated by reference to Exhibit 2.1 to the S-3 as filed with the Commission on September 20, 2001.

(2) Incorporated by reference to Exhibit 3.3 to the S-3 as filed with the Commission on September 20, 2001.(3) Incorporated by reference to Exhibit 3.2 to the S-3 as filed with the Commission on

September 20, 2001.(4) Incorporated by reference to Exhibit 3.1 to the S-3 as filed with the Commission on September 20, 2001.(5) Incorporated by reference to Exhibit 3.4 to the S-3 as filed with the Commission on September 20, 2001.(6) Incorporated by reference to Exhibit 10.1 to the S-3/A as filed with the Commission on October 31, 2001.(7) Incorporated by reference to Exhibit 10.2 to the S-3/A as filed with the Commission on October 31, 2001.(8) Incorporated by reference to Exhibit 10.3 to the S-3 as filed with the Commission on September 20, 2001.(9) Incorporated by reference to Exhibit 10.4 to the S-3 as filed with the Commission on September 20, 2001.(10) Incorporated by reference to Exhibit 10.5 to the S-3 as filed with the Commission on September 20, 2001.(11) Incorporated by reference to Exhibit 10.6 to the S-3 as filed with the Commission on

September 20, 2001.(12) Incorporated by reference to Exhibit 10.7 to the S-3 as filed with the Commission on September 20, 2001.(13) Incorporated by reference to Exhibit 10.8 to the S-3 as filed with the Commission on September 20, 2001.(14) Incorporated by reference to Exhibit 10.9 to the S-3/A as filed with the Commission on October 31, 2001.(15) Incorporated by reference to Exhibit 10.10 to the S-3/A as filed with the Commission on October 31, 2001.

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(16) Incorporated by reference to Exhibit 10.11 to the S-3 as filed with the Commission on September 20, 2001.
(17) Incorporated by reference to Exhibit 10.12 to the S-3 as filed with the Commission on September 20, 2001.(18) Incorporated by reference to Exhibit 10.13 to the S-3 as filed with the Commission on September 20, 2001.(19) Incorporated by reference to Exhibit 10.14 to the S-3 as filed with the Commission on September 20, 2001.(20) Incorporated by reference to Exhibit 10.15 to the S-3 as filed with the Commission on September 20, 2001.(***) Certain confidential portions of the exhibits were omitted by means of marking such portions with an asterisk (the Mark). This exhibit has been filed separately with the Secretary of the Securities and Exchange Commission (SEC) without the Mark pursuant to the Company s Application Requesting Confidential Treatment under SEC

Rule 24b-2.

(b) Reports on Form 8-K

Endocare filed a current report on Form 8-K on September 26, 2001 regarding the strategic alliance entered into by and between the Company and CryoCath Technologies, Inc. with the signing of a five-year exclusive global supply and market access agreement.

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SIGNATURES

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

Date: November 9, 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)