

ENDOCARE INC  
Form 10-Q  
August 14, 2002

**Table of Contents**

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

**FORM 10-Q**

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED **JUNE 30, 2002**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_.  
COMMISSION FILE NUMBER: 000-27212

**ENDOCARE, INC.**  
(Exact Name of Registrant as Specified in Its Charter)

DELAWARE  
(State of Incorporation)  
33-0618093  
(I.R.S. Employer I.D. No.)  
201 TECHNOLOGY DRIVE, IRVINE, CALIFORNIA 92618  
(Address of Principal Executive Office, Including Zip Code)  
(949) 450-5400  
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

(1) Yes ☒ No ☐; (2) Yes ☒ No ☐.

The number of shares of the Registrant's common stock, par value \$.001 per share, outstanding at August 1, 2002 was 24,279,229.

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**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

**ITEM 1. Consolidated Financial Statements**

Condensed Consolidated Statements of Operations

Condensed Consolidated Balance Sheets

Condensed Consolidated Statements of Cash Flows

Notes to Condensed Consolidated Financial Statements

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

**ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

**PART II OTHER INFORMATION**

**ITEM 1. Legal Proceedings**

**ITEM 2. Changes in Securities**

**ITEM 3. Defaults Upon Senior Securities**

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

**ITEM 5. Other Information**

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

**SIGNATURES**

**EXHIBIT INDEX**

Exhibit 2.3

Exhibit 2.4

Exhibit 99.1

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**Table of Contents**

**Endocare, Inc.  
Form 10-Q, Quarter Ended June 30, 2002**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I FINANCIAL INFORMATION</b>	<b>3</b>
ITEM 1. Consolidated Financial Statements	3
Condensed Consolidated Statements of Operations (Unaudited)	3
Condensed Consolidated Balance Sheets	4
Condensed Consolidated Statements of Cash Flows	5
Notes to Condensed Consolidated Financial Statements	6
ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	11
ITEM 3. Quantitative and Qualitative Disclosures About Market Risk	26
<b>PART II OTHER INFORMATION</b>	<b>27</b>
ITEM 1. Legal Proceedings	27
ITEM 2. Changes in Securities	27
ITEM 3. Defaults Upon Senior Securities	27
ITEM 4. Submission of Matters to a Vote of Security Holders	27
ITEM 5. Other Information	28
ITEM 6. Exhibits and Reports on Form 8-K	28
SIGNATURE PAGE	30

**Table of Contents****PART I FINANCIAL INFORMATION****ITEM 1. Consolidated Financial Statements**

**ENDOCARE, INC.**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Revenues	\$ 11,378,006	\$ 3,537,849	\$ 19,151,070	\$ 6,293,436
Costs and expenses:				
Cost of revenues	3,437,194	1,272,403	6,197,949	2,446,293
Research and development	1,041,191	923,445	1,989,058	1,826,264
Selling, general and administrative	5,808,809	3,440,374	10,023,441	6,464,494
Total costs and expenses	10,287,194	5,636,222	18,210,448	10,737,051
Income (loss) from operations	1,090,812	(2,098,373)	940,622	(4,443,615)
Other income (expense):				
Interest income, net	327,244	34,467	643,407	37,541
Loss on investment	(250,000)		(250,000)	
Total other income	77,244	34,467	393,407	37,541
Income (loss) before taxes	1,168,056	(2,063,906)	1,334,029	(4,406,074)
Provision for income taxes	(33,500)		(33,500)	
Net income (loss)	\$ 1,134,556	\$ (2,063,906)	\$ 1,300,529	\$ (4,406,074)
Net loss per share of common stock:				
Basic	\$ .05	\$ (.13)	\$ .06	\$ (.29)
Diluted	\$ .05	\$ (.13)	\$ .05	\$ (.29)
Weighted average common shares:				
Basic	24,000,348	15,601,688	23,081,773	15,379,381
Diluted	25,177,964	15,601,688	24,399,150	15,379,381

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

**Table of Contents**

**ENDOCARE, INC.**  
**Condensed Consolidated Balance Sheets**  
**(unaudited)**

	June 30, 2002	December 31, 2001
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 45,723,372	\$ 83,238,915
Short-term investments	17,267,875	35,928
Accounts receivable, net	11,347,866	5,733,563
Inventories	5,285,229	2,415,744
Prepaid expenses and other current assets	1,690,797	757,097
Total current assets	81,315,139	92,181,247
Property and equipment, net	5,284,864	1,814,714
Goodwill	32,619,810	
Investments, intangible and other assets, net	12,677,410	4,037,981
Total assets	\$ 131,897,223	\$ 98,033,942
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,376,458	\$ 1,260,214
Accrued compensation	1,332,957	1,334,168
Other accrued liabilities	1,209,901	826,119
Total current liabilities	5,919,316	3,420,501
Stockholders' equity		
Preferred stock, \$.001 par value; 1,000,000 shares authorized; none issued and outstanding at June 30, 2002 and December 31, 2001, respectively		
Common stock, \$.001 par value; 50,000,000 shares authorized; 24,277,289 and 22,057,905 issued and outstanding at June 30, 2002 and December 31, 2001, respectively	24,277	22,058
Additional paid-in capital	163,777,812	133,716,105
Receivables from stockholders	(1,028,125)	(1,028,125)
Accumulated deficit	(36,796,057)	(38,096,597)
Total stockholders' equity	125,977,907	94,613,441
Total liabilities and stockholders' equity	\$ 131,897,223	\$ 98,033,942

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

Table of Contents

**ENDOCARE, INC.**  
**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**

	Six Months Ended June 30,	
	2002	2001
Cash flows from operating activities:		
Net income (loss)	\$ 1,300,529	\$ (4,406,074)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	615,089	196,460
Amortization of warrant value	81,280	98,124
Amortization of deferred financing costs		89,937
Changes in operating assets and liabilities:		
Accounts receivable	(4,868,287)	(1,556,863)
Inventories	(1,155,882)	(617,172)
Prepaid expenses and other current assets	(888,351)	38,656
Other assets	(203,070)	(118,053)
Accounts payable	1,154,035	(233,861)
Accrued compensation	(785,236)	176,119
Other accrued liabilities	(846,373)	(92,939)
Net cash used in operating activities	(5,596,266)	(6,425,666)
Cash flows from investing activities:		
Purchase of investment securities	(17,231,947)	
Acquisitions, net of cash acquired	(12,970,027)	(458,850)
Deposit for USMD acquisition	(900,000)	
Purchases of property and equipment (including assets for placement of \$1.4 million in 2002)	(2,709,683)	(117,054)
Net cash used in investing activities	(33,811,657)	(575,904)
Cash flows from financing activities:		
Borrowings under credit facility		558,011
Issuance of common stock	1,892,380	354,805
Net cash provided by financing activities	1,892,380	912,816
Net decrease in cash and cash equivalents	(37,515,543)	(6,088,754)
Cash and cash equivalents, beginning of period	83,238,915	22,016,448
Cash and cash equivalents, end of period	\$ 45,723,372	\$ 15,927,694
Non-cash activities:		
Convertible debentures and accrued interest converted to common stock, net of unamortized deferred financing costs	\$	\$ 2,837,293
Common stock issued for the purchase of patents	1,410,000	
Forgiveness of recourse loan and compensation to employees		81,747
Transfer of inventory to property and equipment for placement at customer site		42,930

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Total non-cash activities	\$ 1,410,000	\$ 2,961,970
Fair value of net assets acquired:		
Intangible assets acquired	\$ 5,694,000	\$
Tangible assets acquired, net	2,463,572	
Costs in excess of net assets (goodwill)	32,619,810	
Fair value of assets acquired, net	\$ 40,777,382	\$
Common stock and options issued	(26,680,277)	
Cash paid	14,097,105	
Less cash acquired	(1,127,078)	
Net cash paid for acquisition	\$ 12,970,027	\$

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



**Table of Contents**

**ENDOCARE, INC.  
Notes to Condensed Consolidated Financial Statements**

**1. Financial Information**

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements contain all adjustments necessary (consisting only of normal recurring accruals) to present fairly the financial information contained therein. These statements do not include all disclosures required by accounting principles generally accepted in the United States of America and should be read in conjunction with the audited consolidated financial statements and other information included in the Company's Annual Report on Form 10-K for the year ended December 31, 2001. Financial results for this interim period are not necessarily indicative of results to be expected for the full year 2002.

**Accounting Principles**

In July 2001, the FASB issued SFAS No. 141, Business Combinations and No. 142, Goodwill and Other Intangible Assets. SFAS No. 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. SFAS No. 141 also specifies criteria for intangible assets acquired in a purchase method business combination must meet to be recognized and reported apart from goodwill, noting that any purchase price allocable to an assembled workforce may not be accounted for separately. SFAS No. 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also requires 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 adopted the provisions of SFAS No. 141, except with regard to business combinations initiated prior to July 1, 2001, and SFAS No. 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-SFAS No. 142 accounting literature. The adoption of SFAS Nos. 141 and 142 did not have a material effect on the Company's financial position or results of operations. The Company accounted for the acquisition of Timm Medical and effective in February 2002 and Cryomedical, Inc. in June 2002 in accordance with SFAS Nos. 141 and 142.

In June 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. The Company intends to adopt SFAS No. 143 beginning January 1, 2003. This Statement is not expected to have a material impact on the Company's financial reporting and related disclosures.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS No. 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 No. 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.

**Table of Contents**

The Company adopted the provisions of SFAS No. 144 in the quarter ending March 31, 2002. The implementation of SFAS No. 144 did not have a material effect on the Company's financial statements.

In July 2002, Statement of Financial Accounting Standards No. 146, Accounting for Costs Associated with Exit or Disposal Activities, (SFAS No. 146) was issued and is effective for periods beginning after December 31, 2002. SFAS No. 146 requires, among other things, that costs associated with an exit activity (including restructuring and employee and contract termination costs) or with a disposal of long-lived assets be recognized when the liability has been incurred and can be measured at fair value. Companies must record in income from continuing operations costs associated with an exit or disposal activity that does not involve a discontinued operation. Costs associated with an activity that involves a discontinued operation would be included in the results of discontinued operations. The Company believes that the implementation of the provisions of SFAS No. 146 will not have a material effect on the Company's financial statements.

**2. 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.

**3. Acquisition of Timm Medical**

On March 25, 2002, the Company completed a merger with Timm Medical under which Timm Medical became a wholly-owned subsidiary of the Company. In connection with the merger, all outstanding shares of capital stock of Timm Medical were exchanged for 1,620,530 shares of the Company's common stock with an aggregate value of \$23.8 million and approximately \$10.8 million in cash. The Company also issued stock options to purchase 168,172 shares of the Company's common stock to employees of Timm Medical who accepted employment with the Company, with an aggregate value of \$1.4 million. The value of the options issued by the Company was computed using an option pricing model. The primary purpose of the merger was to gain access to Timm Medical's products, sales personnel and operations capacity. This transaction was accounted for under the purchase method of accounting and, accordingly, the consolidated financial statements of the Company for the three month and six month periods ended June 30, 2002 include the financial results of Timm Medical from February 21, 2002, the date the purchase transaction was effective, and which represents the date when the Company effectively took control of Timm Medical.

The Company recorded goodwill of approximately \$32.1 million as a result of the acquisition. The Company acquired \$2.5 million in an intangible asset representing a trade name. The name is being amortized over a useful life of 15 years. The Company incurred costs and expenses in connection with the acquisition, including legal, accounting and other various expenses. Eligible costs were included as part of the purchase price. The allocation of the purchase price for the acquisition and other purchase accounting adjustments is as follows:

Total purchase price, net	\$37,083,382
Net assets acquired	(4,963,572)
	<hr/>
Goodwill	\$32,119,810
	<hr/>

The following table presents unaudited pro forma results of operations for the three month and six month periods ended June 30, 2002 and 2001 assuming the acquisition occurred as of January 1, 2001:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Net revenues	\$ 11,378,000	\$ 7,245,000	\$ 20,750,000	\$ 13,692,000
Net loss	\$ 1,135,000	\$ (2,532,000)	\$ 990,000	\$ (5,239,000)
Net loss per share, basic and diluted	\$ 0.05	\$ (0.15)	\$ 0.04	\$ (0.31)
Weighted average shares outstanding				
Basic	24,000,348	17,222,218	23,933,475	16,999,911
Fully diluted	25,177,964	17,222,218	24,785,177	16,999,911



**Table of Contents**

It was assumed, for the purposes of the pro forma results above, that 1,620,530 shares of common stock issued in connection with the acquisition were outstanding as of January 1, 2001.

**4. Other Acquisitions of Assets**

On June 27, 2002, the Company completed the acquisition of the cryosurgical business line and assets of Cryomedical Sciences, Inc. (OTC BB: CRYM.OB) for \$2.2 million in cash and 120,022 shares of common stock valued at \$1.5 million. This transaction was accounted for under the purchase method of accounting. Due to the closing of the acquisition in late June, none of the revenue, expenses or installed base metrics of the cryosurgical business acquired from Cryomedical Sciences, Inc. will be included in the Company's results for its second quarter ending June 30, 2002. The Company is still reviewing the allocation of the purchase price, but has, for the purposes of these interim financial statements, allocated \$3.2 million to intangible assets consisting primarily of patents and customer lists, and \$0.5 million to goodwill.

In April, 2002, the Company acquired certain patents and a consulting arrangement related to its cryosurgical business by issuing 100,000 shares of common stock valued at \$1.4 million. The value of the acquired assets, which are included in intangible assets, is being amortized over a useful life of 10 years.

**5. Supplemental Financial Statement Data**

	<b>June 30, 2002</b>	<b>December 31, 2001</b>
Inventories:		
Raw materials	\$ 2,479,883	\$ 1,456,482
Work in process	404,879	501,687
Finished goods	2,400,467	457,575
Total inventories	<u>\$ 5,285,229</u>	<u>\$ 2,415,744</u>

**6. Collaborative Agreements**

In October 1999, the Company 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 the Company in Sanarus totaling \$300,000. The Company 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. In June 2001, the Company provided a bridge loan to Sanarus in the amount of \$250,000. This amount was subsequently repaid in July 2001 upon Sanarus' receipt of additional equity financing, which financing along with other financings by Sanarus reduced the Company's current ownership percentage to 2% and its potential ownership percentage to approximately 22% on a fully-diluted basis. The investment is included in Investments, intangible and other assets, net in the Company's consolidated balance sheets as of June 30, 2002 and December 31, 2001 and is reflected at cost as the Company does not have significant influence over the operations of Sanarus.

In September 2000, the Company invested \$250,000, representing approximately 833,000 shares of common stock, in Medical Resources Management, Inc., or MRM. In July 2001, these shares were converted into approximately 308,000 shares of common stock of Emergent Group, Inc., upon its acquisition of MRM as a wholly owned subsidiary. The investment in MRM was included in Investments, intangible and other assets, net in our balance sheet as of December 31, 2001 in accordance with SFAS 115 as an available for sale investment. During the quarter ended June 30, 2002, the Company reflected a decline in value of \$250,000 which is included in the statement of operations as a loss on investment, as we determined that the decline in value on this investment was other than temporary. We monitor our investments for other than temporary declines in value which should be written down and included in earnings as a loss.

In June 2001, the Company signed an exclusive original equipment manufacturer agreement with Qualigen, Inc., pursuant to which the Company will distribute Qualigen's 15 minute PSA test known as the FastPack System as part of the Company's diagnostic workstation for urology which is currently under development. The

## **Table of Contents**

agreement has a term of five years and includes one year of exclusivity with the option of four one-year extensions of exclusivity based upon minimum purchase commitments. In September 2001, the Company entered into a new expanded distribution agreement with Qualigen, Inc. Under this new agreement, the Company will non-exclusively sell Qualigen's FDA-cleared 15-minute total prostate-specific antigen test as a stand alone product directly to urology practices.

In June 2001, the Company issued 213,010 shares of its common stock with a fair value of \$2,837,293 as consideration for a membership interest in the form of Class A Units of U.S. Medical Development, Inc. (formerly, U.S. Therapies, LLC), equal to approximately 9% of the total issued and outstanding Class A Units of U.S. Medical Development and approximately 5% of the Class A Units on a fully-diluted basis. U.S. Medical Development is a national urology group representing more than 150 urologists across the nation. In a related Distributor Agreement, U.S.M.D. Ltd., (formerly, U.S. Medical Devices, Ltd.), a subsidiary of U.S. Medical Development, was appointed a distributor and given exclusive distribution rights to the Company's Cryocare Surgical System and associated disposable products in 16 states. U.S.M.D., Ltd. (USMD) 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 U.S. Medical Development is included in Investments, intangible and other assets, net in the accompanying consolidated balance sheet at June 30, 2002 and December 31, 2001 and is carried using the cost method of accounting. The Company has recognized sales of \$1,000,000 and \$1,310,000 to USMD for the quarters ended June 30, 2002 and June 30, 2001, and \$2,849,397 and \$1,955,000 for the six months ended June 30, 2002 and June 30, 2001, respectively. As of June 30, 2002, USMD accounted for approximately \$1,275,000 of net accounts receivable.

In September 2001, the Company entered into a strategic alliance with CryoCath Technologies, Inc. pursuant to an exclusive global market access and supply agreement, whereby CryoCath Technologies, Inc. and the Company would co-develop a new, advanced line of surgical probe systems to surgically treat cardiac arrhythmias. CryoCath will purchase the systems from Endocare and is marketing them on a global basis under the CryoCath trademark, Surgifrost.

## **7. Legal Proceedings**

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

## **8. Major Customers and Concentration of Credit Risk**

The Company currently operates in one industry segment—the design, manufacture and marketing of surgical devices and related procedures to treat urological disorders. The Company markets and sells its devices worldwide to distributors of medical devices and directly to hospitals and other medical professional organizations.

Customer credit may be extended based upon evaluation of the customer's financial condition. The Company maintains reserves for credit losses, and Company management considers such reserves to be adequate based upon historical experience. International shipments are billed and collected by the Company in U.S. dollars.

During the three months ended June 30, 2002, no customer accounted for more than 10% of the Company's total revenues compared to one customer that accounted for 37% for the three months ended June 30, 2001. During the six months ended June 30, 2002, one customer accounted for 15% of the Company's total revenues compared to

## **Table of Contents**

31% for the six months ended June 30, 2001. As of June 30, 2002, one customer accounted for approximately 11% of net accounts receivable. By significant geographic area, approximately 95% of the Company's revenues were from the United States for both the three month and six month periods ended June 30, 2002 and June 30, 2001.

## **9. Related Party Transactions**

### **Loans to Officers and Employees**

In November 1999, the Company received a full recourse promissory note for \$1,028,125 in connection with the sale of 175,000 shares of its common stock at the fair market value on the date of sale to Jerry W. Anderson, its former Senior Vice President, Sales and Marketing and current President of Advanced Medical Procedures, Inc., its wholly owned subsidiary. The note bears interest at 5.99% per annum, compounded semi-annually. Accrued and unpaid interest is payable annually each September and the principal is due and payable in one lump sum in September 2003. The amount outstanding under this note as of June 30, 2002 was \$1,185,420, including principal and interest.

In March 2001, the Company received full recourse promissory notes from other officers and employees totaling \$149,800 due March 2003. These notes bear interest at above market rates, payable in one lump sum in March 2003. The amount outstanding under these notes as of June 30, 2002 was \$136,301, including principal and interest.

## **10. Common Stock Repurchase Program**

In June 2002, the Company's Board of Directors authorized a stock repurchase program. Under the program, the Company may repurchase up to one million shares of its common stock in the open market at then prevailing prices. As of June 30, 2002, the Company had not repurchased any shares of common stock under the program.

## **11. Net Earnings (Loss) Per Share**

For the three and six month periods ended June 30, 2001, the Company was in a consolidated net loss position. Accordingly, the potential dilution during these periods from the conversion of options, warrants and convertible debentures to common stock of approximately 3,435,000 was not used to compute diluted loss per share as the effect was antidilutive. Consequently, diluted EPS equals basic EPS for the fiscal 2001 periods.

## **12. Subsequent Events**

The Company and U.S. Medical Development, Inc., a privately held urology services company based in Dallas, Texas, began discussions in March 2002 regarding the Company's acquisition of the business of U.S. Medical Development, Inc. and U.S.M.D., Ltd. and U.S.M.D. I, L.L.C., two affiliates of U.S. Medical Development, Inc. (collectively, the "USMD Entities"). U.S.M.D., Ltd. has been an exclusive distributor of the Company's Cryocare Surgical System and related disposable products to urologists located in 16 western states and to HealthTronics Surgical Services, Inc. (Nasdaq: HTRN) and its affiliates. Sales to U.S.M.D., Ltd. represented 9% and 37% of the Company's revenues for the three months ended June 30, 2002 and 2001, respectively, and 15% and 31% of the Company's revenues for the six months ended June 30, 2002 and 2001, respectively.

During the course of negotiations in July 2002, the Company loaned U.S. Medical Development, Inc. \$6.8 million, bearing interest at the prime rate plus one percent and fully secured by partnership, limited liability membership and other equity ownership interests in the mobile prostate treatment businesses of the USMD Entities. The loan was to be credited against the final purchase price paid by the Company for the mobile prostate treatment businesses of the USMD Entities. U.S. Medical Development, Inc. contemporaneously transferred the entire \$6.8 million of loan proceeds to acquire the general and limited partnership interests in U.S. Lithotripsy, L.P., an affiliate of USMD, owned by Litho Management, Inc., a wholly-owned subsidiary of HealthTronics Surgical Services, Inc.

On August 12, 2002, the Company and the USMD Entities signed a definitive Partnership and Limited Liability Company Membership Interest Purchase Agreement (the "Purchase Agreement"), pursuant to which the USMD Entities agreed to sell their mobile prostate treatment businesses to the Company. Pursuant to the Purchase Agreement, the Company will pay a total of approximately \$11,210,000 in the form of cash of \$3,330,000, assumption of debt of \$180,000, forgiveness of the above described debt of \$6,800,000 and application of a \$900,000 earnest money deposit previously made by the Company on April 2002. Upon closing, the exclusive distribution agreement between the Company and U.S.M.D., Ltd. will terminate and the Company will market its products directly to urologists previously served by the USMD Entities. The Company will retain its approximately 5% fully-diluted ownership interest in U.S. Medical Development, Inc. (the parent company of the USMD Entities), which will continue to independently operate its lithotripsy and orthotripsy businesses. The transaction is expected to close within 30 days, and is subject to customary closing conditions. The purchase price will be funded from the Company's working capital. The

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consideration for and the other terms and conditions of the asset purchase transaction were determined by arms-length negotiations between the Company and the USMD Entities. The Company has engaged a financial advisor to provide a fairness opinion at closing. The description of the transaction set forth above is qualified in its entirety by reference to the Purchase Agreement and related documents that the Company intends to file on Form 8-K.

## **Table of Contents**

### **ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Part I Item 1 of this report, and the audited consolidated financial statements, and notes thereto, and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in the Annual Report on Form 10-K for the fiscal year ended December 31, 2001.*

The following Management's Discussion and Analysis of Financial Condition and Results of Operations may contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended and are subject to the Safe Harbor provisions created by that statute. Our business and results of operations are subject to various risks and uncertainties including, but not limited to, those discussed under the caption "Factors That May Affect Our Future Results and the Trading Price of our Common Stock" included elsewhere in this report, and in risk factors contained in our other periodic reports filed with the Securities and Exchange Commission. Such risk factors include, but are not limited to, limited operating history of our business with a history of losses; risks associated with integrating newly acquired businesses into our existing business operations; uncertainty regarding market acceptance of our current and new products; uncertainty of product development and the associated risks related to clinical trials; uncertainty regarding the levels of third-party reimbursement for our products; and our limited sales, marketing and manufacturing experience. 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.

#### **Overview**

We are a medical device company focused on developing, manufacturing and selling urological healthcare products with the potential to dramatically improve men's health and quality of life. Our primary focus is on the diagnosis, management and treatment of the two most common diseases of the prostate, prostate cancer and benign prostate hyperplasia, or BPH. Our FDA-cleared Cryocare Surgical System occupies a leading position in the market for the cryosurgical treatment of prostate cancer. We are currently developing a urologic stent, the Horizon Prostatic Stent, for the treatment of BPH. In February 2002, we significantly expanded our urological product offerings by acquiring Timm Medical Technologies, Inc., or Timm Medical. Through this acquisition, we now own or have marketing rights for an additional product used in the treatment of BPH, five products used in the diagnosis and treatment of erectile dysfunction, six products used in the diagnosis and management of urinary incontinence and one product used in the diagnosis of bladder cancer. This acquisition also increased our sales and marketing organization from 26 to approximately 80 people, including 55 field sales representatives. We also acquired additional intellectual property assets related to our cryosurgical business from Gary M. Onik, M.D. in April 2002 and Cryomedical Sciences in June 2002. Our strategy is to increase sales of our current products through targeted sales and marketing efforts, to continue to develop and obtain regulatory approval for our Horizon Prostatic Stent, and to develop and acquire additional products in urology that leverage our existing sales and marketing organization.

Our 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 direct 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 lithotripsy 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 \$9.3 million in 1999, \$12.4 million in 2000 and \$5.9 million in 2001. We achieved our first profitable quarter for the three months ended March 31, 2002 by earning approximately \$166,000 in net income followed by approximately \$1,135,000 for the second quarter ended June 30, 2002. As of June 30, 2002, we had an accumulated deficit of \$36.8 million. We expect our operating expenses to increase as we expand our sales and marketing efforts and continue to develop new products.



## **Table of Contents**

### **Critical Accounting Policies**

We believe the following critical accounting policies affect our more significant judgment and estimates used in the preparation of our consolidated financial statements.

*Revenue Recognition.* During the quarter ended June 30, 2002, we generated revenues primarily from sales of our Cryocare Surgical System units and from the recurring sales of our disposable cryoprobes and erectile dysfunction products. We recognize revenues, including revenues from sales to distributors, upon shipment for sales of system units and disposable products, provided acceptance is assured and collectibility is probable. In the second quarter, we placed 21 of 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 a fee relating to each use of the Cryocare Surgical System unit, which we recognize as revenue upon completion of the procedure. The cost of the placed Cryocare Surgical System units are depreciated into cost of revenues over an estimated useful life of three years. The Company periodically reviews the value of these placed units for recoverability, based on projected cash flows from the placed units.

*Allowance for Doubtful Accounts and Warranty Claims.* Accounts receivable are presented net of an allowance for doubtful accounts. The allowance for doubtful accounts is determined through a specific identification process whereby management assesses the collectibility of receivables based in part on the financial condition of the client. For all other accounts receivable, we record an allowance for doubtful accounts based on a combination of factors including the age of receivable balances, historical bad debt experience, general customer creditworthiness, and current economic trends. The Company sells products to certain customers on payment terms of up to 180 days. At June 30, 2002 and December 31, 2001, approximately 32% and 42%, respectively, of the Company's accounts receivable was aged greater than 90 days since the date of sale. Based on its review of these accounts, management believes its existing allowance for doubtful accounts is adequate to cover any exposure on its existing accounts receivable.

We accrue a liability for estimated warranty claims. The amount of the accrual is based on historical claims by product group and other factors. Claims could be materially different from actual results for a variety of reasons, including a change in our warranty policy, competition or other external forces, manufacturing changes that could impact product quality, or as yet unrecognized defects in products sold. If future product quality standards or policies are less favorable than current analyses, additional warranty accruals may be required and would be reflected in cost of sales in the period the revision is made.

*Investments.* We have both marketable and non-marketable equity investments. We classify our marketable equity investments as available-for-sale securities. The non-marketable equity investments represent investments in other medical technologies or strategic alliances and are recorded at cost and are evaluated periodically for impairment. Non-marketable equity investments are evaluated for impairment through a review of the financial position and operating results of the investee. If it is determined that a decline of a non-marketable investment is other than temporary, then the investment basis would be written down to fair value and the write-down would be included in operations as a loss. If it is determined that a decline of a marketable investment is other than temporary, the amount recorded as other comprehensive loss would be charged as an investment loss.

*Use of Estimates.* The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America requires our 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 revenues and expenses during the reporting period. Our actual results could differ materially from those estimates as a result of selected factors, including those set forth under Factors that may Affect Our Future Results and the Trading Price of Our Common Stock set forth below.

*Inventories.* Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out method. Reserves for slow moving and obsolete inventories are provided based on historical experience and product demand. We have only recently begun the commercialization of our products and have limited experience in assessing obsolescence. We evaluate the adequacy of these reserves periodically based on forecasted sales and market trends.

## **Table of Contents**

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### **Reimbursement**

We sell our Cryocare Surgical System and related disposable guidewires and cryoprobes to hospitals and other entities that provide services to hospitals. Most procedures involving the Cryocare Surgical System are performed in hospitals on an inpatient basis. While occasional patients pay for cryosurgical procedures, virtually all patients depend upon third party payors, including Medicare, Medicaid, Tricare and other federal healthcare programs, as well as private insurers to pay for their procedures. Accordingly, our revenue is dependent upon third party reimbursement.

Reimbursement for cryosurgical procedures using our products as a primary treatment alternative for localized prostate cancer began July 1999. Effective July 2001, Medicare coverage was approved for secondary cryosurgical treatment of prostate cancer patients who have failed radiation therapy.

When Medicare reimbursed services are provided on an inpatient basis, the hospital is reimbursed under the Medicare prospective payment system, based on the applicable diagnosis related group, or DRG. A single payment covers all facility services, including the cost of cryosurgical supplies.

Outpatient reimbursement for cryosurgical procedures for Medicare beneficiaries is in accordance with the newly effective Hospital Outpatient Prospective Payment System, or HOPPS. Under HOPPS, reimbursement is made on a per procedure basis. The physician is paid a professional fee and the hospital receives payment for the technical portion of the fee. The hospital's technical fee includes the per procedure share of the cost for any depreciable equipment, such as our Cryocare Surgical System unit, and the provision of disposable devices, such as our guidewires and cryoprobes. The reimbursement to the hospital for the technical portion of the cryosurgical procedure increased 45% effective April 1, 2002, from \$1,900 to \$2,750. In August 2002, CMS proposed an increase in the technical component of 31% from \$2,750 to \$3,601, effective January 1, 2003.

Medicare makes additional payments to hospitals when certain qualifying new medical devices are used to perform a procedure or service on a program beneficiary on an outpatient basis. As a result, these pass-through payments help to compensate hospitals for the additional costs of utilizing new technology in treating Medicare beneficiaries. Our guidewires and cryoprobes are currently paid on a pass-through basis. Commencing April 1, 2002, CMS implemented a pro-rata reduction of 63.6% related to the pass-through payments for eligible devices for the 2002. To date, no impact has been observed in procedure volume as a result of this reduction. In August 2002, CMS proposed to eliminate all, or a significant portion, of the April 2002 reduction, effective January 1, 2003.

The items we acquired through our acquisition of Timm Medical also are reimbursed by Medicare and other federal healthcare programs, as well as private insurers. Timm Medical provides certain items pursuant to physicians' orders directly to patients, and bills the patient or payor.

### **Costs and Expenses**

Cost of revenues consists primarily of:

costs relating to the manufacture of our products;

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 and obtaining and maintaining regulatory approval for our products;

expenditures for purchases of laboratory supplies; and



**Table of Contents**

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 Six Months Ended June 30, 2002 Compared to Three and Six Months Ended June 30, 2001***

*Revenues.* Revenues for the three months ended June 30, 2002 increased 222% to \$11,378,000 compared to \$3,538,000 for the three months ended June 30, 2001. The increase in revenues was attributable to an increase in sales of our Cryocare Surgical System units and disposable cryoprobes. In addition, products we acquired or obtained a right to distribute from Timm Medical contributed revenues of approximately \$4,000,000 in the quarter ended June 30, 2002.

Revenues for the six months ended June 30, 2002 increased 204% to \$19,151,000 compared to \$6,293,000 in 2001. The increase is attributed to the reasons stated above. In addition, products we acquired or obtained a right to distribute from Timm Medical contributed revenues of approximately \$5,835,000 for the six months ended June 30, 2002.

*Cost of Revenues.* Cost of revenues for the three months ended June 30, 2002 increased 170% to \$3,437,000 compared to \$1,272,000 for the three months ended June 30, 2001. The increase in cost of revenues resulted primarily from an increase in the cost of manufacturing an increased number of Cryocare Surgical System units and disposable cryoprobes sold during the second quarter of 2002, partially offset by a reduction in the per unit production costs of our products due to increased manufacturing efficiencies. In addition, costs related to the manufacture and sale of the products we acquired or obtained a right to distribute from Timm Medical contributed approximately \$1,448,000 to the cost of revenues for the quarter ended June 30, 2002.

Cost of revenues for the six months ended June 30, 2002 increased 153% to \$6,198,000 compared to \$2,446,000 in 2001. The increase is attributed to the reasons stated above. In addition, costs related to the manufacture and sale of the products we acquired or obtained a right to distribute from Timm medical contributed approximately, \$2,103,000 to the cost of revenues for the six months ended June 30, 2002.

*Gross Margins.* Gross margins on revenues increased to 70% for the three months ended June 30, 2002 compared to 64% for the three months ended June 30, 2001. The increase in gross margins on revenues is due primarily to the company reaching critical mass, operating in a new manufacturing facility as well as reducing raw material costs and overall manufacturing efficiencies.

Gross margins on revenues for the six months ended June 30, 2002 increased to 68% compared to 61% for the same period in 2001. The increase is due to the reasons described above.

*Research and Development Expenses.* Research and development expenses for the three months ended June 30, 2002 increased 13% to \$1,041,000 compared to \$923,000 for the three months ended June 30, 2001. The increase was primarily attributable to hiring additional personnel, increased spending on product development

## **Table of Contents**

efforts and clinical costs associated with our Horizon Prostatic Stent and increased product development costs related to our strategic alliance with CryoCath Technologies Inc. As a percentage of revenues, research and development expenses decreased from 26% in the year 2001 to 9% in 2002, due to the combination of fairly consistent spending levels and a significant increase in revenues.

Research and development expense for the six months ended June 30, 2002 increased 9% to \$1,989,000 compared to \$1,826,000 for the same period in 2001. As a percentage of revenues, research and development expenses decreased from 29% to 10%. The variances are attributable to the reasons stated above.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses for the three months ended June 30, 2002 increased 69% to \$5,809,000 compared to \$3,440,000 for the three months ended June 30, 2001. This increase reflects increased sales and marketing costs, an increase in our direct sales and marketing personnel, and costs associated with our increased sales force following the Timm Medical acquisition. As a percentage of revenues, selling, general and administrative expenses decreased from 97% in the second quarter of 2001 to 51% in the second quarter of 2002, reflecting the Company's ability to leverage its existing administrative infrastructure.

Selling, general and administrative expenses for the six months ended June 30, 2002 increased 55% to \$10,023,000 compared to \$6,464,000 for the same period in 2001. The increase is primarily attributable to the reasons stated above. As a percentage of sales, selling general, and administrative expenses decreased from 103% in the six months ended June 30, 2001 compared to 52% for the six months ended June 30, 2002, for the reasons stated above.

*Interest Income, Net.* Interest income, net for the three months ended June 30, 2002 was \$327,000 compared to \$34,000 for the three months ended June 30, 2001. The change was due to the reduction of interest expense associated with the reduction of debt in 2001 and increased cash and investment balances following our secondary public offering in 2001.

Interest income, net for the six months ended June 30, 2002 was \$643,000 compared to \$38,000 for the six months ended June 30, 2001. The increase is primarily due to reasons stated above.

*Provision for Income Taxes.* Provision for income taxes for the quarter ended June 30, 2002 relates primarily to state taxes payable in some states for which the company conducts business. We have deferred tax assets of approximately \$20 million that we review for recoverability and then value accordingly. We evaluate the realizability of our deferred tax assets on a quarterly basis and assess the need for valuation allowances. These deferred tax assets are evaluated by considering historical levels of income, estimates of future taxable income, and the impact of tax planning strategies. Given our limited history of positive earnings, we maintain a valuation allowance that is equal to our deferred tax assets. If we later determine that it is more likely than not that we would realize all or part of the deferred tax assets, we would adjust the deferred tax asset valuation allowance and record the adjustment to income in the period we made the determination.

*Loss on Investment.* Loss on investment for the quarter ended June 30, 2002, relates to the charge taken to reflect a decline, other than temporary, for the Company's investment in Medical Resources Management.

*Net Income ( Loss).* Net income for the three months ended June 30, 2002 was \$1,135,000 or \$0.05 per diluted share on 25,178,000 weighted average shares outstanding, compared to a net loss of (\$2,064,000), or (\$0.13) per share on 15,602,000 weighted average shares outstanding for the same period in 2001. The net income compared to net loss resulted from higher revenues, improved margins and increased interest income partially offset by higher selling, general and administrative expenses and increased research and development expenses.

Our net income for the six months ended June 30, 2002 was \$1,301,000 or \$0.05 per diluted share on 24,399,000 weighted average shares outstanding, compared to a net loss of (\$4,406,000) or (\$0.29) per share on 15,379,000 weighted average shares outstanding for the same period in 2001. The net income compared to net loss resulted from the reasons stated above.

## **Table of Contents**

### **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 securities, loans that were subsequently converted into equity securities, the use of short-term and long-term debt, a public offering of equity securities and sales to customers. At June 30, 2002, we had cash and cash equivalents of \$45.7 million compared to \$83.2 million at December 31, 2001. In addition, as of June 30, 2002 the company invested \$17.3 million in short-term marketable securities. At June 30, 2002, our working capital was \$75.4 million and the ratio of current assets to current liabilities was 14 to 1.

On November 21, 2001, we closed a public offering of 4 million shares of our common stock at a price of \$17.00 per share. On December 4, 2001, we sold an additional 600,000 shares of our common stock at the public offering price of \$17.00 per share upon exercise of the over-allotment granted to the underwriters in the public offering. We raised \$78.2 million in proceeds through the public offering before deducting commissions and offering expenses of \$5.6 million.

*Cash Used in Operations.* Net cash used in operating activities was \$5.6 million for the six months ended June 30, 2002 compared to \$6.4 million for the six months ended June 30, 2001. Net income plus non-cash operating expenses totaled \$2.0 for the first six months of 2002, and was offset by increases in accounts receivable, inventories and prepaid expenses, aggregating \$6.9 million, commensurate with the growth in revenues. Accrued liabilities decreased \$1.6 million, reflecting payment of compensation and consulting related expenses, and accounts payable increased \$1.2 million during 2002, due primarily to increases in inventory purchase obligations.

*Investing Activities.* Net cash used in investing activities was approximately \$33.8 million for the six months ended June 30, 2002 compared to \$576,000 for the six months ended June 30, 2001. The net cash used in investing activities was due primarily to the purchase of \$17.2 million in short-term marketable securities, cash used in the acquisitions of Timm Medical and Cryomedical Sciences, Inc. totaling \$13.0 million, payment of \$900,000 earnest money deposit to U.S. Medical Development, Inc., additions to property, equipment and leasehold improvements related to the new facility, and costs associated with placed Cryocare Surgical Systems.

*Cash Provided by Financing Activities.* Net cash provided by financing activities was approximately \$1.9 million for the six months ended June 30, 2002 compared to \$0.9 million for the six months ended June 30, 2001. The net cash provided by financing activities was primarily attributable to exercise of stock options and warrants.

*Working Capital.* Our working capital decreased to \$75.4 million at June 30, 2002 from \$88.8 million at December 31, 2001. The decrease in working capital was due to cash paid in the Timm Medical and Cryomedical acquisitions, investments in fixed assets for the new facility, and costs associated with placed Cryocare Surgical Systems.

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. 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 current ownership percentage to 2% and our potential maximum ownership percentage to approximately 22% on a fully-diluted basis. The investment is included in investments, intangible and other assets, net in our consolidated balance sheets as of June 30, 2002 and December 31, 2001, and is reflected at cost as we do not have significant influence over the operations of Sanarus.

In June 2001, we signed an exclusive original equipment manufacturer agreement with Qualigen, Inc., pursuant to which we will distribute Qualigen's 15 minute PSA test known as the FastPack System as part of our diagnostic workstation for urology which is currently under development. The agreement has a term of five years and includes one year of exclusivity with the option of four one-year extensions of exclusivity based upon minimum purchase commitments. In September 2001, we entered into a new expanded distribution agreement with Qualigen,

## **Table of Contents**

Inc. Under this new agreement, we will non-exclusively sell Qualigen's FDA-cleared 15-minute total prostate-specific antigen test as a stand alone product, directly to urology practices.

In June 2001, we issued 213,010 shares of our common stock valued at its fair market value of \$2.8 million in consideration for a membership interest, in the form of Class A units of U.S. Medical Development, Inc (formerly, U.S. Therapies, LLC), equal to approximately 5% of the total issued and outstanding Class A units of U.S. Medical Development on a fully-diluted basis. We simultaneously entered into a distribution agreement with U.S.M.D. Ltd. (USMD), a subsidiary of U.S. Medical Development, under which USMD 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. The investment in U.S. Medical Development is included in Investments, intangible and other assets, net in our balance sheet as of June 30, 2002 and December 31, 2001 using the cost method of accounting. During the three and six months ended June 30, 2002, the Company recognized sales of \$1.0 million and \$2.8 million, respectively, to USMD. All of these sales were made under normal business conditions, are expected to be used or resold by USMD in the ordinary course of business, and are not expected to be returned to the Company as a result of a concession or due to the potential acquisition of a portion of U.S. Medical Development's operations.

In March 2002, we completed the acquisition of Timm Medical for a purchase price of approximately \$10.8 million in cash and 1,620,530 shares of our common stock. Pursuant to the acquisition agreement, we registered the shares of common stock issued in the acquisition in May 2002. In April 2002, we acquired intellectual property assets and contract services related to our cryosurgical business from Gary M. Onik, M.D. by issuing 100,000 shares of common stock valued at \$1.41 million. In June 2002, we completed the acquisition of the cryosurgical business line and assets of Cryomedical Sciences, Inc. for \$2.2 million in cash and 120,022 shares of common stock valued at \$1.5 million.

We expect increased sales and marketing expenses related to the promotion of our Cryocare Surgical System and the urological products we acquired or obtained a right to market through our acquisition of Timm Medical, increased expenses related to developing and obtaining regulatory approval for 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, our ability to successfully integrate the operations of Timm Medical into our business, including its sales and marketing personnel, market acceptance of the products we acquired from Timm Medical, the resources we devote to developing and supporting our products, including the costs associated with placed units, continued progress of our research and development of potential products, the need to acquire licenses to technology and potential future merger and acquisition activity. We believe that our current cash balances, together with the revenue to be derived from sales of our products, 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 with no outstanding balance. 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 do raise additional equity financing, our stockholders will be further diluted. 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.

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

**We have a limited operating experience and a history of net losses, and we may not maintain or increase profitability.**

Since our inception, we have engaged primarily in research and development activities, and have minimal experience in manufacturing, marketing and selling our Cryocare Surgical System in commercial quantities. In addition, we closed our acquisition of Timm Medical in March 2002 and the acquisition of the cryosurgical business line and assets of Cryomedical Sciences, Inc. in June 2002. As a result, we have a short history in marketing and selling the products we acquired or have rights to commercialize through these acquisitions. Although we recorded

## **Table of Contents**

net income of approximately \$1.1 million for the three months ended June 30, 2002, we have incurred annual operating losses each year since our inception. For the fiscal years ended December 31, 1999, 2000 and 2001, we had net operating losses of approximately \$9.3 million, \$12.4 million and \$5.9 million, respectively. As of June 30, 2002, our accumulated deficit was approximately \$36.8 million. It is possible that we will not generate sufficient revenues from product sales to maintain or increase our profitability. Even if we do achieve significant revenues from our product sales, we expect to incur increased operating expenses over the next several quarters, as we, among other things:

expand our selling and marketing activities as we attempt to gain market share for our Cryocare Surgical System and our other urology products;

incur costs related to the integration of acquired businesses;

increase our research and development efforts to improve our existing products and develop new products, including our Horizon Prostatic Stent; and

perform clinical research and trials in an effort to obtain governmental clearance and approval for the commercial sale of our developed products.

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

### **We recently acquired Timm Medical and the assets of Cryomedical Sciences, Inc., and face risks associated with integrating these businesses into our existing business operations.**

We are in the process of integrating the operations, personnel and products of the businesses we acquired from Timm Medical and Cryomedical Sciences. The integration involves numerous risks and expenses, including, among others, difficulties and expenses incurred in assimilating operations, personnel and products, difficulties in operating a new business and marketing new products, difficulties in training sales personnel to effectively sell new products, the diversion of management's attention from other business concerns and the potential loss of key employees. In addition, the acquired businesses may suffer as the attention of both its management and employees are diverted during the integration process. If we do not successfully integrate and grow the acquired businesses, our business will suffer.

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

We introduced our Cryocare Surgical System to the market in July 1999. We derived a significant portion of our revenues in the three and six month periods ended June 30, 2002 and 2001 from sales of Cryocare Surgical Systems and related disposable supplies. We expect that sales of Cryocare Surgical Systems and related disposable supplies will constitute a significant portion of our sales for the foreseeable future. Accordingly, our success is reliant on the acceptance by doctors and patients of the Cryocare Surgical System as a preferred treatment for prostate cancer. 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 gave cryosurgical treatment a bad reputation. Now that ultrasound guidance and temperature sensing are available for more precise monitoring in our Cryocare Surgical System, we will need to overcome this reputation to obtain market acceptance for our product. In addition, use of our Cryocare Surgical System requires significant physician education and training. As a result, we may have difficulty obtaining recommendations and endorsements of physicians and patients for our Cryocare Surgical System. We may also have difficulty raising the brand awareness necessary to generate interest in our Cryocare Surgical System. Any adverse side effects, including impotence or incontinence, recurrence of cancer or future reported adverse events or other unfavorable publicity involving patient outcomes from the use of cryosurgery, whether from our products or the products of our competitors, could adversely affect acceptance of cryosurgery. In addition, emerging new technologies and procedures to treat cancer, prostate enlargement and other prostate disorders may negatively affect



**Table of Contents**

the market acceptance of cryosurgery. If our Cryocare Surgical System does not achieve market acceptance, we will likely remain unprofitable.

**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 before obtaining necessary regulatory or reimbursement approvals. In addition, our competitors may succeed in developing commercially viable products that render our products obsolete or less attractive. 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, healthcare providers, such as hospitals and physicians, that purchase our products 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 on reimbursement for our products and procedures in which our products are used. 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 healthcare 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 cryosurgical 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. For calendar years 2002 and 2003, federal law caps the total cost of pass-through payments to 2.5% of expenditures for hospital outpatient services for the year. The cap is set at 2.0% for calendar year 2004 and each year thereafter.

This statutory limit on pass-through payments, first implemented by CMS for calendar year 2002, will result in a pro rata reduction in pass-through payments for calendar year 2002 of 63.6%. This means that payments to hospitals for our disposable products used in outpatient procedures in calendar year 2002 will be reduced by this percentage.

We have no assurance that once pass-through status for our disposable guidewires and cryoprobes for cryoblation ends and CMS sets an all inclusive technical fee, total reimbursement will not be further reduced. Private healthcare payors are also expected to incorporate the costs of our products into the overall cost of the procedures in which they are used, meaning that there will no longer be separate, additional reimbursement for our disposable products. This too may affect our charges to hospitals and resulting revenues.

International market acceptance of our products may depend, in part, upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in

## **Table of Contents**

international markets vary significantly by country, and include both government sponsored healthcare and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. Our failure to receive international reimbursement approvals may negatively impact market acceptance of our products in the international markets in which those approvals are sought.

Furthermore, 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. Nonetheless, we cannot and do not promise that we actually will experience any growth in the future. We recently experienced significant growth in our operations and number of employees as a result of our acquisition of Timm Medical. This growth has placed and 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 with our Cryocare Surgical System and any failure to significantly expand sales of this product 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 Cryocare Surgical System in commercial quantities or on a nationwide basis. We will face significant challenges and risks in training, managing and retaining our sales and marketing teams, including managing geographically dispersed efforts and adequately training our people in the use and benefits of our Cryocare Surgical System. We may not be able to hire significant additional personnel to create increased demand for our Cryocare Surgical System. In addition, we have distribution arrangements, some of which are exclusive, for the sale of our Cryocare Surgical System both domestically and internationally and are dependent upon the sales and marketing efforts of our third-party distributors. These distributors may not commit the necessary resources to effectively market and sell our Cryocare Surgical System. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our Cryocare Surgical System.

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

During 2001 and 2002, the United States and other international markets experienced a significant economic downturn. In addition, the United States and other countries suffered significant acts of hostility and terror. Such acts may increase or prolong such negative economic conditions. The economic downturn may impact our ability to maintain or increase profitability by negatively affecting growth in demand for our products. There can be no certainty as to the degree or severity of the duration of this downturn. We also cannot predict the extent and timing of the impact of the economic downturn in the United States and in other countries and geographic regions in which we conduct our business.

## **Table of Contents**

### **If our relationship with U.S.M.D., Ltd. is disrupted, our revenues could be significantly reduced.**

We have an exclusive distribution agreement with U.S.M.D., Ltd. For the six months ended June 30, 2002 and 2001, 15% and 31%, respectively, of our revenues were derived from sales made to U.S.M.D., Ltd. As a result, our revenues are dependent in large part on continued sales to this distributor. If sales to this distributor were to be discontinued, our revenues could be materially and adversely affected.

### **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 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.

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

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

### **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. 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. Also, even if we prevail in litigation, the litigation would be costly in terms of management distraction as well as in money. In addition, confidentiality agreements with our employees, consultants, customers, and key vendors may not prevent the unauthorized disclosure or use of our technology. It is possible that these agreements will be breached or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Enforcement of these agreements may be costly and time consuming. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States.

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

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

## **Table of Contents**

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.

### **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 maintain profitability, or if we undertake or accelerate significant research and development projects for new products or pursue corporate acquisitions, we may need additional outside financing. We may raise these additional funds by selling 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 regulations and other regulatory requirements in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs.

### **We are dependent upon a 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 suppliers could be a lengthy process and there may not be adequate alternatives to meet our needs, which will have a material adverse effect on our business. 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.**

## **Table of Contents**

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

## **Table of Contents**

interests in an entity and compensation arrangements with an entity. Many states have similar or even broader laws prohibiting referrals by any licensed healthcare 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 have financial relationships with physicians and physician-owned entities, which in turn have financial relationships with hospitals and other providers of designated health services. Although we believe that our financial relationships with physicians and physician-owned entities, as well as the relationships between physician-owned entities that purchase or lease our products and hospitals, are not in violation of applicable laws and regulations, governmental authorities might take a contrary position. If our financial relationships with physicians or physician-owned entities or the relationships between those entities and hospitals were found to be illegal, we and/or the affected physicians and hospitals could be subject to civil and criminal penalties, including fines, exclusion from participation in government and private payor programs and requirements to refund amounts previously received from government and private payors. In addition, expansion of our operations to new jurisdictions, or new interpretations of laws in our existing jurisdictions, could require structural and organizational modifications of our relationships with physicians, physician-owned entities and others to comply with that jurisdiction's laws.

### **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. 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;

**Table of Contents**

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 seek to 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 expand our urology product offerings 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, in March 2002, we closed the acquisition of Timm Medical, and in June 2002, we closed the acquisition of the cryosurgical business of Cryomedical Sciences. We cannot assure you that we will be able to identify suitable acquisition opportunities in the future. In addition, even if we do identify 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. We are not experienced in acquiring businesses or managing facilities or operations in geographically distant areas. The failure to successfully 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. 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 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;

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.

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.

**Table of Contents**

**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.

**ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. Our financial instruments include cash, cash equivalents, short-term investments, accounts receivable, investments, accounts payable and accrued liabilities. At June 30, 2002, the carrying values of our financial instruments approximated their fair values. Although there is not a readily available market value for our cost method and available for sale investments, in general we do not believe that the fair value of these investments would significantly differ from the carrying value. We monitor our investments for other than temporary declines in value which would be written down and included in earnings as a loss.

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.



**Table of Contents****PART II OTHER INFORMATION****ITEM 1. Legal Proceedings**

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

From time to time, we receive correspondence alleging infringement of proprietary rights of third parties. We cannot assure you that any relevant claims of third parties would not be upheld as valid and enforceable, and therefore we could be prevented from practicing the subject matter claimed or would be required to obtain licenses from the owners of any such proprietary rights to avoid infringement. We do not expect any material adverse effect on our consolidated results of operations or financial condition because of such actions.

**ITEM 2. Changes in Securities**

During the period from April 1, 2002 through June 30, 2002, we granted stock options to eleven individuals covering an aggregate of 58,500 shares of our common stock, pursuant to our 1995 Stock Plan. All such options were granted at exercise prices equaling the 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 the option grants. 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**

We held our Annual Meeting of Stockholders on Tuesday, June 11, 2002. Our stockholders adopted the following matters at the Annual Meeting by the votes indicated:

1. The stockholders elected the following five directors to our Board of Directors to serve during the ensuing year or until their respective successors are duly elected and qualified:

	Number of Shares:	
	For	Withheld
<b>Name of Director Elected</b>		
Paul W. Mikus	17,103,895	1,602,752
Peter F. Bernardoni	18,411,422	295,225
Robert F. Byrnes	18,411,422	295,225
Benjamin Gerson, M.D.	18,411,422	295,225
Michael J. Strauss, M.D.	18,411,422	295,225

2. The stockholders approved an amendment to our 1995 Stock Plan to modify the automatic share increase feature under the Plan by increasing the maximum yearly increase cap from 500,000 shares to 1,000,000 shares, beginning with the 2003 calendar year.

Number of Shares

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For:	12,441,150
Against:	2,007,241
Abstained:	49,104

**Table of Contents**

3. The stockholders ratified the selection of KPMG LLP as our independent auditors for the fiscal year ending December 31, 2002.

	<b>Number of Shares</b>
For:	18,298,881
Against:	398,115
Abstained:	9,651

**ITEM 5. Other Information**

In accordance with SEC Rule 10b5-1, three of our stockholders, Technology Funding Partners III, L.P., Technology Funding Venture Partners IV, an Aggressive Growth Fund, L.P. and Technology Funding Venture Partners V, an Aggressive Growth Fund, L.P. (collectively, the Funds ), jointly established a written plan for gradually liquidating a portion of their holdings of our common stock. Under the plan, the Funds intend to sell an aggregate of 300,000 shares of our common stock in four equal installments upon our common stock reaching specific trading price levels, with no more than 25,000 shares being sold on any single trading day. Peter F. Bernardoni, one of our directors, is an officer of Technology Funding, Inc. and a partner of Technology Funding, Ltd., each a general partner of the Funds. Mr. Bernardoni has sole voting and shares investment power with respect to all shares owned by the Funds.

**ITEM 6. Exhibits and Reports on Form 8-K.****(a) Exhibits**

Exhibit No.	Description
2.1(1)	Agreement and Plan of Reorganization, dated February 21, 2002, by and among the Company, Technologies, Inc., TMT Acquisition Corporation and certain stockholders of Timm Medical Technologies, Inc. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.2(2)	Agreement and Plan of Merger, dated June 30, 1999, by and among the Company, Advanced Medical Procedures, Inc., Advanced Medical Procedures, LLC, Gary M. Onik, M.D., Robert F. Byrnes and Jerry Anderson. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.3	Asset Purchase Agreement, dated February 6, 2002, by and between the Company and Gary M. Onik, M.D. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.4	Asset Purchase Agreement, dated May 28, 2002, by and among the Company and Cryomedical Sciences, Inc. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
3.1 (2)	Certificate of Amendment of Restated Certificate of Incorporation of the Company.
3.2 (2)	Certificate of Designation of Series A Junior Participating Preferred Stock of the Company.
3.3 (2)	Restated Certificate of Incorporation.
3.4 (2)	Amended and Restated Bylaws of the Company.
99.1	Certification under Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Previously filed on Form 8-K on March 5, 2002.

**Table of Contents**

- (2) Previously filed with our Registration Statement on Form S-3 filed on September 20, 2001 and October 31, 2001.  
(b) **Reports on Form 8-K**

On April 9, 2002, we filed a Form 8-K regarding our acquisition of Timm Medical Technologies, Inc., which we consummated on March 25, 2002. On June 7, 2002, we filed a Form 8-K/A in which we amended Item 7 of the Form 8-K filed on April 9, 2002 to include financial statements of Timm Medical Technologies, Inc. and pro forma financial information of the combined companies in accordance with Item 7(a)(4) and Item 7(b)(2) of Form 8-K.

**Table of Contents**

**SIGNATURES**

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

Date: August 14, 2002

ENDOCARE, INC.

By: /s/ Paul W. Mikus

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

By: /s/ John V. Cracchiolo

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

30

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**Table of Contents****EXHIBIT INDEX**

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